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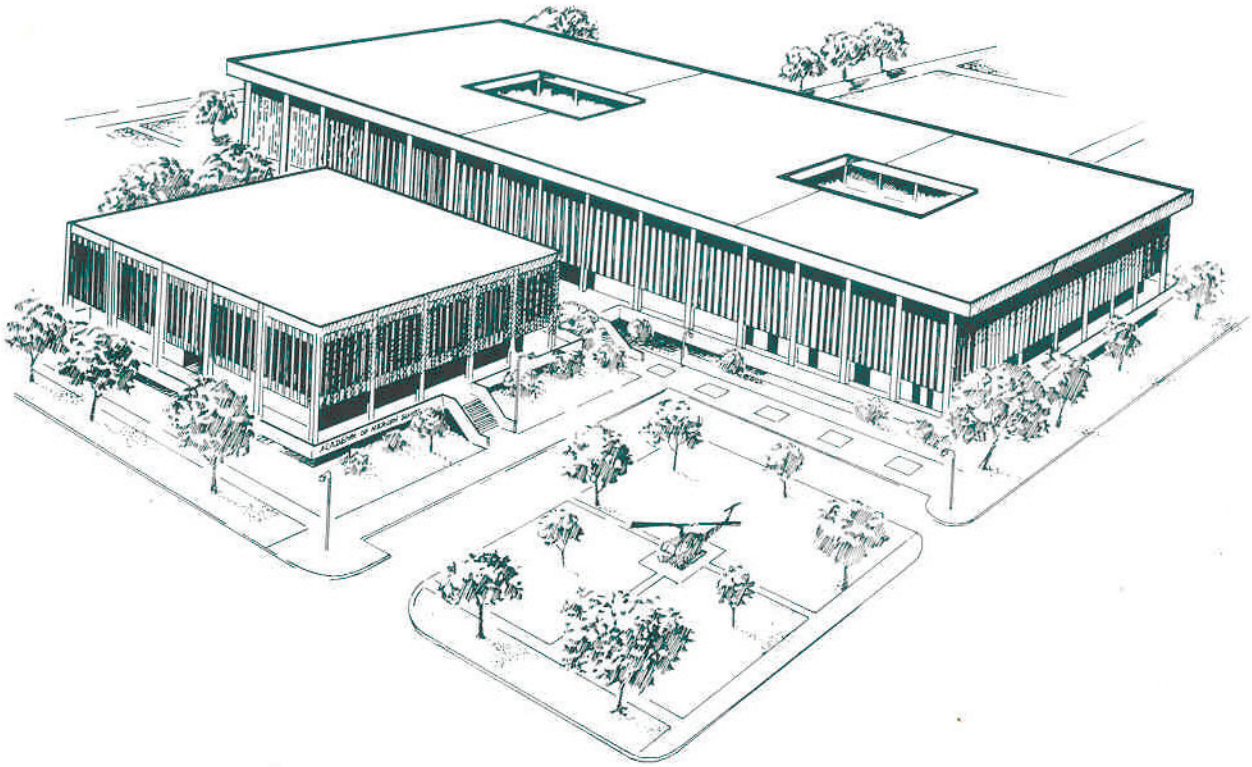

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Joint Base San Antonio-Fort Sam Houston, Texas

Antibiotics in the Treatment of Patients With Lower Back Pain Associated With Modic Changes: A Case Series

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Abstract

Purpose: To determine the clinical effect of antibiotic treatment for patients with low back pain and Modic 1 changes.

Methods: This is a retrospective case series of patients treated at the Canadian Forces Health Services Centre in Ottawa and the McGill University Health Centre. Where available, pain, functional, and imaging outcomes in 11 patients treated between 2013 and 2015 were analyzed to determine effect of antibiotic treatment for patients with low back pain and associated Modic 1 changes on magnetic resonance imaging.

Results: Conservatively, only 3 of 11 patients met the criteria for improvement for pain and/or function. While a larger proportion improved in the long term, outcomes were not thought to be temporally attributable to antibiotic treatment, as in most cases, ongoing therapy, medications, and/or injections were required. There did not appear to be a correlation between clinical improvement and associated end plate volume involvement for Modic changes.

Conclusion: Antibiotics for the treatment of low back pain in the context of Modic changes on MRI did not generally provide significant improvement in pain and function for patients in this small cohort. Despite early excitement regarding this treatment, further research is required.

With a worldwide point prevalence of 12%, low back pain (LBP) is responsible for significant health care costs and lost productivity.[1,2] Historically, the classification of LBP has been complicated by poorly validated clinical tools and nonspecific imaging findings.[3,4] Thus, the treatment for so-called "nonspecific" LBP has been disappointing with various modalities used. This includes, but is not limited to lifestyle, rehabilitation, medications, injections, and surgical treatments.[5-9]

Until recently, the prevailing theoretical framework was that nonspecific LBP was a mechanical phenomenon complicated by genetic, biopsychosocial, and environmental factors. Similar to previous conceptualizations regarding disease,[10] this notion was challenged by a landmark randomized placebo controlled study by Albert et al[11] that investigated the use of antibiotic treatment for patients with type 1 Modic changes and disc herniation on MRI. Type 1 Modic changes refers to findings found on T1 and T2 weighted sagittal MRI scans of the spine that are hyperintense on T2 and hypointense on T1, thought to reflect localized inflammation and edema.[12] Using the study protocol of Albert et al, patients with low back and/or lower limb pain had significant improvement in clinical, imaging, work, and medical resource related measures one year after initiating treatment with 100 days of amoxicillin/clavulanate.[11]

The background leading to the investigation of antibiotic treatment for LBP was well described by Albert et al.[11] While it is known that the prevalence of Modic changes are higher in patients with LBP,[13] numerous pathobiology studies[14-17] showed that intervertebral disc herniations had colonization rates of 19% to 71% with bacteria such as *proprionibacterium acnes*, *staphylococcus*, and *corynebacterium propinquum*. Furthermore, a much greater percentage of patients with disc herniation colonized with bacteria went on to develop Modic changes long-term.[14] However, the true culture rate may be significantly higher than what has been reported given the technical issues with sampling and bacterial preservation techniques, or lower given the potential risk of contamination.[17] The authors themselves had also previously carried out a nonrandomized pilot study on the effects of antibiotics in patients with chronic LBP post disc herniation, which also showed improved clinical outcomes.[19]

Proprionibacterium acnes is a part of the normal human flora, colonizing the mouth and skin, possibly associated with protecting the host against certain cancers.[20] It can be pathological at sites of injury or indwelling medical devices by precipitating an inflammatory response in adjacent bone through the release of cytokines and propionic acid.[21,22] As an anaerobe, it thrives in the disc environment, which is low in vascularity, oxygen tension, and pH. Colonization of a degenerated disc can occur via hematogenous spread, local infection, or a transvenous retrograde pathway from the pelvis.[23]

Significant discussion ensued following the publication by Albert et al.[11] It has been clarified that the response to treatment was not influenced by injection/surgical history.[24] Amoxicillin/clavulanate was the selected antibiotic based on its safety profile and ease of administration,[24] but the efficacy outcomes could be influenced by regional variations in colonizing organisms.[24] Furthermore, the authors explained the rationale for the antibiotic doses used in the trial, reasons for selecting the treatment length,[25] issues regarding study design, the authors' potential conflicts of interest,[26] the reasons behind the creation of MAST (Modic Antibiotic Spine Therapy) Medical (http://www.mastmedical.com) and related financial interests,[27] and why disc biopsy and culture should not be undertaken prior to treatment.[28]

Based on the results of Albert et al,[11] we sought to monitor the long-term outcomes in patients presenting with LBP and Modic 1 changes, after treatment with antibiotics.

Methods

Patients were recruited across 3 clinics, including the Canadian Forces Health Services Center Ottawa, the Montreal General Hospital Spine Clinic, and the Alan Edwards Pain Management Unit. We obtained research ethics board approval for this study from both the McGill University Health Centre and the Defence Research and Development Canada.

Inclusion criteria were patients ranging in age from 18 to 70 years with low back and/or lower limb pain for at least 6 months, leading to at least mild to moderate effect on function, coupled with the presence of Modic 1 changes and related disc herniation at least one level. The subject had to have had MRI imaging within the previous year and inadequate response to standard physical therapy and anti-inflammatory treatment for at least 3 months. Patients were included in the case series with mixed Modic changes or if multiple levels were affected and Modic 1 changes predominated. The study protocol permitted the subjects to exercise during the treatment as prescribed by their treating physician.

Patients were excluded if psychiatric comorbidities were thought to be a significant contributor to distress, if follow up could not be maintained for at least one year following treatment initiation, if there was an allergy/sensitivity to the medication, kidney disease (ie, estimated glomerular filtration rate less than 90 ml/min/1.73m^2), pregnancy, or breastfeeding.

Patients provided informed consent for the treatment protocol after discussion of potential risks including *clostridum diffiicile* infection and death. The data supporting the protocol was discussed at length with each patient prior to initiation of treatment. All patients were treated with at least 90 days of amoxicillin/clavulanate 500/125 mg po 3 times per day (TID). One patient developed hepatitis with treatment, and was then placed on 100 days of doxycycline 100 mg twice daily (BID) after consultation with an infectious disease specialist.

As per our protocol for standard clinical evaluations, baseline pain and functional measures were established. This was reevaluated at least one year after completion. Follow up imagery was also obtained for comparison to baseline with respect to volume of the end plate involved.

All patients provided written consent to publish the study findings which were retrospectively analyzed. A positive outcome was determined a priori to be at least at a 30% reduction in numeric rating scale (NRS) and/or a 20% improvement in Oswestry Disability Index (ODI), which is commonly used as the minimally important clinical difference for patients with LBP.

Results

A total of 11 patients were followed for at least one year following initiation of antibiotic treatment for LBP in the setting of Modic 1 changes. Eight patients were actively serving in the Canadian Armed Forces, while 3 others were followed through clinicians at the McGill University Health Centre. Mild Modic changes were defined as less than 30% of the end plate volume, moderate between 30% and 60%, and severe greater than 60% of volume.[12] Figures 1 and 2 show pre- and postantibiotic use MRI findings (respectively) in Patient 5.

Tables 1 and 2 present specifics related to patient demographics, baseline, outcomes, and imaging findings. Age at initiation of treatment ranged from 37 to 49 years, and there were 2 female patients in the series. All patients had LBP for at least 2 years. Prior to treatment with antibiotics, all patients had considerable therapy including medications, physical therapy, injection treatments, and spinal manipulation. Two patients (Patients 2 and 4), had Modic 1 changes at multiple levels; one with

changes at the cervical level and lumbar spine (Patient 6), and one patient with Modic changes at the thoracic level (Patient 2). Modic 2 only changes were present in one patient at one level (Patient 2) and mixed Modic 1 (ie, with minor Modic 2) changes were present in 5 patients (Patients 6, 7, 8, 10, 11). Patient 1 had mixed Modic 1 and 3 changes.

Optimistically, 9 patients (82%) reported improvement at follow up (Patients 1, 2, 3, 4, 7, 8, 9, 10, 11). However the time period of improvement made it improbable that the improvement was secondary to the antibiotic regimen for most of these cases.

Three (27%) patients (Patients 3, 4, 7) met the criteria for successful treatment for pain and/or functional improvement that could conceivably be related to the antibiotics themselves. Patient 3 had almost full resolution of symptoms and disability at 4 months, but was lost to follow up. Patient 4 had greater than 50% resolution for pain and a large improvement in function. The improvement may have been the result of physical therapy directed at sacroiliac joint mobilization and stabilization that were started one year after antibiotic treatment initiation. Patient 7 had good improvement in pain, and minor improvement in function at one year, but wished to try other treatments that included injections.

Patient 1 improved with medication and spinal manipulation initiated one year after antibiotics. Patient 2 reported a 50% improvement in global perception, but objective pain and functional scores remained unchanged, and ongoing medication treatment was required. Patient 5 required medication treatment (started one year after initial antibiotic treatment) and ongoing injection treatment. Patient 9 had a resolution in pain after an injection, done after the one year initiation of antibiotics. Patient 10 had an improvement in symptoms after an artificial disc replacement done more than one year after the initiation of antibiotic treatment. Patient 11 reported an improvement in pain of about 50%, but not function, and he attributed his well-being as tied to consistent meditation and exercise (cycling).

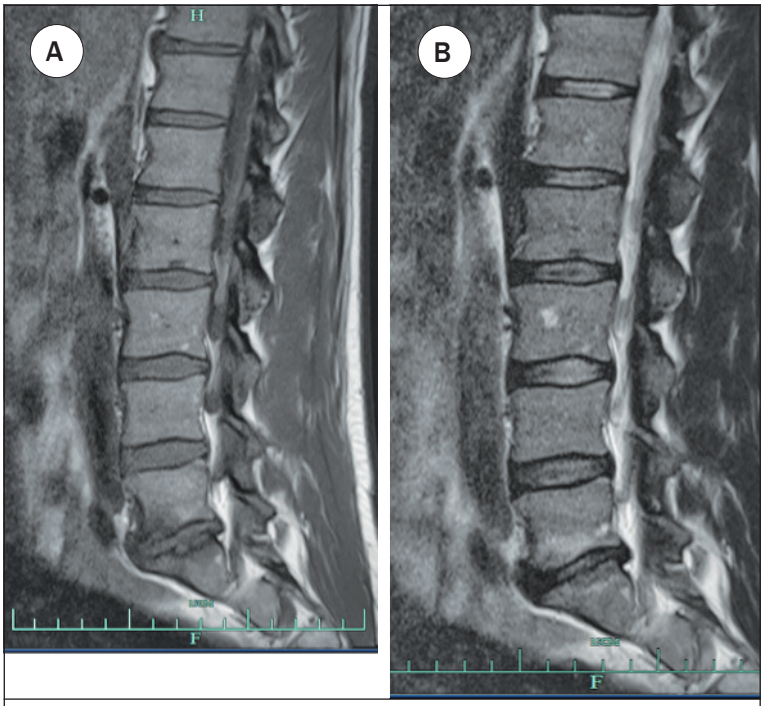

Figure 1. Saggital T1 (image A) and T2 (image B) MRI for Patient 5 pre-antibiotic use, demonstrating moderate volume Modic 1 changes at the L5/S1 endplates.

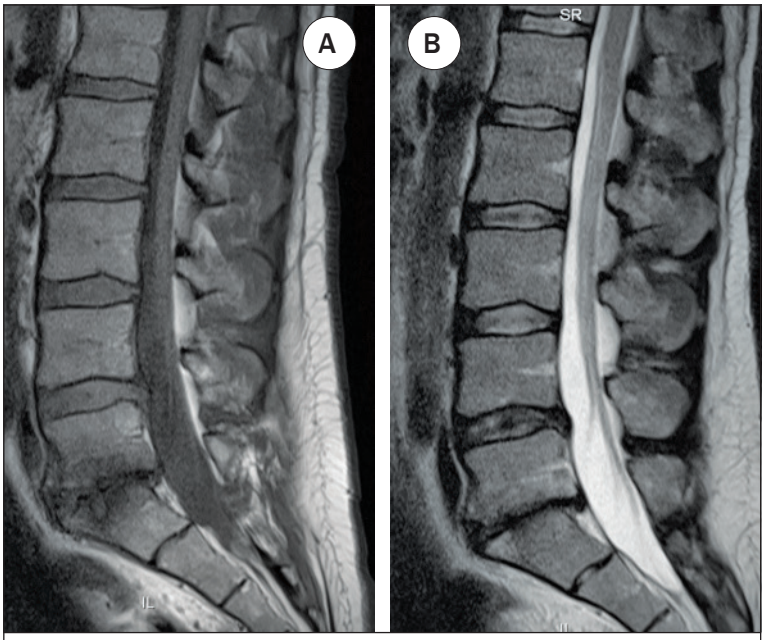

Figure 2. Saggital T1 (image A) and T2 (image B) MRI for Patient 5 post-antibiotic use, showing progressive loss of disk height and substance as well as increasing T1 signal abnormality, mixed Modic changes, and endplate irregularity.

Main side effects reported were mild gastrointestinal symptoms in 3 patients, which did not preclude treatment. There was one case of Hepatitis that required cessation of standard treatment, and normalization of liver function tests thereafter. Consistent with the earlier findings of Albert et al,[11] most adverse effects were low grade gastrointestinal complaints such as loose bowel movements, increased flatus or burping, with less than

Table 1. Patient Clinical Data and Outcomes Pre- and Postantibiotic Use (1 of 3, continued).

	Patient 1	Patient 2	Patient 3	Patient 4
Demographics (sex, age) & Pain Region -Treatment	Male, 45 y; LBP-100 days of Doxycycline. Had Hepatitis with Amox/Clav	Male, 49 y; LBP-Amox/Clav, 90 days	Male, 44 y; LBP-Amox/Clav, 90 days	Female, 37 y; LBP- Amox/Clav, 90 days
Past Medical History	Knee pain NYD, left post hernia repair pan syndrome, depression	Gout, knee OA, right radial nerve injury, right shoulder pain, left wrist pain, obesity	Right inguinal hernia repair	Cholelithiasis, whiplash associated disorder, iron deficiency, urinary stress incontinence
Treatment prior to antibiotics	Physiotherapy and NSAIDS	Physiotherapy, acetaminophen, ibuprofen	Physiotherapy and NSAIDs prn	Hydromorphone, Oxycocet, yoga, prolotherapy, Amitryptiline, Nortriptyline, Gabapentin, inversion table
How Long Pain Present	2 years	27 years (worse 3 years ago)	Worse in last 2 years	7 years
Location & Type of Modic Changes	L4-5 Modic 1 & 3 changes	Modic 1 at T12/ L1, L3/L4. Modic 2 L5 & S1. Disc protrusion L3/L4 and L4/L5	L5/S1 Modic 1 with small disk herniation	L4/5 & L5/S1 Modic 1. Disc protrusion L4-L5
Pain and Function Score at Treatment Day 0	NRS 2/10 ODI 34%	NRS 3-8/10 ODI 50%	NRS not documented ODI 34%	NRS 7/10 ODI 42%
Pain and Function Score after Treatment	At 6 months; NRS no change ODI 26%	At 4 months; improved night pain/ sleep, ODI 56% At 6 months; NRS decreased 25% but also taking Gabapentin	At 4 months; ODI 0%	At 4 months; NRS >50% relief with hydromorphone and activity restrictions post gynecologic surgery, ODI 26% At 11 months; severe increased pain and limited function associated with psychosocial stressors.
Pain Function 1 year After Treatment	NRS no change ODI 22%	Global Perception is 50% improved but ODI 52%, NRS unchanged	Lost to follow up	16 months NRS >3/10, ODI 6%
MRI Findings at One year	Unchanged from previous	Mild worsening of Modic 1 L3/4 and Modic 2 L5/S1		Modic 1 unchanged at L5/S1, mild progression at L4/5
Other Treatments/ Considerations, Postantibiotics	Currently has 50% reduction in pain with spinal manipulation therapy and Pregabalin.	Gabapentin; dosing was increased at one year follow-up.	Flare of pain 6 weeks after treatment initiation. Treatment included activity modification, spinal manipulation therapy. Report of low back pain would have precluded promotion/posting.	Tridural, long acting morphine, mental health support. Numerous psychosocial issues treated with counseling citalopram, venlafaxine quetiapine, trazadone. Found pain improved with improved mental health and physiotherapy focused on SI joint mobilization.

LBP indicates low back pain; NYD, not yet diagnosed; NRS, Numerical Pain Rating Index; ODI, Oswestry Disability Index; NSAIDS, nonsteroidal antinflammatories; OA, osteoarthritis; SI, sacroiliac.

3% of patients discontinuing therapy because of drug-related adverse reactions.

Follow up imaging at least one year post treatment was available in 8 of 11 cases. All patients had at least a small disc herniation/protrusion associated with Modic changes at the same level. There did not appear to be a correlation between improvement in symptoms and change in endplate volume involvement within the available sample.

COMMENT

Recent work[11] has created a paradigm shift in the treatment of chronic LBP when it was determined that a proportion of patients suffering from low back/lower limb pain had indolent infections remediable with a protracted course of antibiotics. The results of antibiotic treatment in the setting of disc herniation with Modic 1 changes was interesting for many reasons: (*a*) The regions affected by Modic 1 changes reduced on MRI at one year follow-up in only the antibiotic treated group. (*b*) There was an insignificant trend toward more pain relief in the higher dose group. (*c*) Leg pain fell from 5.3 to 1.7 in the antibiotic group, but rose from 4 to 4.3 in the placebo group. (*d*) The number of sick days off work during the year was 19 days in the antibiotic group and 45 days in the placebo group. (*e*) The number of times a patient visited a doctor was nearly double in the placebo

Table 1. Patient Clinical Data and Outcomes Pre- and Postantibiotic Use (2 of 3, continued).

	Patient 5	Patient 6	Patient 7
Demographics (sex, age) & Pain Region -Treatment	Male, 38 y; LBP- Amox/Clav, 100 days	Male, 46 y; Cervicalgia and LBP– Amox/Clav 90 days	Male, 39 y; LBP–Amox/Clav 90 days
Past Medical History	Depression, Right knee arthroscopy x 3, bilateral knee osteotomies, right hand tendon repairs, steroid induced central serous choroid retinopathy	Left ankle fracture, NRSectomy, septorhinoplasty	Psoriasis, GERD,left knee arthroscopy, inguinal hernia repairs bilaterally, NRSectomy
Treatment prior to antibiotics	Increased Paroxetine, lumbar facet radiofrequency denervation, NSAIDS, Capsaicin cream, acetaminophen, bilateral SI joint prolotherapy, physiotherapy	Acetominophen, codeine, NSAIDS	NSAIDS, Chiropractics, physiotherapy, massage therapy, mental health support
How Long Pain Present	3 years	7 years	9 years
Location & Type of Modic Changes	L5/S1 Modic 1 changes Disc herniation L5/S1	C5/6 Modic 1 changes. L5-S1; Modic 1&2. Disc protrusion L5/S	L4/5 Modic 1/2 changes Disc herniation L4/5
Pain and Function Score at Treatment Day 0	NRS 3-5/10 ODI not available	NRS 3-8/10, ODI-? Difficulty with running, twisting, squats, bicep curls, shoveling, mowing the lawn, lifting groceries.	NRS 5-7/10 ODI 48%
Pain and Function Score after Treatment	At 6 months; NRS no change ODI 36%	NRS no change ODI 28%	At 7 months; NRS decreased 20% ODI 36%
Pain Function 1 year After Treatment	At 1 year; NRS unchanged ODI 44%	NRS no change ODI 35 %	NRS decreased 50% Minimal leg pain ODI 32%
MRI Findings at One year	Increased Modic L5/S1	No follow-up available	Improved Modic 1 L4/5
Other Treatments/ Considerations, Postantibiotics	Spinal manipulation therapy, gabapentin- had significant improvement when taking pregabalin (7 months postantibiotic treatment). Continued with radiofrequency denervation of lumbar facet joints.	Most recently treated for thyroid cancer.	Significant improvement in lower limb, pain, less severe constant pain, ongoing limitations for sitting and standing. Stopped running. Benefit from epidural steroid injection.

LBP indicates low back pain; NRS, Numerical Pain Rating Index; ODI, Oswestry Disability Index; NSAIDS, nonsteroidal antinflammatories; SI, sacroiliac; GERD, gastroesophageal reflux disease.

group compared to the antibiotic group. (*f*) Quality of life measures improved significantly in the antibiotic group, but remained stable in the placebo group. (*g*) Blood CBC, LDH, and alk phos remained normal in most cases throughout the trial.[11]

In our case series, however, only 3 of 11 patients conservatively met the criteria for a successful outcome from a pain and/or functional standpoint at long-term follow up. One of these required ongoing yoga exercise to manage symptoms and another wished to move forward with medications and injections. There also did not appear to be a correlation with improvement in symptoms, and the available follow up imaging. This contradicts the findings of the 2 previous studies using antibiotics to treat low back pain in the setting of Modic 1 changes and disc herniation.[11,18]

Factors associated with Modic changes continue to be developed. While it is possible that Modic 1 and 2 changes are different stages of the same process,[11] fat distribution and metabolic processes may also play roles.[29] Other authors have theorized that mechanical forces across the disc can result in Modic changes.[30]

From a treatment perspective, in the setting of Modic changes and LBP, exercise has not been shown to be advantageous when compared to rest.[31] Intradiscal steroid injections have been shown to be effective for pain relief and functional improvements at 6 months in patients with LBP and Modic 1 and 2 changes when compared to placebo.[32] While one could argue that steroids may relieve the inflammation associated with bacterial production of proprionic acid,[11] it is surprising that the long-term outcomes are not poorer[33] given that the potential anti-immune effects of steroids[34] could limit the remediation of the infecting organisms. Alternately, in a case-controlled series of patients undergoing microdiscecotmy associated with low back, radicular pain and degenerative disc disease, those with Modic 1 and 2 changes had a trend to less overall improvement in pain and function than those without end plate changes.[35]

Table 1. Patient Clinical Data and Outcomes Pre- and Postantibiotic Use (3 of 3).

	Patient 8	Patient 9	Patient 10	Patient 11
Demographics (sex, age) & Pain Region -Treatment	Male, 41 y; LBP–Amox/Clav 90 days	Female, 39 y; LBP–Amox/Clav 90 days	Male, 39 y; Amox/Clav 100 days	Male, 38 y; Amox/Clav 90 days
Past Medical History	Left sided hemorrhagic stroke 2001, reflux, left elbow bursitis, tonsillectomy	No PMHx Undergoing fertility treatments	No PMH	No PMHx
Treatment prior to antibiotics	Physical therapy, lumbar prolotherapy, lumbar radiofrequecy, NSAIDS, Tylenol 3	Has tried physio, meds (NSAIDS, acetominophen), injections no help.	Has tried physio, ergotherapy, acupunture, injections, medications	Physio, core strengthening
How Long Pain Present	15 years. Worse in past 5 years. Multiple flares per year	3 years. Worse in past 2 years. Patient not at work at time of treatment	11 years. Worse in past 2 years.	4 years
Location & Type of Modic Changes	L5/S1 Modic 1/2 changes. Mild disc protrusion L5/S1	Modic 1 changes Disc herniation level of L4-L5	L5-S1 discopathy. Moderate Modic 1 changes mostly in inferior endplate of L5	Moderate to severe mix Modic 1-2 at inferior endplate of L4. Minimal Modic 1 at superior endplate of L5
Pain and Function Score at Treatment Day 0	NRS- 6/10 ODI not done	NRS 9/10 ODI 38%	NRS 6-7/10 ODI 48	NRS 7/10 OSW 30%
Pain and Function Score after Treatment	Done at 10 months. No change in NRS. Reports no change in function. ODI 26%	NRS 9/10 ODI 48%	NRS 6-7/10 ODI 48	At 6 months post completion: OSW 26% NRS 2-3/10. NRS improvement not attributed to ABX, better due to exercises.
Pain Function 1 year After Treatment	No change in NRS ODI 22%	NRS 0/10 ODI not available One year after antibiotic; no pain due to cortisone injection	15 months post abx; NRS 6-7/10, ODI 48%. 2 years post ATB and 1 year post surgery; NRS 1-2/10, ODI 32%	14 month post Abx; NRS 3-4 ODI 24%
MRI Findings at One year	Slightly improved Modic 1	No follow-up available	No changes from previous images	L4-L5 mix Modic 1-2, increase changes at L5 superior endplate Modic 1
Other Treatments/ Considerations, Postantibiotics	Ongoing pain and exercise limitations. Not pursuing other treatment at this time.	Patient feels better with yoga, epidural steroid injection.	Artificial disc replacement, L5/S1	Pain better controlled but with regular cycling and meditation.

LBP indicates low back pain; NRS, Numerical Pain Rating Index; ODI, Oswestry Disability Index; NSAIDS, nonsteroidal antinflammatories; SI, sacroiliac; PMHx, past medical history; Abx, antibiotic.

A recent systematic review concluded that in the setting of disc herniation, there was moderate evidence for low virulent bacteria being associated with back pain related to Modic 1 changes. When looking specifically at causation, it was felt the criteria for temporal relationship, consistency, dose response relationship, and analogy was not met in the existing literature. Given that Modic 1 changes can occur in other disc pathologies, lower quality trials did not show an association with Modic changes, bacterial infection, and LBP. Therefore, at best, there may only be a small subset of patients with LBP who would be candidates for antibiotic treatment.[29]

Numerous questions regarding the role of antibiotic treatment in LBP remain to be answered. It is still unclear how long treatment is required, and whether resolution of the Modic changes relates to the alleviation of pain given the potential lag in resolution on MRI. It also remains to be determined whether serology-based tests can be developed to help monitor treatment response. Clinicians may need to consider the patient's environmental exposures (ie, military postings, region of residence at onset of pain) when considering which antibiotics to use as well as have other antibiotic choices and routes available for patients that fail or cannot tolerate standard therapy. Further clarification regarding the importance of findings at other spinal levels and the significance of other types of Modic changes will be required. Finally, the most important issue is how to manage patients with pain while they are undergoing treatment, waiting for clinical response, or have a suboptimal result from antibiotic treatment.[36]

Table 2. MRI Findings Pre- and Postantibiotic for Available Patients.

Patient	Pre-MRI	Post-MRI
Patient 1	Mild Modic 1 changes at L4 and L5 Small disk protrusion (improved from 2014) Moderate Modic 3 changes at L4 endplates	Unchanged posttreatment
Patient 2	Mild Modic 1 at T12 and L1 Mild Modic 1 at L3 and L4 Moderate Modic 2 L5 & S1 Small disc protrusion L3/L4 and L4/L5	T12-L1 no change L3/4 worsening Modic 1 volume (still mild range) L5/S1- worsening Modic 2 (still moderate range)
Patient 4	Moderate Modic 1 at L4 Minor Modic 1 at L5 Small protrusion L4/5 Minor Modic 1 L5-S1	Unchanged at L5S1 Mild progression at L4/5 (no change to volume classification) Minor improvement in L4-5 protrusion
Patient 5	Mild Modic 1 changes L5/S1 Small disk herniation L5/S1	Moderate Modic 1 changes L5/S1, (increased endplate involvement) Stable disk herniation
Patient 7	Predominantly Modic 1 moderate volume L4 and L5 Minor Modic 2 at L4/5 Small disk herniation L4/5	Improved Modic 1 (less endplate involved but still in moderate range) Slight progression Modic 2 – still in minor range
Patient 8	Predominantly mild L5/S1 Modic 1 with Modic 2 Small disk protrusion L5/S1	Slightly improved Modic 1 – no change in endplate volume No change in disk protrusion
Patient 10	L5-S1 discopathy Moderate Modic 1 changes mostly in inferior endplate of L5	No changes from previous images
Patient 11	Moderate to severe mixed Modic 1-2 at inferior endplate of L4. Minimal Modic 1 at superior endplate of L5	Increased Modic 1 changes at L4 superior endplate L4/5 with small disk herniation

There are numerous limitations to our study. This was a small, retrospective analysis that analyzed incomplete data and did not have a comparator group. Our outcomes also did not include effect on the patient's work productivity and health care utilization. We also used the lower dose of the antibiotic (ie, 500/125 one pill 3 times daily) compared to the higher dose, which may have a clinical advantage given the difference shown in the Albert et al trial.[11] We also included patients with Modic changes at multiple levels, as we theorized the bacterial infection could be present at multiple levels and mixed Modic 1 and 2/3 changes, where Modic 1 changes predominated. Finally, this was a retrospective effectiveness analysis since our patients were a true representation of our clinical setting, which included patients with coexisting mental health issues and were not restricted in exercise during treatment. Our experience is that these trials still make an important contribution to the literature, as similar studies have questioned the results of other landmark randomized controlled trials when applied in other clinical settings.[37]

Therefore, while we understand the limitations of the data presented here, we have stopped the use of antibiotics in the treatment of patients with LBP and Modic changes until other centers have reported on their outcomes.

Conclusion

The use of amoxicillin/clavulanate for 3 months in patients with Modic changes and LBP had limited effect on reducing long-term pain and clinical outcomes in a small case series of patients.

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Low Rate of Early Disabling Back Pain Following Traumatic or Posttraumatic Major Extremity Amputation

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Major extremity amputation has a well-documented association with persistent back pain, with rates of chronic low back pain in patients with major extremity amputation reported in the range of 35% to 80%.[1-8] The effect of back pain on the patient with major extremity amputation is known to decrease health-related quality of life and is associated with increased levels of chronic pain development as well as decreased reported levels of activity.[2,9,10] It is also suggested that back pain can be more bothersome to the patient with amputation than pain related to either the residual limb or phantom limb.[4,8] Most studies that have evaluated back pain in the setting of a prior amputation have included diverse populations with variable patient ages, comorbidities, or even amputation etiologies ranging from tumor to infection to trauma in the same cohort.[2-5] As a result, based on current published data, it is difficult to draw useable prognostics regarding the likelihood of developing disabling back pain for patients with traumatic or posttraumatic amputation.

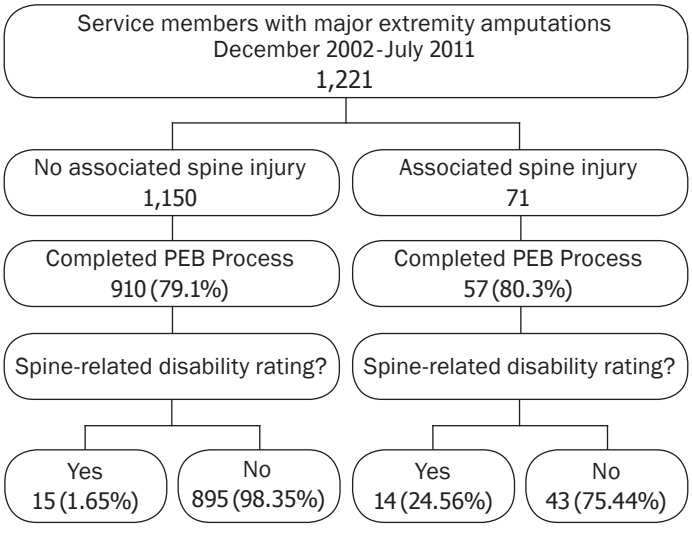
The recent military conflicts have resulted in many US service members sustaining trauma-related major extremity amputations.[11,12] The most common mechanism of injury leading to amputation in recent US combat operations has been by high energy blast, which is unique to this retrospective review in comparison to the published reports from civilian trauma settings.[13-15] Review of the medical records for this relatively homogenous group of US service members with amputation (SMAs) has created the largest retrospective cohort of trauma-related major extremity amputations of which the authors are aware. The focus of this retrospective analysis was to evaluate the prevalence of disabling back pain in service members with traumatic and posttraumatic major extremity amputation following the recent US military conflicts. We further sought to compare the prevalence of disabling back pain in a military population to the currently published rates.

Methods

This retrospective study was conducted under a protocol approved by our institutional review board. The Military Amputation Database (Extremity Trauma and Amputation Center of Excellence, Fort Sam Houston, Texas) was used to identify all primary major extremity amputations (MEA), defined as an amputation proximal to the carpals or tarsals, sustained by US service members between December 1, 2002, and July 30, 2011.[11,12] The injury characteristics, diagnoses, and other medical treatment information for each identified service member with a MEA was cross-referenced with the Joint Theater Trauma Registry (US Army Institute of Surgical Research, Fort Sam Houston, Texas), the Armed Forces Health Longitudinal Technology Application, and the Theater Medical Data System, specifically looking for dates of injury and level of amputation(s), the presence of associated traumatic spine injuries, and any pre- or postinjury treatment for back pain.

The Physical Evaluation Board Liaison Office for each military service branch was also queried for each of the identified SMAs. In the military, the Physical Evaluation Board (PEB) is a medical evaluation process that occurs following a major injury. The PEB determines whether a service member is fit for duty, requires a change in occupational role or restricted duty, requires further recovery time, or must permanently separate from the military with disability benefits. The PEB process also assigns final disability ratings to the service members for their various disabling conditions on a 0 to 100 point scale, where a total rating greater than 75 indicates that a service member is fully disabled.[16]

For the purpose of this study, the presence of a PEB disability diagnosis related to back pain with a rating greater than zero signified the presence of disabling back pain. This was the primary outcome measure for the current study. Those SMAs treated for back pain prior to amputation, including narcotic medication, physical therapy, or chiropractic manipulation were excluded from final calculations of de novo disabling back pain (DDBP). A significant spine injury was considered to be any fracture or dislocation of the spine requiring surgical stabilization, any fracture of the vertebral body, or



Distribution of the 1,221 SMA study subjects according to the criteria of associated significant spine injury, completion of the PEB process, and assignment of a spine-related disability rating.

fracture of the posterior elements with the exception of isolated transverse process or spinous process fractures. The time from initial amputation until completion of the PEB process was calculated for each SMA, as was the duration from index injury until the first appearance of a back pain diagnosis in the health record. A Fisher's exact test was used for categorical data and a Student's *t* test was used for the subgroup analysis, with significance set at *P* less than .05.

Results

A total of 1,221 US service members were identified as sustaining one or more MEA between December 2002 and July 2011. The most common amputation level was transtibial, followed by unilateral above the knee, bilateral above the knee, and bilateral transtibial amputations as previously characterized by Krueger et al.[12] At the time of data collection, 967 of the 1,221 SMAs had completed a PEB and had final disability diagnoses and ratings available for review. Among these 967 SMAs, 57 sustained a significant spine injury as part of their index traumatic injury profile, and 910 did not. Fifteen of these 910 SMAs without a significant traumatic spine injury were given a PEB disability rating related to back pain (DDBP), for a rate of 1.65%. Fourteen of the 57 SMAs with a traumatic spine injury received back pain-related disability ratings, for a rate of 24.56% (1.65% vs 24.56%, *P*=.0001). This distribution is presented in the Figure. Breaking down the SMAs into upper extremity, lower extremity, and combined upper and lower extremity amputation groups failed to show any statistically significant difference in the rate of DDBP when compared to the group as a whole (Table 1).

Table 1. Rate of de novo Disabling Back Pain (DDBP).

Amputation(s)	Total Subjects	Subjects with DDBP	Rate of DDBP
Unilateral upper extremity (UE)	134	2	1.49%
Bilateral UE	8	0	0%
Unilateral lower extremity (LE)	544	11	2.02%
Bilateral LE	187	1	0.53%
Combined UE and LE	37	1	2.70%
All service members with amputation with completed PEB and no spine injury	910	15	1.65%

Among those SMAs whose PEB results were available for review, 690 included the date of PEB result, including 11 of the 15 SMAs with the primary outcome measure, DDBP. The average time from amputation until PEB completion for these 11 SMAs was 817 days, compared to an average of 547 days for the remaining 679 SMAs whose PEB dates were reviewed. This is a difference of 270 days which was not significant (*P*=.096). The duration from index traumatic injury until the first appearance of a back pain-related diagnosis in the health record was also calculated for the 15 SMAs with DDBP and averaged 15.1 months.

Comment

We found that in the absence of a traumatic spine injury, the prevalence of early DDBP was 1.65% in this cohort of SMAs. Those SMAs who had sustained a traumatic spine injury were more likely to receive a back pain disability rating as part of the PEB process (*P*=.0001) than those SMAs without a spine injury. The anatomic location of the major extremity amputation did not appear to directly correlate with the rate of DDBP; however, there were few SMAs with DDBP in total from which conclusions could be drawn. Although not statistically significant, the average time of final PEB disability ratings for SMAs with DDBP was longer than those without DDBP.

Recent epidemiologic studies have estimated a global point prevalence of back pain at 10% to 33% of the population, and there have been multiple publications over the past decade reporting an even higher rate of back pain among patients with major extremity amputations (Table 2).[17,18] For instance, low back pain (LBP) rates were 64% among surveyed New Zealand patients with transfemoral amputation, and the percentage of patients with restrictions in activities of daily living as a result of LBP were 39%.[1] While the majority of literature regarding back pain in patients with MEA has been based upon survey responses

Table 2. Summary of the back pain prevalence among patients with amputation in the literature.

Study	Population	Patients With Amputation	Amputation Etiology	Prevalence of Back Pain	Notes
Hammarlund et al[2]	Swedish civilian	68	Trauma, tumor	35%: daily or several times per week	Lower extremity amputation only, average of 23 years postamputation at time of surveys.
Ehde et al[3]	US civilian	255	Trauma, vascular, infection, diabetes, tumor, other	52%: "persistent, bothersome back pain" of which 25% considered the pain severe and interfering with daily activities	56% survey response rate. Average time since amputation 14.2±15.7 years.
Reiber et al[7]	US Veterans	581	Trauma	Chronic back pain: 36.2% in Vietnam veterans 42.1% in OIF/OEF veterans	Mail and telephone surveys. Includes partial hand and partial foot amputations. Mean number of years since initial limb loss was 38.6±4 years for the Vietnam cohort, and 3.1±1.2 years for the OIF/OEF cohort.
Kulkarni et al[8]	UK civilian	202	Trauma	63%: moderate to severe back pain	Back pain more frequent than stump or phantom limb. 20% of participants were examined with MRI. Average follow-up was 19 years (range 2-40 years). 60% of amputees who responded reported back pain within 2 years of the amputation.
Smith et al[5]	Irish civilian	107	Trauma, peripheral arterial disease, diabetic vascular disease, malignancy, osteomyelitis, other	47.7% with chronic back pain, and of those with back pain, 39.2% rated it severely bothersome.	Mean age 51 years. Mean duration since amputation was 17 years.

with patient-reported levels of pain and disability, this study used the results of a medical evaluation, the PEB process, as a quasi-objective measure of disabling back pain.[19] This is an important point of distinction when comparing this study to previously reported results, because the PEB process attempts to quantify and objectively measure for the presence of disabling back pain, whereas other published rates on the prevalence of back pain merely report on the presence of chronic back pain as part of a survey, but do not necessarily account for the intensity or the level of disability associated with the back pain.[7]

As previously mentioned, there are several factors which make it difficult to extrapolate previously published data to the current study. Namely, prior studies have almost uniformly included at least one significant variable within the studied cohort, such as multiple etiologies of amputation, widely variable patient age groups, or patients ranging from healthy to those with multiple comorbidities. This study included only amputations resulting from traumatic injury and only included active duty service members aged from 18 to 47 years (mean 25 years) and only 2% of SMAs over age 40. The lack of a significant difference in the rate of early disabling back pain between the upper extremity, lower extremity, or combined amputation groups when compared to the entire cohort was not surprising, given the very low overall number of SMAs developing early DDBP.

The average time from amputation to PEB completion was 817±485 days, and, in general, the evaluation occurs several months prior to the issuance of final results. Hence, the short time from amputation to the medical evaluation may be a rather significant confounding factor in the lower than expected rate of disabling back pain seen in the results. While the short duration between amputation and final evaluation may be one contributing cause for the low rate of DDBP found in this study, another potential contribution to the infrequent development of DDBP may be the abundant resources available to the SMAs. This includes highly trained medical, surgical, and ancillary care providers as well as access to high end prosthetics and rehabilitation, and even a state-of-the-art facility dedicated entirely to rehabilitation of the war-wounded (Center for the Intrepid, Ft Sam Houston, Texas).[20,21] The lower rate of DDBP is somewhat unexpected, particularly when contrasted against Kulkarni et al reporting a 38% prevalence of moderate to severe back pain which limited activity level in patients with

MEA, which we considered to be a correlate to our term "disabling back pain."[8] Kulkarni et al found that there were no differences in lumbar magnetic resonance imaging between the back pain and pain-free groups, but did find differences in gait asymmetries and standing stability differences, suggesting that early intervention with gait retraining may prevent disabling back pain.[8] Although our analysis of these data was not aimed at showing definitive correlation to the early rehabilitation components, specifically with respect to gait analysis and retraining, these are early fundamental components of the rehabilitation that service members receive at the Center for the Intrepid. As such, it may help to explain the difference in disabling back pain in this specific cohort.

These resources are not necessarily available to all patients with MEA outside of the US military, especially when considering those patients without health insurance, as is not an uncommon circumstance in the United States. This fact is further highlighted when considering the published findings of Smith et al[5] on patients attending outpatient prosthetic fitting clinics. In their study, survey results of 107 patients with amputation that attended outpatient prosthetic fitting clinics, 47.7% of patients reported back pain, and 31.3% experienced back pain at least 4 times per week. There was no correlation found regarding amputation level, although they did report that the intensity of back pain increases with age. In their study, 39.2% of surveyed patients reported "disabling" back pain, or pain that interfered with activities of daily living, which is higher than our cohort of patients, but the prevalence may be overestimated to some extent because the pain may have been related to prosthetic fitting issues.

This study has limitations inherent to retrospective reviews, particularly as in this case being limited by the quality and uniformity of the information included in the medical records. This review included multiple electronic medical records across several years and as such the methods of documenting various injuries and medical diagnoses varied throughout. There is also only a single definitive value for back pain in this study, which is the presence of a PEB disability rating related to back pain. The PEB analysis to identify patients with disabling back pain can be viewed as a more objective means of determining disability compared to survey analysis; however, it is limited in that it represents a brief snapshot of disability while a service member remains on active duty status. In the current study, the endpoint for determining DDBP was the PEB evaluation for each SMA. That endpoint was, on average, 547 days after amputation for the cohort as a whole, and was 270 days longer for those who developed the primary outcome measure, DDBP, and received a back-related disability rating. It is possible that a larger number of the SMAs would be found to have disabling back pain if their PEB evaluations occurred later following their amputation, as Kulkarni et al found that only 60% of their respondents reported the onset of back pain within 2 years of amputation.[8] It would be potentially very informative to perform a follow-up study of the same population with patient-answered surveys regarding the frequency and severity of back pain experienced by each SMA. Such a study may support the findings from the current study or could potentially find patient-reported prevalence of back pain more in agreement with that reported in the references cited throughout this article.

Conclusion

The prevalence of early disabling back pain in the absence of concomitant traumatic spine injury is lower in this cohort of US service members with amputation than would be expected based on currently published literature. Further research or even a follow-up survey of the same cohort may help establish whether this is in fact a lower prevalence of disabling back pain or merely a lower rate of capturing the diagnosis due to the timing of the evaluations and the limitations of the PEB disability rating system.

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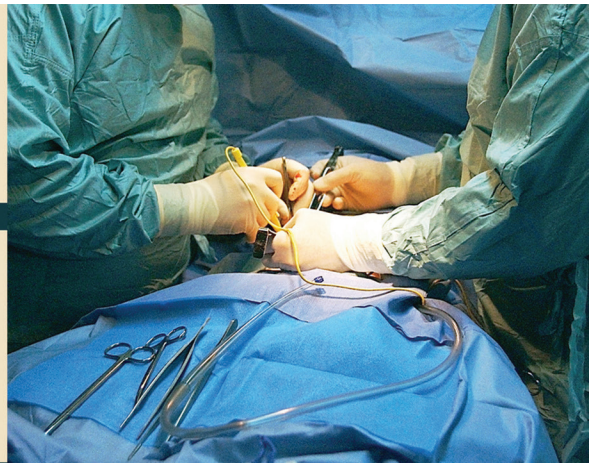

Use of Ankle Magnetic Resonance Imaging in the Active Duty Military Population: The Results of a Process Improvement Project

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Abstract

Background: Preventing overuse of magnetic resonance imaging (MRI) for diagnosing ankle pathology was the goal of a process improvement project at a military treatment facility.

Methods: Ordering patterns for MRI of nonorthopaedic providers and orthopaedic surgeons were evaluated over 2 separate periods. An educational initiative on appropriate use of MRI in evaluating ankle complaints was conducted between the 2 periods.

Results: Between October 2009 and March 2010, 230 ankle MRIs were performed at our institution, compared to 347 ankle MRIs performed between December 2012 and August 2013. A lower number of patients underwent operative procedures after the education process than before (17% versus 25%). Fellowship-trained foot and ankle surgeons produced the highest number of operative patients with their MRI ordering practices (P=.003 and P=.0001 for Phases 1 and 2 respectively). There was no change in the number of ankle MRI studies ordered each month following the educational initiative (38.3 and 38.5 for Phases 1 and 2 respectively).

Conclusions: The majority of patients undergoing ankle MRI did not undergo operative intervention. Foot and ankle surgeons produce the highest number of operative patients with their MRI ordering practices. Education alone was ineffective in altering ankle MRI ordering patterns.

The active duty military population is an athletic community that participates in a variety of physically challenging activities and is subject to a wide variety of musculoskeletal injuries. Specifically, ankle injuries are among the most common injuries, with reported incidence rates as high as 58.4 per 1,000 person-years among cadets at the United States Military Academy, amounting to a 10-fold increase compared to civilian epidemiologic reports.[1] Performing a thorough history and physical examination and obtaining appropriate radiographs should be the first step in identifying the diagnosis of a musculoskeletal complaint. When these modalities fail to elicit an appropriate diagnosis, primary care providers are frequently ordering advanced imaging, including magnetic resonance imaging (MRI) studies, prior to referral to specialists.[2] Avoiding unnecessary, costly advanced imaging and preventing overuse of MRI in a primary care setting for diagnosing ankle pathology was the goal of a recent process improvement project at a military treatment facility.

Magnetic resonance imaging is best used in cases where the differential diagnosis is narrow, and a precise understanding of the pathology is required for preoperative planning.[3] Current trends, however, show magnetic resonance imaging being used more frequently as a screening tool.[4] Magnetic resonance imaging can be overly sensitive in demonstrating findings that are not clinically significant, and can lead to misdiagnosis or overdiagnosis and treatment.[5] Increasing medical costs, decreasing reimbursements, and overuse of imaging modalities have led to a growing interest in processes to decrease use of costly, oftentimes unnecessary, tests.[6]

Concern regarding the use of ankle MRI studies prompted fellowship-trained foot and ankle surgeons at our institution to hypothesize that ankle MRI was overused in the military setting, and inspired a process improvement initiative. The purpose of the initiative was to: evaluate the use of ankle MRI studies ordered by all health care providers in the military population; correlate the MRI results to their treatment pathway of operative or nonoperative treatment; and propose solutions to improve use of ankle MRI. To evaluate this, we studied the MRI ordering patterns of both orthopaedic surgeons and nonorthopaedic providers (NOPs) from internal medicine,

family medicine, etc. Further, in an effort to improve overall ankle MRI use, we undertook an educational outreach initiative to improve understanding of NOPs of the clinical utility of advanced imaging.

Methods

This process improvement project consisted of 2 phases and was led by the Department of Orthopaedics. The radiographic database at our institution (Impax) was queried for all ankle MRI studies performed consecutively from October 1, 2009 to March 31, 2010 (Phase 1). We limited the results of the search to only active duty servicemembers aged 18 years and older. The data collected from the electronic radiographic database included the chief complaint, clinical indication, findings of the ankle MRI, date of the MRI, and specialty of provider who ordered the study. Next, the orthopaedic clinical scheduling system (AHLTA) was queried and cross-referenced to the list of ankle MRI studies to determine if patients were ultimately referred for orthopaedic evaluation. Finally, the surgery scheduling system (S3) was referenced to determine what surgeries were performed on patients from the ankle MRI studies list. No personal patient identifiers were recorded. The clinical indication for the MRI and subsequent operative procedure(s) were assessed with the primary outcome measure defined by whether or not the patient underwent an orthopaedic operative intervention. Secondary measures evaluated included the specialty of the provider ordering the study, changes in referral patterns, and whether or not plain radiographs were obtained prior to MRI.

The results of Phase 1 of the process improvement project were then presented to hospital leadership, and an education plan was developed and implemented. Approved measures were implemented from August to November 2012 and included updated clinical referral guidelines on the health system intranet available to all providers. This update specifically stated that ankle MRIs should not be ordered prior to referral to an orthopaedic surgeon, and included recommendations for ordering plain radiographs prior to referral to an orthopaedic surgeon. This update was announced to all providers electronically as well as at 3 different professional staff meetings for the hospital. Since quarterly attendance at this meeting is mandated by hospital leadership, it was felt that the information would be disseminated appropriately. Finally, the orthopaedic foot and ankle surgeons provided 3 in-services on indications for advanced imaging, including MRI, for outlier clinics and the Departments of Internal Medicine and Family Medicine. Once the education process was completed, the radiographic database was once again searched from December 1, 2012 to August 30, 2013 (Phase 2) with the same criteria as the initial time period. Statistical analysis was performed using Fisher's exact test (GraphPad Software, Inc, La Jolla, CA). Statistical significance was set at $P < .05$.

Results

Phase 1

From October 1, 2009 to March 31, 2010, 230 ankle MRI studies were performed on active duty personnel. Of the 230 active duty servicemembers with ankle MRI studies, 143 (62%) patients had an MRI ordered by NOPs and 87 patients (38%) had an MRI ordered by an orthopaedic provider. There were 17 patients (7%) who did not have plain radiographs performed prior to the MRI. Of the 143 MRI scans ordered by the NOPs, 98 patients (69%) were referred to an orthopaedic provider. During Phase 1 of the process improvement initiative, 185 of 230 patients, (80%) of this cohort were evaluated and treated by the orthopaedic surgery department at our facility. The most common complaints stated as reasons for obtaining an MRI were pain followed by instability. The most common diagnoses obtained by MRI included chronic injuries to the lateral ankle ligaments, talus osteochondral defects, and Achilles tendinosis.

Of the entire cohort of patients undergoing ankle MRI, 59 of 230 patients (25%) were eventually indicated for surgery. Of the 143 patients for which an ankle MRI study was ordered by NOPs, 98 (69%) patients were referred to orthopaedics for evaluation, and of those, 33 (23%) underwent an operative procedure (Figure 1). By comparison, the orthopaedic group ordered 87 ankle MRI studies and 26 (30%) patients underwent an operative procedure (Figure 2). Within the orthopaedic group, foot and ankle surgeons and podiatrists were evaluated as groups separate from the rest of the orthopaedic department. Ankle MRI studies ordered by podiatrists

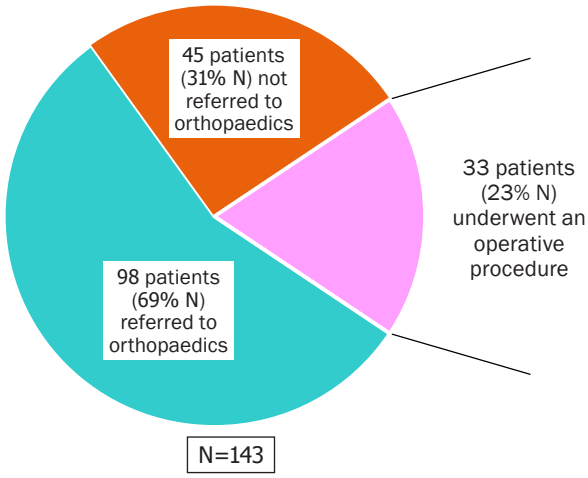

Figure 1. Results from Phase 1: 143 patients with ankle MRI studies ordered by nonorthopaedic providers.

resulted in 6 out of 40 (15%) patients undergoing an operative procedure, while 20 of 47 (43%) patients with MRI studies ordered by an orthopaedic surgeon underwent an operative procedure. When fellowship-trained foot and ankle orthopaedic surgeons were excluded from this analysis, only 8 of 26 patients (30%) underwent an operative procedure. Of the 21 patients evaluated by a fellowship-trained foot and ankle surgeon, 12 (57%) underwent an operative procedure.

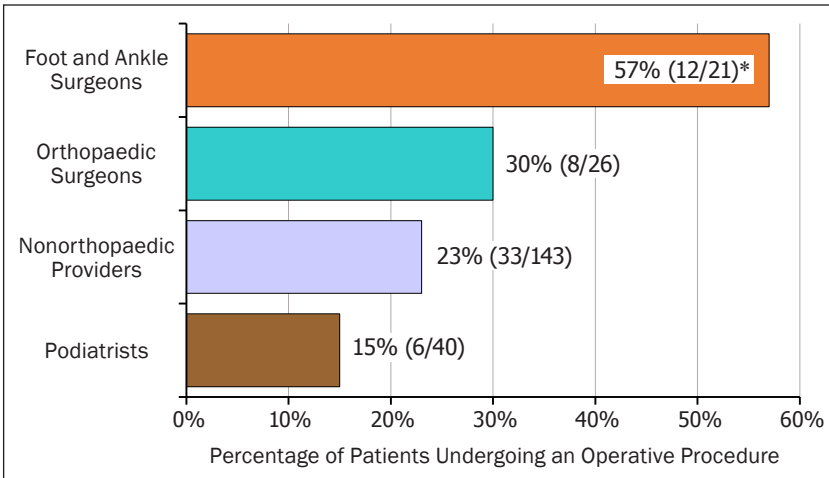

Figure 2. Results of Phase 1 data collection. Percentages represent the yield of operative patients based on the provider group that ordered the ankle MRI. Included next to percentages are the number of operative patients relative to the total number of ankle MRIs ordered. Note: * indicates statistical significance.

When comparing the NOPs to the orthopaedic group, there was no significant difference in yield of operative patients with ankle MRI studies between the 2 groups (P=.28). However, there was a significant difference in the proportion of patients with ankle MRI associated with an eventual operative intervention ordered by fellowship-trained foot and ankle orthopaedic surgeons compared to those with ankle MRI ordered by NOPs (P=.003). When comparing fellowship-trained foot and ankle orthopaedic surgeons and orthopaedic surgeons, there was no significant difference in yield of operative patients with ankle MRI studies between the 2 groups (P=.08). The most common operative procedures performed are listed in the Table.

Phase 2

From December 1, 2012 to August 30, 2013, 347 ankle MRI studies were performed on active duty personnel. Of the 347 active duty servicemembers with ankle MRI studies, 228 (66%) patients had ankle MRI studies ordered by NOPs and 119 patients (34%) had an MRI ordered by an orthopaedic provider. There were 58 patients (17%) who did not have plain radiographs performed prior to the MRI. Of the 228 MRI studies ordered by the NOPs, 143 patients (63%) were referred to an orthopaedic provider, which was not significantly different from Phase 1 (P=.27). There were 262 of 347 (76%) patients evaluated and treated by the orthopaedic surgery department, which was not significantly different from Phase 1 (P=.19). Pain and instability remained the most common patient complaints, and there were no changes in the most common diagnoses obtained by MRI.

The most common procedures performed on patients with preoperative ankle MRI studies.
Lateral ankle ligament reconstruction
Ankle arthroscopy with debridement
Microfracture of osteochondral defects
Reconstruction of cavovarus foot
Reconstruction of planovalgus foot
Excision of osteophytes

Of the entire cohort of patients undergoing ankle MRI, 58 of 347 (17%) patients were eventually indicated for surgery. Of the 228 patients for which an ankle MRI study was ordered by NOPs, 143 (63%) patients were referred to orthopaedics for evaluation, and of those, 29 (13%) underwent an operative procedure (Figure 3). By comparison, the orthopaedic group ordered 119 ankle MRI studies and 29 (24%) patients underwent an operative procedure (Figure 4). Foot and ankle surgeons as well as podiatrists were evaluated as groups separate from the rest of the orthopaedic department once again. Ankle MRI studies ordered by podiatrists resulted in 4

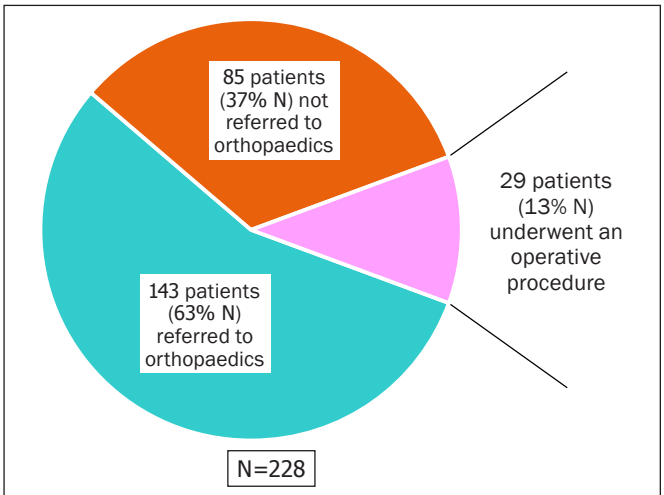

Figure 3. Results from Phase 2: 228 patients with ankle MRI studies ordered by nonorthopaedic providers.

out of 29 (14%) of patients undergoing an operative procedure, while 25 out of 90 (28%) of patients with MRI studies ordered by an orthopaedic surgeon underwent an operative procedure. When the foot and ankle surgeons were excluded from this analysis, only 9 of 50 patients (18%) underwent an operative procedure. Of the 40 patients with ankle MRI studies ordered by foot and ankle surgeons, 16 (40%) had an operative procedure performed.

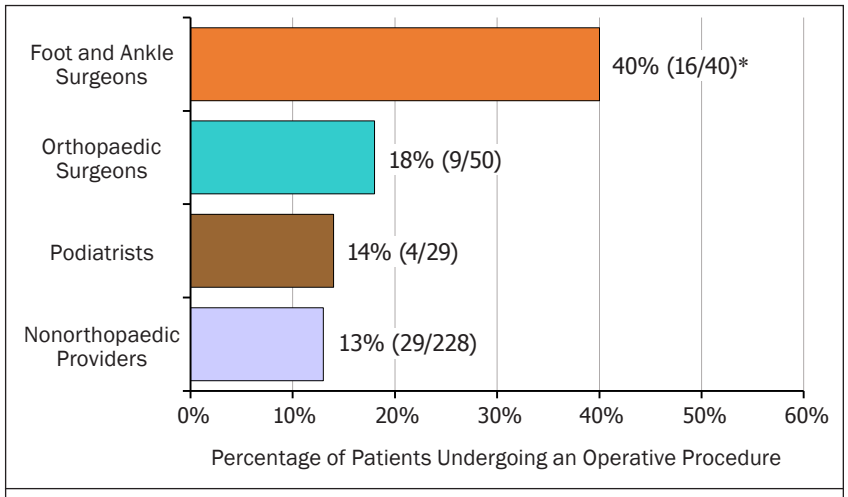

Figure 4. Results of Phase 4 data collection. Percentages represent the yield of operative patients based on the provider group that ordered the ankle MRI. Included next to percentages are the number of operative patients relative to the total number of ankle MRIs ordered. Note: * indicates statistical significance.

When comparing the NOPs to the orthopaedic group, there was a significantly higher yield of operative patients (P=.01) with ankle MRI studies in favor of the orthopaedic group for Phase 2. There continued to be a significantly higher yield of operative patients from the subgroup of patients with an ankle MRI ordered by foot and ankle surgeons compared to those with an ankle MRI ordered by NOPs (P=.0001). When comparing fellowship-trained foot and ankle surgeons to orthopaedic surgeons, foot and ankle surgeons had a significantly higher yield of operative patients following MRI for Phase 2 (P=.03). The most common procedures performed during Phase 2 were no different compared to Phase 1.

A lower yield of patients underwent an operative procedure after the education process than before (17% versus 25%). There was a significant decrease from Phase 1 to Phase 2 in the overall number of operative patients with an ankle MRI study, regardless of which provider ordered the ankle MRI (P=.01). There was no difference in patient referral rates to orthopaedics in Phase 1 versus Phase 2 following the order of an ankle MRI by NOPs (P=.27). Significantly fewer plain films were ordered prior to ordering advanced imaging in Phase 2 compared to Phase 1 (P=.001). There was no change in the number of ankle MRI studies ordered each month (38.3 ordered in the preeducation process, and 38.5 posteducation).

Comment

Throughout both phases of the process improvement initiative, fellowship-trained foot and ankle surgeons produced the highest yield of operative patients with their MRI ordering practices (P=.003 and P=.0001 for Phase 1 and Phase 2 respectively). Following the educational initiative, there was no decrease in the number of monthly ankle MRI studies performed, fewer patients with ankle MRI studies underwent operative procedures, and fewer radiographs were ordered before advanced imaging. Additionally, the decrease in operative candidates between orthopaedics surgeons and fellowship-trained foot and ankle surgeons in Phase 2 could suggest that the necessity of ongoing training on the indications for ankle MRI is not isolated to the NOPs, and should include orthopaedic surgeons as well. The fact that referral rates did not change also raises concern that there remains a large group of patients (>30% in both phases) that may have undergone unnecessary advanced imaging.

Few studies in the orthopaedic literature evaluate use of MRI. In a study by Tocci et al, researchers identified 201 patients that were evaluated over a 3-month period; 19.9 % had MRI studies of the ankle during their course of treatment, 15.4% presented to the initial visit with a MRI scan from an outside provider, and 4.5% of the patients received an MRI scan ordered by the foot and ankle specialist.[3] This study further mentions that 87% of the prereferral MRI scans were thought to be unnecessary, and all 9 MRI studies ordered by the foot and ankle specialist were useful in the care of the patient.[3] Bradley et al evaluated the use of MRI in chronic shoulder pain patients and identified that the majority of the preevaluation MRI scans had no effect on the outcomes of the patients, and although not statistically significant, further analysis revealed a tendency towards patients with an MRI to choose surgery over nonoperative treatment when patients had knowledge of pathologic anatomy from an advanced imaging modality.[4] These authors concluded that routine preevaluation with MRI does not appear to have a significant effect on the treatment or outcome and should not be used as a screening tool for atraumatic shoulder pain before a comprehensive clinical evaluation of the shoulder.[4] When ordering an MRI, caution must also be taken, as false positive results occur

and can further alter the perception of the diagnosis and subsequent treatment plan.

Saxena et al evaluated 100 patients with asymptomatic ankles who had an ankle MRI performed, and noted that 66% of the patients had no history of an ankle sprain and 34% had a history of at least one ankle sprain.[5] Results from the study showed that 30% of asymptomatic patients had abnormal findings with the anterior talofibular ligament and peroneal tendons, and 11% had an abnormal calcaneofibular ligament.[5] Schneck et al have documented that 90% of patients with lateral ankle instability can be treated nonoperatively.[6] In our process improvement initiative, 93% of patients had a radiographic abnormality, but few underwent an operative procedure. This is further highlighted by the fact that Achilles tendinosis appeared as one of the most common diagnoses based on MRI findings. However, Achilles procedures are not among most commonly performed procedures as shown earlier in the Table. The large number of radiographic abnormalities does not necessarily correlate with the necessity for operative intervention, confirming results previously published.

Overuse of advanced imaging studies increases medical costs, places undue stresses on the patient's time, and can lead to adverse outcomes.[7-8] Radiologists have recognized that more expensive imaging modalities are being overused, and are taking the lead in the reform process by implementing strategies to decrease the unnecessary use.[9,10] Solutions have been proposed for improving use of medical imaging which include a national collaborative effort to develop evidence-based appropriateness criteria for imaging, greater use of practice guidelines in requesting and conducting imaging studies, decision support at point of care, education of referring physicians, accreditation of imaging facilities, management of self-referral and defensive medicine, as well as payment reform.[11-14] Decision support at the point of care can include radiologist or fellowship-trained specialist approval of advanced imaging concurrent with a patient referral. From 2000 to 2006, Medicare expenditures for diagnostic imaging represented the highest growth rate compared with all other specialties, and spending on imaging studies per beneficiary nearly doubled.[15] Even though solutions have been proposed, overuse of advanced imaging modalities continues to be an area of ongoing concern.

This study has several limitations. First, it is possible that patients were indicated for surgery outside the interval we chose to analyze; however, the percentage of patients evaluated during Phase 1 and Phase 2, 80% and 76% respectively, suggests that the patterns of evaluation and treatment among groups appear to be relatively similar. Second, the utility of advanced imaging such as an ankle MRI is multifaceted, and this study only considered the value MRI may provide in terms of preoperative planning. We concede that measuring the treatment pathway is an imperfect outcome measure to assess the utility of ankle MRI, but in this process improvement initiative, we did not intend to evaluate the effect of the MRI on surgeon decision making. Third, the process improvement strategy was limited to educational initiatives primarily targeted at primary care physicians in the clinical decision pathway, but no formal decision support system or imaging approval pathway was implemented to target overuse of MRI. Studies of managed care systems have demonstrated that preauthorization of studies or clinical decision support systems can decrease the use of advanced imaging modalities.[11-14] The importance of systematic changes to control overuse is paramount considering the high rates of turnover among military healthcare providers who may be missed by any education program during deployments and frequent changes of station. It is unclear as the extent to which provider turnover during the intervals we chose to analyze affected the current results. Finally, the percentage of patients indicated for surgery in the foot and ankle surgeon subgroup may also be artificially decreased because the foot and ankle service is often called upon as the final authority to rule out a diagnosis, and advanced imaging is often required. Results of this process improvement initiative support the assertions of the fellowship-trained foot and ankle surgeons that advanced imaging should be obtained at the discretion of the foot and ankle service.

Conclusion

Among servicemembers undergoing ankle MRI, there was a relatively low proportion of patients that ultimately underwent an operative intervention. With this in mind, physicians should reserve advanced imaging of the ankle after conservative treatment measures fail, and the decision to order advanced imaging may be best reserved for the fellowship-trained foot and ankle surgeons. Moreover, these data suggest that a process improvement initiative to decrease rates of advanced imaging use through education alone was ineffective in altering practice patterns among both orthopaedic and NOPs. Future analysis focused on education coupled with decision support systems or image utilization pathways may reveal improved use of advanced imaging in a military setting.

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A Randomized Controlled Trial Evaluating Methylsulfonylmethane Versus Placebo to Prevent Knee Pain in Military Initial Entry Trainees

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ABSTRACT

Background: Methylsulfonylmethane (MSM) is a naturally occurring sulfur containing substance that has been shown to have anti-inflammatory and antioxidative properties. Previous studies using MSM as an oral supplement to improve pain in those patients with knee osteoarthritis have shown superiority compared to placebo. However, these studies are not translatable to active individuals performing high impact activities and have not evaluated MSM as a preventative measure.

Methods: A total of 180 subjects ranging in age from 18 to 40 years were enrolled. Subjects were randomized into 2 groups receiving either 3 grams OptiMSM methylsulfonylmethane (Bergstrom Nutrition, Vancouver, WA) or a placebo for 8 weeks. Outcomes measured were the Knee Osteoarthritis Outcome Score (KOOS) and the Profile of Moods States (POMS).

Results: Three grams of MSM administered daily did not provide significant improvements in the 5 KOOS subscales or the 6 POMS subscales at 30 days or 60 days.

Conclusion: Although 3 grams of MSM daily can be used safely, there does not appear to be a significant improvement in KOOS or POMS.

Methylsulfonylmethane (MSM) is a sulfur-containing compound, a metabolite of dimethyl sulfoxide, and occurs naturally at low levels in many common foods including fruits and vegetables.[1,2] Basic science literature supports that MSM is rapidly absorbed, well distributed, and completely excreted from the body.[3]

Methylsulfonylmethane has been shown to exert some anti-inflammatory and antioxidant effects, which has led to the use of MSM as a dietary supplement.[4-6] Animal and human studies have demonstrated beneficial effects in ulcerative colitis and lower extremity edema.[7,8] MSM has also shown promise as an ergogenic antioxidant in untrained men and women initiating an exercise regimen.[4,6] Recent medical trials in humans with MSM in the treatment of osteoarthritis have demonstrated that MSM was superior to placebo in controlling pain related to mild-to-moderate osteoarthritis of the knee, is at least as effective as celecoxib and significantly reduces the patient's need for anti-inflammatory drugs.[3,8] Furthermore, multiple trials have demonstrated multiple positive effects with no significant adverse effects of MSM use.[3,8-10]

The attrition rate during initial entry military training has become one of the most serious and costly concerns for all military services. Injuries account for 5 to 22-fold greater days lost to training than illnesses.[11] Among trainees, 80% to 90% of the lost to training days were due to training-related injuries.[12] The cumulative incidence of injuries requiring an outpatient visit in the initial 8 weeks of US Army Initial Entry Training is 25% to 55%.[12] The cumulative incidence of overuse injuries in trainees was 37% and comprised 80% of all injuries.[13] Discharge rates due to injury vary between 0.3% and 8.3% for initial entry Soldiers, but have been reported as high as 36% for Soldiers not completing their initial contractual obligation.[11-15] Following this, studies from the US Army Center for Health Promotion and Preventive Medicine* have demonstrated that intervention strategies can successfully reduce injuries without compromising mission effectiveness.[15]

The purpose of this study was to evaluate the use of 3 mg (750 mg tablets with 2 tablets twice daily) of orally administered MSM to improve patient reported outcome measures at 30 and 60 days. Our hypothesis was that the patients taking the MSM would demonstrate improved patient-reported outcomes at 30 and 60 days following

*Redesignated as the US Army Public Health Center in 2016.

initiation of supplementation during their training program as compared to placebo.

Methods

A randomized, double-blind, placebo controlled trial was conducted under an Institution Review Board approved protocol. A total of 180 men and women ranging in age from 18 to 40 years were enrolled from the Army initial Basic Officer Leadership Course (BOLC) at Joint BAse San Antonio-Fort Sam Houston, Texas. All trainees were invited to participate during the initial week of BOLC, a course that covers approximately 8 weeks of training, including 4 weeks spent in field conditions. Interested subjects were then screened and examined by one of the study investigators. Exclusionary criteria included a history of cancer, current statin use, use of other anti-inflammatories such as NSAIDS or pain medicine such as narcotics, a history of renal or hepatic dysfunction, a history of cardiac abnormality, current pregnancy, or other medical condition that would prevent full participation in the study.

Randomization was conducted using an unbound random number generator that was maintained by the dispensing pharmacy and blinded from all study investigators until completion of the study. The 2 arms of study intervention consisted of OptiMSM methylsulfonylmethane (Bergstrom Nutrition, Vancouver, WA) and a matched placebo. Both of these were provided in 750 mg tablets and participants were instructed to take 2 tablets twice daily for 8 weeks or until the completion of their training program.

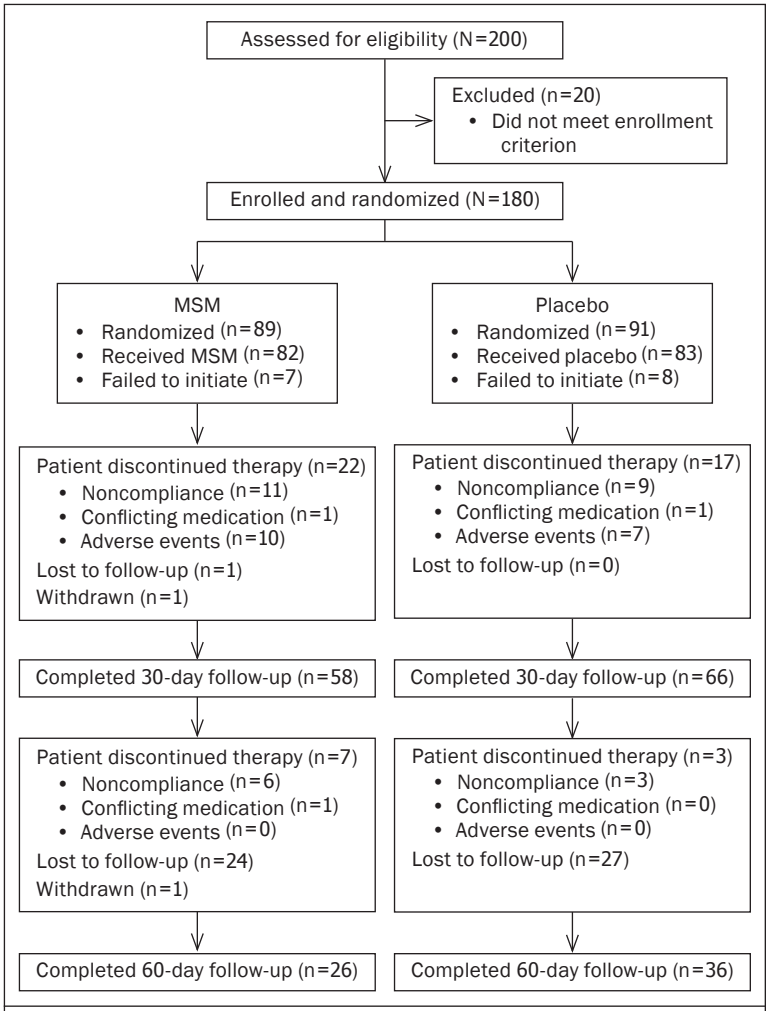
Patient reported outcome measures were obtained at the time of study enrollment, at 30-day follow-up and at 60-day follow-up. Measures included were the Knee Osteoarthritis Outcome -Score (KOOS) and the Profile of Moods States (POMS). The KOOS consists of 5 subscales: Pain, other Symptoms, Function in Daily Living (ADL), Function in Sport and Recreation, and Knee Related Quality of Life (QOL). The Profile of Mood States (POMS) measures present mood state (disturbance) by a list of adjectives. The POMS measures 6 dimensions of affect or mood, including tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment. This study uses the fatigue-inertia subset as an endpoint.

The 30-day follow-up was conducted while the subjects were in the middle of their field-training exercises. These involve 4 weeks spent in field conditions which include sleeping in tents and performing daily activities such as carrying gear, marching, combatives training, rifle and handgun firing, land navigation, and more. Physical fitness training was included for all trainees during their entire BOLC course. The 60-day follow-up was conducted when subjects had returned to a classroom setting and prior to their graduation from the course.

Statistical analysis was conducted using descriptive statistics, one-way ANOVA with repeated measures, and paired *t* tests where appropriate. A moderate Bonferroni correction was used and significance set at 0.025 due to comparisons being made at 30 and 60 days. The application SAS 9.2 (SAS Institute Inc, Cary, NC) was used for all statistical analysis.

Results

As shown in the Figure, a total of 180 subjects were enrolled in the study and initiated treatment. Of these, 13



CONSORT flow diagram.

subjects randomized to the MSM group and 9 subjects randomized to the placebo group were withdrawn from the study for an adverse event related to an injury sustained during training. Data was available on 124 subjects for the 30-day collection and 62 subjects for the 60-day collection. A summary of group demographic characteristics is presented in Table 1. There were no significant differences in height (m), weight (kg), body mass index (BMI), or gender. The MSM group was significantly older (28 vs 26 years) than the placebo group.

Table 1. Initial demographics for all subjects.

	MSM	Placebo	*P* value
Age (years)	28±6.9	26.4±5.0	.041
Height (m)	1.7±0.1	1.7±0.1	.722
Weight (kg)	75.4±13.7	74.9±13.8	.368
BMI	24.9±3.1	24.7±3.1	.171
Gender (male/female)	53/36	54/37	.843

There were no significant differences in any KOOS or POMS subscales at baseline, 30 days, or 60 days (Table 2). Whereas no significant changes in the KOOS subscale for MSM were seen from baseline to 30 days (3.41±2.68, P=.0135) or baseline to 60 days (5.81±3.51, P=.0013), improvement in the quality of life subscale for placebo was seen from baseline to 30 days and baseline to 60 days (Table 3).

When analyzing the POMS from baseline to 30 days, subscale worsening was seen for MSM in Anger (3.38±0.72, P<.0001), Vigor (1.62±0.70, P=.193), and Fatigue (2.62±0.51, P<.0001), and for Placebo in Depression (2.28±0.55, P<.0001), Anger (2.46±0.69, P=.0004), Vigor (1.64±0.66, P=.0137), Fatigue (2.83±0.49, P<.0001), and Confusion (0.82±0.34, P=.0148) (Table 3). These differences were not seen at baseline to 60 days.

Comment

This study found that those patients who took 3 mg MSM daily displayed no improvements in any KOOS or POMS subscale when compared to placebo when taken for 30 days or 60 days in a high-impact, initial entry military training population. Subjects taking MSM supplementation for 30 days or 60 days also did not have appreciable improvements in either patient-reported outcome measure. No differences were found in adverse events between groups.

Several studies have previously demonstrated the efficacy of MSM as an adjunct for the treatment of osteoarthritis by using the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) as an outcome measure. In a double-blind, randomized, controlled trial, Debbi et al displayed significant differences in WOMAC physical function and total scores, and VAS pain scores with 3.375 g MSM orally administered daily.[10] Kim et al also displayed significant decreases in WOMAC pain and physical function impairment when 6 grams of MSM was administered orally.[16] Likewise, Pagonis et al found significant decreases in all WOMAC subscales at 26 weeks with 6 g MSM administered orally.[17]

In contrast to those studies, the current study used the KOOS as a primary outcome measure as it encompasses

Table 2. Primary outcomes over 60 day treatment period comparing MSM to placebo (values presented as mean±SD).

	MSM			Placebo			Significance Between Groups (*P* value)		
	Baseline	30 Day	60 Day	Baseline	30 Day	60 Day	Baseline	30 Days	60 Days
KOOS									
Pain	87.04±2.78	84.60±2.96	85.29±3.69	87.96±2.77	89.25±2.87	90.44±3.48	.6489	.0281*	.0477*
Symptom	83.07±2.79	82.86±2.96	83.02±3.63	84.67±2.78	85.60±2.87	87.18±3.41	.4273	.1944	.1023
ADL	92.79±2.11	91.22±2.27	91.56±2.94	93.42±2.10	94.33±2.19	94.57±2.73	.6757	.0543	.1420
Sport	79.21±3.91	80.29±4.17	80.12±5.31	80.50±3.88	82.50±4.04	85.11±4.99	.6476	.4564	.4564
QOL	77.39±3.92	78.58±4.09	78.47±4.82	79.10±3.90	82.50±4.00	84.91±4.60	.5460	.1801	.0586
POMS									
Tension	14.01± 0.79	14.62±0.86	13.21±1.16	14.13±2.78	14.81±0.82	13.8±1.07	.8248	.7579	.4635
Depression	16.03±0.89	17.16±0.98	16.47±1.38	15.56±0.88	17.84±0.93	16.81±1.26	.4637	.3207	.7217
Anger	14.80±1.10	18.15±1.21	15.75±1.71	14.89±0.55	17.35±1.16	16.35±1.56	.9055	.3493	.6117
Vigor	27.06±1.31	25.43±1.41	27.20±1.85	25.19±1.29	23.55±1.36	25.87±1.71	.0479*	.0606	.3022
Fatigue	11.08±0.87	13.70±0.95	10.67±1.29	11.31±0.86	14.14±0.91	10.69±1.19	.7162	.5088	.918
Confusion	11.60±0.67	12.01±0.72	11.00±0.95	11.14±0.66	11.97±0.70	10.96±0.88	.3473	.9376	.9539
Total Mood	58.37±2.23	59.06±2.44	59.75±3.42	55.56±2.19	56.53±2.34	59.17±3.13	.0786	.1418	.8053

KOOS indicates Knee Osteoarthritis Outcome Score; ADL, Function in Daily Living; QOL, Quality of Life.
POMS indicates Profile of Moods States.
*Significance set at P<.05 with a Bonferroni correction of 2.

Table 3. KOOS and POMS scores over study period (values presented as mean±SD).

	MSM				Placebo			
	Difference 0-30 Days	*P* value	Difference 0-60 Days	*P* value	Difference 0-30 Days	*P* value	Difference 0-60 Days	*P* value
KOOS								
Pain	2.44±2.45	.0540	1.75±3.31	.3013	1.29±2.39	.2899	2.48±3.09	.1161
Symptom	0.51±1.95	.8617	0.84±3.15	.9742	0.93±2.25	.4183	2.51±2.90	.0908
ADL	1.57±2.09	.1438	1.23±2.81	.3920	0.91±2.01	.3787	1.15±2.59	.3856
Sport	1.08±3.65	.5622	0.91±4.90	.7168	2.01±3.51	.2633	4.61±4.56	.049
QOL	1.19±2.80	.4068	1.07±3.78	.5780	3.41±2.68	.0135*	5.81±3.51	.0013*
POMS								
Tension	0.62±0.45	.3494	0.80±0.60	.3494	0.72±0.43	.1194	0.57±0.55	.5470
Depression	1.13±0.58	.0512	0.44±0.76	.5612	2.28±0.55	<.0001*	1.25±0.70	.0763
Anger	3.38±0.72	.0001*	0.66±0.95	.3138	2.46±0.69	<.0004*	1.46±0.87	.0960
Vigor	1.62±0.70	.0193*	0.14±0.92	.8758	1.64±0.66	.0137*	0.68±0.85	.4215
Fatigue	2.62±0.51	<.0001*	0.41±0.68	.5505	2.83±0.49	<.0001*	0.61±0.61	.3296
Confusion	0.41±0.35	.2438	0.60±0.47	.2026	0.82±0.34	.0148*	0.18±0.43	.6724
Total Mood	0.69±1.42	.6268	1.38±1.87	.4622	0.97±1.36	.4799	3.61±1.72	.0379

KOOS indicates Knee Osteoarthritis Outcome Score; ADL, Function in Daily Living; QOL, Quality of Life.
POMS indicates Profile of Moods States.
*Significance set at *P*<.05 with a Bonferoni correction of 2.

a greater degree of symptoms and range of injuries and is more responsive than the WOMAC. Using this validated patient reported outcome measure, as expected, the scores increased from baseline to the 30-day point, which is related to the increased physical demands placed on the subjects during their time in field conditions. Of particular note is that subscale scores were not significantly improved when compared directly to placebo at either the 30-day or 60-day time points. This difference may be representative of the difference in patient population, the lower total MSM ingestion, or the more demanding activities expected of a military training population compared to the general patient with osteoarthritis.

To our knowledge, this is the first study that uses the POMS to further assess the physical and mental well-being of those individuals taking supplemental MSM. In this study, Anger, Fatigue and Vigor worsened from baseline to 30 days for the MSM group, then again during a time of increased physical and emotional stressed placed on the subjects as part of their field military training period. Similar increases in mood abnormalities were also seen in the placebo group, which correlates to the physical, mental, and emotional demands that accompany military training.

While other studies have evaluated MSM for those patients with documented knee pain, this is the first study to evaluate the use of MSM as a preventative adjunct to improve functional outcome measures. However, despite the enrollment of this study, its conclusions are limited by the loss to follow-up that was experienced from 30 to 60 days as a result of changes in military training needs. This decreased the overall power of this study and may limit the relevant conclusions regarding the effectiveness of MSM over the entire 60-day period.

This study was also conducted in a highly active population with physical demands above those of the average population. As such, the conclusions of this study may be most translatable to a higher level athlete rather than the average person, and further studies evaluating MSM in individuals with average demands is required. Furthermore, the total daily dosage of MSM used in this study was well below that of previous studies finding functional improvements, and also used different outcome measures. This may limit its comparability to findings reported in previous literature.

Conclusions

The results of this study suggest that 3 grams daily of orally administered MSM does not improve patient reported outcomes over 30 days or 60 days in this young, healthy, active military population as compared to a placebo. The results do not support our tested hypothesis. However, further investigation is warranted to determine if higher doses are more effective and if less active populations might exhibit a greater treatment response.

Acknowledgment

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GEHS Neurophysiological Classification System for Patients with Neuropathy of the Ulnar Nerve at the Elbow

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Abstract

Background: Neuropathy of the ulnar nerve at the elbow is one of a number of muscle-related and nerve-related disorders that affect people performing intensive work with their hands and upper extremities, and is the second most prevalent peripheral nerve mononeuropathy. There are several classification systems currently being used by the medical community for patients with neuropathy of the ulnar nerve at the elbow. However, few of these classification systems include the clinical electrophysiologic parameters nerve conduction (NCS) and electromyographic (EMG) studies.

Purpose: This article describes the GEHS (Greathouse, Ernst, Halle, and Shaffer) neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow and includes 2 case studies of patients with electrophysiological evidence of neuropathy of the ulnar nerve at the elbow.

Case Studies: Two case studies of patients with electrophysiological evidence of neuropathy of the ulnar nerve at the elbow are presented. The GEHS neurophysiological classification system is incorporated into the discussion of these case studies.

Summary and Clinical Relevance: This article describes the GEHS neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow which incorporates findings for both the NCS and EMG components of the electrophysiological examination. Availability of expanded electrophysiological data that includes both NCS and EMG testing provides the healthcare team and the patient with more detailed information that may be useful in determining next treatment steps as well as long-term prognosis. Future research comparing the psychometric properties and prognostic utility of the GEHS neurophysiologic classifications is warranted.

Neuropathy of the ulnar nerve at the elbow is one of a number of muscle-related and nerve-related disorders that affect people performing intensive work with their hands and upper extremities, and is the second most prevalent peripheral nerve mononeuropathy.[1-7] There are several classification systems currently used by the medical community for patients with neuropathy of the ulnar nerve at the elbow.[6-12] However, few of these classification systems include the clinical electrophysiologic parameters nerve conduction (NCS) and electromyographic (EMG) studies.

The ulnar nerve is comprised of the anterior primary rami of the C8 and T1 nerve roots.[13-14] In the inferior neck at the level of the anterior and middle scalenes, the C8 and T1 nerve roots form the inferior (lower) trunk and then each trunk of the brachial plexus divides into the anterior and posterior divisions as the plexus passes through the cervico-axillary canal posterior to the clavicle.[13-14] The anterior divisions of the trunks supply anterior (flexor) compartments and posterior divisions supply posterior (extensor) compartments. The anterior division of the inferior trunk continues as the medial cord.[13-14]

The ulnar nerve is the terminal nerve of the medial cord and lies in the anterior compartment of the arm. Proximal to the elbow joint, the ulnar nerve passes into the posterior compartment of the arm and descends between the medial epicondyle of the humerus and olecranon process of the ulna to form the ulnar groove.[13-14] Similar to the median nerve, the ulnar nerve does not give rise to branches during its passage through the arm. In the forearm, the first muscle innervated by the ulnar nerve is the flexor carpi ulnaris (FCU) followed by the ulnar half (ring and little finger) of the flexor digitorum profundus (FDP D4-D5). After sending motor branches to the FCU and FDP D4-D5, the ulnar nerve continues distally, ultimately terminating into 3 primary distal

branches; (1) dorsal ulnar cutaneous nerve; (2) superficial branch of the ulnar nerve; and (3) deep motor branch of the ulnar nerve. The dorsal ulnar cutaneous branch typically bifurcates from the ulnar nerve about 5 cm proximal to the ulnar styloid process and proceeds dorsally and distally to innervate the skin on the dorsum of D5 and the ulnar aspect of D4, along with the adjacent skin over the dorsum of the hand, providing sensation to the skin of that region.[13-14] Apart from this branch, the bulk of the ulnar nerve passes through the ulnar canal (Guyon's canal) at the wrist and divides into a superficial branch which provides motor innervation to the palmaris brevis and skin sensation to the palmar surface of D5 and medial half of D4.[13-14] The deep motor branch of the ulnar nerve then innervates the hypothenar muscles (abductor digiti minimi, flexor digiti minimi, and opponens digiti minimi), lumbricale muscles to D4 and D5, and the ulnar intrinsics including the dorsal and palmar interossei and adductor pollicis.[13-14]

There are 5 anatomic sites of ulnar nerve compromise at the elbow: (1) intermuscular (IM) septum of the distal arm (including the Arcade of Struthers, medial IM septum, hypertrophy of medial head of triceps brachii, and snapping of medial head triceps brachii); (2) medial epicondyle secondary to a valgus deformity of the bone; (3) epicondylar groove (lesions within and outside of the groove and subluxation or dislocation of the nerve); (4) cubital tunnel (due to a thickened Osborne's ligament, a fibrous fascia running between the humeral and ulnar heads to the FCU) or as the nerve passes through the proximal edge of the FCU; and (5) as the ulnar nerve exits through the FCU.[4]

In a review of the clinical, electrodiagnostic, and radiographic features of ulnar neuropathy at the elbow, Landau and Campbell[5] found that there are 3 main sites of ulnar nerve compromise at the elbow: (1) retrocondylar groove, proximal to the medial epicondyle/olecranon; (2) humero-ulnar aponeurotic arch including cubital tunnel syndrome and as the ulnar nerve passes between the arcuate ligament spanning the two heads of the FCU; and (3) flexor/pronator aponeurosis as the ulnar nerve exits from beneath the FCU. They stated that the etiology of neuropathy of the ulnar nerve at the elbow is most commonly due to lesions at the level of the ulnar nerve at the retrocondylar groove at or above the medial epicondyle/olecranon with only 25% occurring distally at the humero-ulnar arcade.[5] Furthermore, they suggested that maintaining across-elbow measurements (above elbow to below elbow) greater than 10 cm improves the diagnostic specificity at the expense of decreased sensitivity of accessing ulnar neuropathy at the elbow.[5]

GEHS Neurophysiological Classification System for Patients with Neuropathy of the Ulnar Nerve at the Elbow

A thorough history and physical examination are considered essential screening tools for detecting signs and symptoms of peripheral neuropathy.[1-3] Nerve conduction measurement is often performed on the ulnar nerve to determine whether certain entrapment neuropathies are present, and nerve conduction studies are considered the gold standard by providing criterion-related validation when assessing the electrophysiological status of the peripheral nerve.[1-3] The electrophysiological examination including both nerve conduction and electromyography studies should identify peripheral nerve dysfunction if present, along with the specific location in the nerve pathway, involvement of sensory and/or motor axons, and the presence of myelinopathy and/or axonopathy neuropathic process.[1-3]

Nerve conduction studies and EMG testing have the advantage of providing potential electrophysiological evidence of pathological conditions of the ulnar nerve including demyelination (myelinopathy) and axon loss (axonopathy).[1-3] In 2015, a new neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow was introduced. The GEHS (Greathouse, Ernst, Halle, Shaffer)[15] neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow is comprised of data from both the NCS and EMG components of the electrophysiological examination. The GEHS neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow, presented in Table 1, provides healthcare providers an enhanced system of electrophysiological evaluation and grading scale so that they may evaluate and treat their patients with this problem using data that includes both NCS and EMG testing results.

Furthermore, this new system provides information which includes specific abnormal findings of sensory and/or motor axons and myelinopathy and/or axonopathy. The GEHS neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow is presently being used by clinical electrophysiologists and has been cited in various research reports.[16-19]

This article describes application of the GEHS neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow in 2 case studies of patients with electrophysiological evidence of the disorder.

GEHS NEUROPHYSIOLOGICAL CLASSIFICATION SYSTEM FOR PATIENTS WITH NEUROPATHY OF THE ULNAR NERVE AT THE ELBOW

Table 1. GEHS Neurophysiological Classification System for Patients with Neuropathy of the Ulnar Nerve at the Elbow.[15]

EARLY MILD (conduction block)
Sensory - >40% decrease in SNAP amplitude; eg, 40 μV SNAP amplitude BE-W, 20 μV SNAP amplitude AE-BE, 20 μV SNAP amplitude difference (50%) and/or
Motor - >20% decrease in CMAP amplitude AE/BE; eg, 8 mV CMAP amplitude BE-W, 4 mV CMAP amplitude AE-BE, 4 mV CMAP amplitude difference (50%).
Normal Findings: Normal motor and sensory NCVs and latencies when compared to a Table of Normal NCS Values; normal EMG of ulnar innervated muscles (1st DI, ADM, FDP D4-5 & FCU).
MILD (myelin only)
Sensory - <50 m/sec SNCV AE-BE or >10 m/sec SNCV AE-BE difference when compared to BE-W, SNCV (AE- BE SNCV >50 m/sec) >40% decrease in SNAP amplitude AE/BE;
Motor - <50 m/sec MNCV AE-BE or >10 m/sec MNCV AE-BE difference when compared to BE-W MNCV (AE- BE MNCV >50 m/sec) >20% decrease in CMAP amplitude AE/BE;
Sensory and Motor - abnormal findings as listed above for both motor and sensory fibers.
EMG: normal EMG of ulnar innervated muscles (1st DI, ADM, FDP D4-5 & FCU).
Normal NCS Findings: Normal MNCV and SNCV BE-W and distal motor and sensory latencies and amplitudes when compared to a Table of Normal NCS Values (Table being used in individual lab).
MODERATE (myelin and axon)
EMG - increased insertional activity and presence of abnormal spontaneous electrical activity in one of the following muscles: 1st DI, ADM, FDP D4-D5, or FCU; may have decreased interference pattern on maximum voluntary contraction in one of the ulnar innervated muscles.*
Conduction Block - normal motor and sensory conduction studies; may have decreased SNAP and/or CMAP amplitudes at the AE stimulation site; abnormal EMG findings as presented above.
Sensory - <50 m/sec SNCV AE-BE >40% decrease in SNAP amplitude AE/BE may have abnormal distal sensory latency and/or amplitude when compared to a Table of Normal NCS Values.*
Motor - <50 m/sec MNCV AE-BE >20% decrease in CMAP amplitude AE/BE* - may have abnormal distal motor latency and/or amplitude when compared to a Table of Normal NCS Values.*
Normal Findings: Normal distal motor and sensory latencies and amplitudes and normal BE-W MNCV and SNCV when compared to a Table of Normal NCS Values; normal shape, amplitude and duration of MUPs in ulnar innervated muscles.
SEVERE (myelin and axon)
EMG - increased insertional activity and presence of abnormal spontaneous electrical activity in two or more of the following muscles: 1st DI, ADM, FDP D4-D5, or FCU; decreased interference pattern on maximum voluntary contraction in two or more of the ulnar innervated muscles* may have increased amplitude (>10 mV) and/or duration (>15 ms) MUPs in one or more of the ulnar innervated muscles.
Conduction Block - Normal motor and sensory conduction studies; may have decreased SNAP and/or CMAP amplitudes at the AE stimulation site; abnormal EMG findings as presented above.
Sensory - <50 m/sec SNCV abnormal distal sensory latency and/or amplitude when compared to a Table of Normal NCS Values.*
Motor - <50 m/sec MNCV AE-BE abnormal distal motor latency and/or amplitude when compared to a Table of Normal NCS Values.*
Summary of Severe Compared to Moderate: 1. Two or more ulnar innervated muscles with EMG changes. 2. Sensory and motor changes are abnormal, not based on percentage decreases, but on comparison to Table of Normal NCS Values being used in individual labs.

*Electrophysiologic evidence of axonal loss neuropathic process.

Glossary

ADM – abductor digiti minimi
AE – above elbow
BE – below elbow
CMAP – compound motor action potential
DML – distal motor latency
D4 – digit 4 (ring finger)
D5 – digit 5 (little finger)
1st DI – first dorsal interosseous
DSL – distal sensory latency
EMG – electromyography
FCU – flexor carpi ulnaris
FPD D4-D5 – flexor digitorum profundus D4 and D5 (ring and little fingers)
MNCV – motor nerve conduction velocity
MUPs – motor unit potentials
NCS – nerve conduction studies
SNAP – sensory nerve action potential
SNCV – sensory nerve conduction velocity
W – wrist

Case Studies

Case 1

A 42-year-old right-hand dominant male was referred by his primary care physician for electrophysiological evaluation of a suspected left ulnar nerve neuropathy. The patient is a computer software developer. In 2015, he noted intermittent pain and numbness and tingling (N/T) in the left upper extremity (LUE). The patient had no past medical history of problems affecting either upper extremity and denied recent trauma to the neck or either upper extremity. The symptoms in the LUE increased over the month preceding presenting for evaluation. He had pain in the left elbow, medial forearm, wrist, and digits 4 and 5 (ring and little finger; D4-D5). Otherwise, he had no

Table 2. Case 1: Nerve Conduction Study Results. Note: clinically noteworthy values identified by shaded data cells.

Anti Sensory Summary

Site	NR	Peak (ms)	Norm Peak (ms)	P-T Amp (μV)	Norm P-T Amp (μV)	Site 1	Site 2	Delta-P (ms)	Dist (cm)	Vel (m/s)	Norm Vel (m/s)
Left Superficial Radial Anti Sensory (Base 1st Digit)											
D1		2.3	<2.7	15.8	>	D1	Base 1st Digit	2.3	10.0	43	
Right Superficial Radial Anti Sensory (Base 1st Digit)											
D1		2.0	<2.7	10.8	>	D1	Base 1st Digit	2.0	10.0	50	

Ortho Sensory Summary

Left Median Ortho Sensory (Wrist)											
Palm		2.1	<2.2	180.5	>15	Palm	Wrist	2.1	8.0	38	
D2		3.4	<3.6	49.2	>15	D2	Wrist	3.4	14.0	41	
Right Median Ortho Sensory (Wrist)											
Palm		2.2	<2.2	171.7	>15	Palm	Wrist	2.2	8.0	36	
D2		3.5	<3.6	28.9	>15	D2	Wrist	3.5	14.0	40	
Left Ulnar Ortho Sensory (Wrist)											
Palm		5.6	<2.2	15.1	>10	Palm	Wrist	5.6	8.0	14	
D5	NR		<3.5		>10	D5	Wrist		14.0		
Right Ulnar Ortho Sensory (Wrist)											
Palm		2.2	<2.2	10.0	>10	Palm	Wrist	2.2	8.0	36	
D5		2.9	<3.5	11.2	>10	D5	Wrist	2.9	14.0	48	

Motor Summary

Site	NR	Onset (ms)	Norm Onset (ms)	O-P Amp (mV)	Norm O-P Amp (mV)	Site 1	Site 2	Delta-0 (ms)	Dist (cm)	Vel (m/s)	Norm Vel (m/s)
Left Median Motor (Abductor Pollicis Brevis)											
Wrist		3.8	<4.2	9.6	>5	Elbow	Wrist	5.3	28.0	53	>50
Elbow		9.1		8.2							
Right Median Motor (Abductor Pollicis Brevis)											
Wrist		3.8	<4.2	12.9	>5	Elbow	Wrist	5.6	31.0	55	>50
Elbow		9.4		10.2							
Left Ulnar Motor (Abductor Digiti Minimi)											
Wrist		3.5	<3.6	4.3	>5	B Elbow	Wrist	5.6	25.5	46	>50
B Elbow		9.1		2.1		A Elbow	B Elbow	2.5	13.5	54	>50
A Elbow		11.6		4.5							
Right Ulnar Motor (Abductor Digiti Minimi)											
Wrist		3.0	<3.6	7.7	>5	B Elbow	Wrist	5.1	26.0	51	>50
B Elbow		8.1		6.6		A Elbow	B Elbow	2.1	12.0	57	>50
A Elbow		10.2		6.6							

Glossary

Amp – amplitude
A Elbow – above elbow
B Elbow – below elbow
D1 – digit 1 (thumb)
D2 – digit 2 (index finger)
Dist – distance
Norm – normal
NR – no response
O – onset
P – peak
T – trough
Vel – velocity

other pain in the LUE. The patient states he had N/T in the palmar and dorsal surfaces of the left D4-D5, but otherwise denied N/T proximal to the wrist in the LUE. The patient denied weakness in the LUE, including hand and digit movements. The patient denied pain, N/T, or weakness in the right upper extremity (RUE) and had no symptoms in either lower extremity. The patient had some stiffness in neck movements but no neck pain or radicular symptoms in either upper extremity. He denied history of headaches, visual or cranial nerve problems. The patient was slightly overweight and is hypertensive (on medication), but otherwise is in good health. The review of systems was noncontributory for cardiovascular, pulmonary, gastrointestinal, genitourinary, or endocrine problems. He denied having diabetes, heavy metal exposure, thyroid disease, renal disease, or alcohol abuse, and has no family history of neuromuscular disease.

The patient was evaluated in January 2017. On physical examination, the patient displayed normal active

Table 3. Case 1: Electromyography Results. Note: clinically noteworthy values are indicated by shaded cells.

Side*	Muscle	Nerve	Root	Ins Act	Fibs	Psw	Amp	Dur	Poly	Recrt	Int Pat	Comment
Left	1stDorInt	Ulnar	C8-T1	Incr	2+	3+	Nml	Nml	0	Reduced	50%	fib amp <100
Left	Abd Poll Brev	Median	C8-T1	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	PronatorTeres	Median	C6-7	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	Flex Poll Long	AIN	C8-T1	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	Biceps	Musculocut	C5-6	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	Triceps	Radial	C6-7-8	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	Deltoid	Axillary	C5-6	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	ABD Dig Min	Ulnar	C8-T1	Incr	2+	3+	Nml	Nml	0	Reduced	50%	fib amp <100
Left	FlexCarpiUln	Ulnar	C8-T1	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Left	Ext Poll Long	Radial (Post Int)	C7-8	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	

*Electromyographic testing of the right upper extremity was not performed.

Glossary

Amp – amplitude Fibs – fibrillation potentials Ins Act – insertional activity Nml – normal Recrt – recruitment
Dur – duration Incr – increased Int Pat – interference pattern Poly – polyphasics

cervical mobility in all planes without neck pain or pain in both upper extremities (BUE). The Spurling's test did not provoke pain in the neck or in either upper extremity. He had normal active mobility of bilateral shoulder, elbow, forearm, wrist, and hand motions. The patient had weakness in the left ulnar hypothenar and intrinsic muscles (3+/5) and the left FDP digits 4 and 5 (3+/5). There was normal (5/5) motor strength of the left FCU, abductor pollicis brevis (APB), opponens pollicis, flexor pollicis longus (FPL), flexor digitorum profundus D2-D3 (index and middle fingers), extensor indicis, and extensor pollicis longus (EPL). In addition, there was normal (5/5) motor strength testing of bilateral shoulder, elbow, forearm and wrist motions; and right hand motions. There was no atrophy or clonus noted in BUE. The biceps, triceps, and brachioradialis muscle stretch reflexes were present and equal in BUE. The Hoffman reflex was absent in both hands. There was a decreased sensation to light touch (LT) and pain (pin prick) in the dorsal and palmar surfaces of the left ring (D4) and little (D5) fingers. Otherwise, sensory testing was normal for LT and pain in BUE, including all peripheral nerves and dermatomes (C4-T1). There was a positive Tinel's test of the left ulnar nerve at the elbow, but otherwise the Tinel's and Phalen's tests were negative for bilateral median and ulnar nerve involvement at the wrists or elbows. There were normal radial pulses bilaterally for thoracic outlet syndrome in the scalene, costoclavicular, and pectoralis minor/clavipectoral fascia humeral maneuvers.

Results of the NCS and EMG studies for case study 1 are presented in Tables 2 and 3, respectively. Clinically noteworthy NCS and EMG abnormal findings are indicated by shaded cells in Tables 2 and 3.

In conclusion of case study 1: this was an abnormal NCS and EMG study of the LUE and a normal NCS study of the RUE. There was electrophysiologic evidence on this examination of a severe, left ulnar nerve mononeuropathy at the elbow, at or distal to the medial epicondyle/olecranon and distal to the innervation of the FCU; demyelinating and axonal loss neuropathic process affecting both motor and sensory fibers; and chronic denervation of the left first dorsal interosseous (1st DI) and abductor digiti minimi (ADM). Electromyographic testing of the left FCU and other muscles tested in the LUE was normal. There was no electrophysiologic evidence on this examination of (1) right ulnar nerve mononeuropathy; (2) bilateral median or superficial radial mononeuropathy, including the left median nerve at or distal to the wrist; (3) left C5-T1 radiculopathy in the LUE (cervical paraspinal muscles not tested); and (4) left brachial plexopathy, including the medial cord and inferior trunk.

Based on the above case study 1 results, the GEHS neurophysiological classification system category was severe mononeuropathy of the left ulnar nerve at the elbow. There was a prolonged left ulnar palmar distal sensory latency (DSL) (5.6 ms, normal <2.2) with a normal amplitude of the sensory nerve action potential (SNAP) (15 μV). There was no sensory response for the left ulnar 5th digit (D5) when tested orthodromically or antidromically. There was a normal left ulnar distal motor latency (3.5 ms), but the amplitude of the compound motor action potential (CMAP) was reduced at 4.3 mV (normal >5). The motor nerve conduction (MNCV) of the left ulnar nerve in the forearm (below elbow (BE) to wrist) was reduced at 46 m/sec (normal >50) with a reduced CMAP amplitude of 2.1 mV (normal >5) at the BE stimulation site. The MNCV of the left ulnar nerve at across the elbow (above elbow to below elbow (AE-BE)) was normal (54 m/sec) with a reduced amplitude CMAP of 4.5 mV (normal >5). On EMG examination, there was increased insertional activity and the presence of abnormal spontaneous electrical activity at rest in the left 1st DI and ADM with a 50% reduction in

interference patterns during maximum voluntary contraction in both of these muscles. Since EMG findings were demonstrated in 2 of the 4 muscles outlined in the "Severe" section of Table 1, EMG of all 4 of the muscles outlined in Table 1 was not performed. In this case, obtaining EMG of the FDP to D4 and D5 was deferred. There was normal EMG testing of the left FCU, APB, FPL, EPL, and other muscles tested in the LUE. These findings are electrophysiological evidence of both a demyelinating and axonal loss neuropathic process of the left ulnar nerve at the elbow.

Case 2

A 48-year-old right-hand dominant male was referred by his orthopaedic surgeon for electrophysiological evaluation of a suspected right ulnar nerve neuropathy. The patient is a pool repair technician. In 2015, he noted intermittent pain and N/T in the RUE. The patient had no past medical history of problems affecting either upper extremity and denied recent trauma to the neck or either upper extremity. The symptoms in the RUE increased over the month preceding presenting for evaluation. He had pain in the right elbow. Otherwise, he had no other pain in the RUE. The patient states he had N/T in the palmar and dorsal surfaces of the right D4-D5 (ring and little fingers), but otherwise denied N/T proximal to the wrist in the RUE. The patient denied weakness in the RUE including hand and digit movements. The patient had occasional N/T in the dorsal and palmar aspects of the left D4-D5 but otherwise denied pain, N/T or weakness in the LUE and had no symptoms in either lower extremity. The patient denied neck pain or radicular symptoms in either upper extremity. He denied history of headaches, visual or cranial nerve problems. The patient is on medication for hypertension but is in good health. Otherwise, the review of systems was noncontributory for cardiovascular, pulmonary, gastrointestinal, genitourinary, or endocrine problems. He denied having diabetes, heavy metal exposure, thyroid disease, renal disease, or alcohol abuse, and has no family history of neuromuscular disease.

The patient was evaluated in May 2016. On physical examination, the patient displayed normal active cervical mobility in all planes without neck pain or pain in BUE. The Spurling's test did not provoke pain in the neck or in either upper extremity. He had normal active mobility of bilateral shoulder, elbow, forearm, wrist, and hand motions. The patient had weakness in the right ulnar hypothenar and intrinsic muscles (3+/5), right FDP D4 and D5 (ring and little fingers) (3+/5), and right FCU (4/5). There was normal (5/5) motor strength of the right APB, opponens pollicis, FPL, flexor digitorum profundus D2-D3 (index and middle fingers), extensor indicis, and EPL. In addition, there was normal (5/5) motor strength testing of bilateral shoulder, elbow, forearm and wrist motions; and left hand motions. There was no atrophy or clonus noted in BUE. The biceps, triceps, and brachioradialis muscle stretch reflexes were present and equal in BUE. The Hoffman reflex was absent in both hands. There was a decreased sensation to LT and pain (pin prick) in the dorsal and palmar surfaces of the right ring (D4) and little (D5) fingers. Otherwise, sensory testing was normal for LT and pain in BUE including all peripheral nerves and dermatomes (C4-T1). There was a positive Tinel's test of the right ulnar nerve at the elbow, but otherwise the Tinel's and Phalen's tests were negative for bilateral median and ulnar nerve involvement at the wrists or elbows. There were normal radial pulses bilaterally for thoracic outlet syndrome in the scalene, costoclavicular, and pectoralis minor/clavipectoral fascia humeral maneuvers.

Results of the nerve conduction and electromyography studies for case study 2 are presented in Tables 4 and 5, respectively. Clinically noteworthy NCS and EMG abnormal findings are indicated by shaded cells in Tables 4 and 5.

In conclusion of case study 2: this was an abnormal NCS and EMG study of the RUE and a normal NCS study of the LUE. There is electrophysiologic evidence on this examination of a severe right ulnar nerve mononeuropathy at the elbow proximal to the olecranon/medial epicondyle and proximal to the innervation of the right FCU; axonal greater than demyelinating neuropathic process affecting motor and to a lesser extent sensory fibers; and a mixture of acute and chronic denervation in the right 1st DI, ADM, and FCU. There was no electrophysiologic evidence on this examination of (1) left ulnar nerve mononeuropathy; (2) bilateral median or superficial radial mononeuropathy, including the right median nerve at or distal to the wrist; (3) right C5-T1 radiculopathy in the RUE (cervical paraspinal muscles not tested); and (4) right brachial plexopathy, including the medial cord and inferior trunk.

Based on the above case study 2 results, the GEHS neurophysiological classification system category was severe mononeuropathy of the right ulnar nerve at the elbow. There was a prolonged right ulnar palmar DSL (2.3 ms, normal <2.2), with a normal amplitude of the SNAP (17 μV). The right D5 (little finger) DSL latency was normal (3.5 ms) with a normal amplitude of the SNAP (12 μV). There was a prolonged right ulnar distal motor latency (3.8 ms, normal <3.6), but the amplitude of the CMAP was normal (7.5 ms). The MNCV of the right ulnar nerve in the forearm (BE to wrist) was normal at 53 m/sec (normal >50), with a normal CMAP amplitude

Table 4. Case 2: Nerve Conduction Study Results. Note: clinically noteworthy values identified by shaded data cells.

Anti Sensory Summary											
Site	**NR**	**Peak (ms)**	**Norm Peak (ms)**	**P-T Amp (μV)**	**Norm P-T Amp (μV)**	**Site 1**	**Site 2**	**Delta-P (ms)**	**Dist (cm)**	**Vel (m/s)**	**Norm Vel (m/s)**
Left Superficial Radial Anti Sensory (Base 1st Digit)											
D1		2.6	<2.7	23.9	>	D1	Base 1st Digit	2.6	10.0	38	
Right Superficial Radial Anti Sensory (Base 1st Digit)											
D1		2.7	<2.7	20.6	>	D1	Base 1st Digit	2.7	10.0	37	
Ortho Sensory Summary											
Left Median Ortho Sensory (Wrist)											
Palm		2.0	<2.2	112.5	>15	Palm	Wrist	2.0	8.0	40	
D2		3.3	<3.6	20.0	>15	D2	Wrist	3.3	14.0	42	
Right Median Ortho Sensory (Wrist)											
Palm		2.1	<2.2	33.8	>15	Palm	Wrist	2.1	8.0	38	
D2		3.5	<3.6	22.6	>15	D2	Wrist	3.5	14.0	40	
Left Ulnar Ortho Sensory (Wrist)											
Palm		2.2	<2.2	15.3	>10	Palm	Wrist	2.2	8.0	36	
D5		3.5	<3.5	13.3	>10	D5	Wrist	3.5	14.0	40	
Right Ulnar Ortho Sensory (Wrist)											
Palm		2.3	<2.2	16.7	>10	Palm	Wrist	2.3	8.0	35	
D5		3.5	<3.5	12.4	>10	D5	Wrist	3.5	14.0	40	
Motor Summary											
Site	**NR**	**Onset (ms)**	**Norm Onset (ms)**	**O-P Amp (mV)**	**Norm O-P Amp**	**Site 1**	**Site 2**	**Delta-0 (ms)**	**Dist (cm)**	**Vel (m/s)**	**Norm Vel (m/s)**
Left Median Motor (Abductor Pollicis Brevis)											
Wrist		4.0	<4.2	9.0	>5	Elbow	Wrist	5.4	29.0	54	>50
Elbow		9.4		9.0							
Right Median Motor (Abductor Pollicis Brevis)											
Wrist		4.1	<4.2	10.0	>5	Elbow	Wrist	6.4	33.0	52	>50
Elbow		10.5		9.4							
Left Ulnar Motor (Abductor Digiti Minimi)											
Wrist		3.5	<3.6	6.5	>5	B Elbow	Wrist	4.7	25.0	53	>50
B Elbow		8.2		6.7		A Elbow	B Elbow	2.0	13.0	65	>50
A Elbow		10.2		6.7							
Right Ulnar Motor (Abductor Digiti Minimi)											
Wrist		3.8	<3.6	7.5	>5	B Elbow	Wrist	4.7	25.0	53	>50
B Elbow		8.5		7.2		A Elbow	B Elbow	2.9	13.0	45	>50
A Elbow		11.4		6.4		Axilla	A Elbow	1.9	14.0	74	
Axilla		13.3		7.0							

Glossary
Amp – amplitude
A Elbow – above elbow
B Elbow – below elbow
D1 – digit 1 (thumb)
D2 – digit 2 (index finger)
Dist – distance
Norm – normal
NR – no response
O – onset
P – peak
T – trough
Vel – velocity

of 7.2 mV (normal >5) at the BE stimulation site. The MNCV of the right ulnar nerve at AE-BE was reduced (45 m/sec, normal >50) with a reduced but normal amplitude CMAP (6.4 mV) at the AE stimulation site. The MNCV of the arm (axilla to AE) was normal at 74 m/sec with a normal CMAP amplitude of 7.0 mV. On EMG examination, there was increased insertional activity and the presence of abnormal spontaneous electrical activity at rest in the right 1st DI, ADM, and FCU, with a 75% reduction in interference patterns during maximum voluntary contraction in the right 1st DI and ADM. Since EMG findings were demonstrated in 3 of the 4 muscles outlined in the "Severe" section of Table 1, EMG of all 4 of the muscles outlined in Table 1 was not performed. In this case, obtaining EMG of the right FDP to D4 and D5 was deferred. There was normal EMG testing of the right APB, EPL, and other muscles tested in the RUE. These findings are electrophysiological evidence of both a demyelinating and axonal loss neuropathic process of the right ulnar nerve at the elbow.

Table 5. Case 2: Electromyography Results. Note: clinically noteworthy values are indicated by shaded cells.

Side*	Muscle	Nerve	Root	Ins Act	Fibs	Psw	Amp	Dur	Poly	Recrt	Int Pat	Comment
Right	1stDorInt	Ulnar	C8-T1	Incr	1+	2+	Nml	Nml	0	Nml	Nml	fib amp <100>
Right	Abd Poll Brev	Median	C8-T1	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Right	PronatorTeres	Median	C6-7	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Right	Ext Poll Long	PIN	C8	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Right	Biceps	Musculocut	C5-6	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Right	Triceps	Radial	C6-7-8	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Right	Deltoid	Axillary	C5-6	Nml	Nml	Nml	Nml	Nml	0	Nml	Nml	
Right	ABD Dig Min	Ulnar	C8-T1	Incr	2+	2+	Nml	Nml	0	Reduced	75%	fib amp <100>
Right	FlexCarpiUln	Ulnar	C8-T1	Incr	1+	1+	Nml	Nml	0	Reduced	75%	fib amp <100>

*Electromyographic testing of the left upper extremity was not performed.

Glossary

Amp – amplitude Fibs – fibrillation potentials Ins Act – insertional activity Nml – normal Recrt – recruitment
Dur – duration Incr – increased Int Pat – interference pattern Poly – polyphasics

COMMENT

The advantage of having information regarding NCS and EMG changes (myelinopathy and axonopathy) for patients with neuropathy of the ulnar nerve at the elbow is that it provides the healthcare team and the patient with information that may be useful in determining next treatment steps as well as long-term prognosis. Nerve conduction studies provide assessment of the peripheral nerve being examined, especially as it relates to myelination or demyelination and location of the site of nerve compromise. In the case of a patient with EMG changes, the combined effects of compression and ischemia are evident with the loss of a subset of axons and the denervation of a segment of the innervated muscle fibers.[1-3] The EMG examination specifically provides information regarding motor fiber denervation as confirmed by the presence of increased insertional activity and abnormal resting potentials (eg, positive sharp wave, fibrillations potentials). Additionally, EMG examination provides the healthcare team with information regarding the presence, morphology, and recruitment pattern of motor units that is critical for determining the extent of motor fiber involvement and if reinnervation (polyphasic or large motor potentials) is truly occurring.[1-3] Collectively, the EMG examination affords critical motor fiber neurophysiologic information that allows the healthcare team, in concert with the patient, to carefully consider interventions.[1-3]

There are several classification systems for patients with neuropathy of the ulnar nerve at the elbow currently being used by the medical community.[6-12,20-22] However, few of these classification systems include clinical electrophysiologic parameters (eg, nerve conduction and electromyographic studies). Ulnar nerve at the elbow neuropathy severity scales based on the patient's subjective (paresthesia and pain) and physical examination findings (sensory and motor strength changes) place the patient into groups,[6] scales,[20,22] or grades[21] based on the severity of symptoms and findings on physical examination. The Patient-Rated Ulnar Nerve Evaluation (PRUNE) was developed to assess pain, symptoms, and functional disability in patients with ulnar nerve compression at the elbow.[7] The PRUNE is a patient-reported outcome measure for patients with ulnar nerve compression that demonstrates strong measurement properties.[7] Decisional algorithms have been developed for patients with neuropathy of the ulnar nerve at the elbow to assist in selecting the surgical procedure for ulnar nerve entrapment[9] and to identify predictors of surgical outcomes.[10]

In a study based on electrophysiologic assessment of the ulnar nerve, Eliaspour et al[8] determined the pattern of muscle involvement in patients with ulnar neuropathy at the elbow. Muscle involvement in patients with neuropathy of the ulnar nerve at the elbow included 1st DI (91.9%), ADM (91.3%), FCU (64.9%), and FDP D4-D5 (56.8%). Using a Bayesian analysis, Logigian et al[23] determined how electrodiagnostic cutoffs (eg, across-elbow MNCV slowing and drop in across-elbow versus forearm MNCV) assist in assessing patients with ulnar nerve at the elbow neuropathy. They determined that above elbow to below elbow distances and stimulation sites should be at least 10 cm. Pretest probability was determined at 0.25 (if there is a greater than 23 m/sec difference between above elbow to below MNCV compared to the below elbow to wrist MNCV, and/or an above elbow to below elbow absolute MNCV value of less than 38 m/sec.[23] A less conservative retest probability of 0.75 was also determined (difference greater than 14 m/sec, and an absolute AE-BE MNCV value less than 47 m/sec, respectively).[23] In a study comparing the prognostic value of electrodiagnostic studies for patients with ulnar neuropathy at the elbow and their postsurgical results, a combination of conduction block across the elbow to the 1st DI and a normal distal compound muscle action potential amplitude from the ADM was

strongly associated with recovery in patients.[24] Friedrich and Robinson concluded that electrodiagnostic studies provide useful prognostic information in ulnar nerve at the elbow neuropathy, but there are no electrodiagnostic predictors of surgery.[24]

Although the GEHS classification scheme provides a framework for reporting and categorizing neuropathy of the ulnar nerve at the elbow based on neurophysiologic findings, further research regarding the predictive and prognostic value of the classification schemes is needed. Additional longitudinal studies examining the predictive and prognostic value of the GEHS classification scheme regarding various interventions (duty limitations, splinting, mobilization, injection, and surgical release) is recommended. Future trials should also go beyond subjective reporting and include various outcomes measures (surgical findings, self-report, strength, sensation, serial NCS/EMG findings, physical performance testing, and healthcare utilization) and rigorous statistical analysis to determine the prognostic utility and cost/benefit of this classification scheme.

Summary and Clinical Relevance

The GEHS neurophysiological classification system for patients with neuropathy of the ulnar nerve at the elbow equips healthcare providers with an enhanced system of electrophysiological evaluation and grading scale. As such, it now provides clinical electrophysiologists with a more complete neurophysiological classification system for use when preparing electrophysiological testing reports for patients with this disorder. Availability of expanded electrophysiological data that includes both NCS and EMG testing provides the healthcare team and the patient with more detailed information that may be useful in determining next treatment steps as well as long-term prognosis. Future research comparing the psychometric properties and prognostic utility of the GEHS neurophysiologic classifications is warranted.

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The Influence of Smoking on Recovery from Subacromial Pain Syndrome: A Cohort from the Military Health System

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ABSTRACT

Background: Smoking rates are higher in the military population than in the civilian sector. Smoking is associated with poor prognosis for many musculoskeletal injuries. The purpose of this study was to investigate the effects of smoking on recovery from a shoulder injury in a prospective cohort seeking care at a military treatment facility.

Methods: Secondary analysis of 98 patients referred to physical therapy for unilateral shoulder pain. Patients received a corticosteroid injection or 6 sessions of physical therapy. Sociodemographic and historical variables were analyzed to assess their influence on whether a patient achieved the minimally clinically important difference of 12 or more points on the Shoulder Pain and Disability Index following treatment.

Results: The mean improvement was almost 50% in both groups and maintained to one year. Smoking was associated with not achieving a clinically significant improvement in disability scores at 4 weeks, but not 6 months. Higher levels of disability at baseline and receiving only the treatment originally assigned (not crossing over) were associated with achieving clinically significant changes at both 4 weeks and 6 months.

Comment: Smoking is a modifiable variable that may help explain lack of improvement in patients with shoulder pain. Healthcare providers in the military setting should keep this in mind when educating this patient population and determining their prognosis, especially given high rates of smoking. Further research is needed to validate these findings and determine their influence on other musculoskeletal injuries.

Shoulder injuries affect up to 33% of the general population and comprise 5% of all consultations from general practitioners.[1-3] They are also common injuries found in military service members.[4-6] In an analysis of US Navy Sailors, upper extremity injuries were the most common (38.1%), and specifically shoulder injuries made up the majority (23.8%).[5] In one study, Soldiers with shoulder injuries were more likely to have limited duty days related to the injury.[7] Noncombat-related shoulder injuries are also among the most common seen during deployment.[8] Treatment is often challenging, and the prognosis is uncertain for many patients. After a first episode of shoulder pain, less than 25% may have full recovery by 3 months.[9] In the longer term, one-year recovery rates range from 32% to 59%.[9-12] Even with recovery, recurrence rates are high with 25% of patients experiencing at least one recurrent episode within 12 months.[13] These findings suggest that shoulder pain frequently becomes a chronic problem. Identification of modifiable risk factors that affect prognosis is an area where more research is needed.

A variety of factors are associated with a poor prognosis. These factors include pain intensity at initial evaluation, age, gender, prior history of pain, duration of symptoms prior to consulting with a general practitioner, inadequate household income, presence of additional chronic illnesses, and level of disability.[3,9,14] Modifiable risk factors that can be addressed include pain intensity with treatment, elevated kinesiophobia or fear avoidance beliefs, obesity, changes in disability over time, muscle weakness, and smoking.[9,14-17]

Smoking is still common among adults seen in primary care for shoulder pain. Although the Centers for Disease Control and Prevention does report a decline in smoking, a recent report estimated that 18.1% of American adults were current smokers in 2012, indicating the problem is still relevant.[18] Smoking rates remain high in military service members, although reported down to 31% in 2005[19] from as high as 47% in 1985.[20] Even so, the rates are much higher than in the civilian population.[20] Smoking is adversely related to functional outcomes after injury, independent of the nature or severity of injury.[14] In military service members, it degrades physical performance,[21,22] is a risk factor for musculoskeletal injury,[23-25] and is associated with higher rates of attrition from the military.[26,27] It is an independent

risk factor across a variety of populations and medical conditions,[28-30] but specifically associated with delayed healing and recurrence of pain in shoulder injuries.[17,31-34] Smoking is associated with an increased risk of rotator cuff tears,[18] and negatively influences healing after shoulder surgeries.[32,35] It has deleterious effects on peak bone mass,[36] bone mineral density,[37] bone healing,[38] and wound healing,[39,40] as well as many other general complications.[41] However, the majority of the research has been observational and cross-sectional, in patients not receiving treatment. The extent that smoking habits have on outcomes after patients receive treatment for a shoulder injury is still not fully understood.

A better understanding of the influence of smoking on persistent shoulder conditions is necessary in a population with high rates of smokers. Treatment decisions could be influenced based on the smoking habits of the patient. Therefore, the purpose of this study was to investigate the effects of smoking on recovery from a shoulder injury after receiving treatment.

Methods

Design

This was a secondary analysis from a cohort of 98 subjects enrolled in a pragmatic randomized clinical trial.[42] It was a prospective assessment on the influence of self-reported smoking status and improvement in shoulder pain and function. The study was approved by the Madigan Army Medical Center Institutional Review Board and specific details of the protocol have been published open access.[43] The project was also registered in the National Institutes of Health clinical trial registry (NCT01190891). All patients provided consent to participate.

Setting

The study took place in the Department of Physical Medicine and Rehabilitation at Madigan Army Medical Center, Tacoma, WA, a military hospital within the US Military Health System.

Subjects

Subjects that met the inclusion criteria for subacromial pain syndrome were recruited from the physical therapy clinic. Eligible patients had a variety of conditions including rotator cuff pathology, partial thickness rotator cuff tears, and subacromial bursitis. All subjects were adults between the ages of 18 and 65 years with unilateral shoulder pain, and were eligible to receive medical care within the Military Health System. They were screened to exclude symptoms that were referred from the cervical spine and to rule out a diagnosis of adhesive capsulitis.

Main Outcome Measures

Patients had been randomized to receive a one-time corticosteroid injection (40 mg triamcinolone acetonide) with instruction on Codman's range of motion exercises or a 6-session protocol of manual physical therapy over 3-weeks. Each patient completed the Shoulder Pain and Disability Index (SPADI) in addition to a social history questionnaire that included questions about smoking:

- Do you currently smoke?
- If YES, how many packs a day?
- If NO, have you quit within the last 6 months?

The SPADI is a 100-point, 13-item, self-administered questionnaire, divided into 2 subscales: a 5-item pain subscale and an 8-item disability subscale. It is valid and responsive to change and accurately discriminates between patients who are improving or worsening in status.[44,45] It has a minimal clinically important difference (MCID) of between 8 to 13 percentage points.[46] In this secondary analysis, we dichotomized patients into those that met the MCID ($\geq$12 point change) and those that did not meet it ($<$12 point change) at the 4-week and 6-month follow-up points.

Data Analysis

Descriptive statistics were used to characterize the sample. Multiple imputation was used to impute missing values.[47] Baseline and intermediate data were used to predict missing outcome data at 4-week and 6-month follow-up periods. Five separate imputed data sets were created and the results of the pooled analyses were interpreted. Logistic regression was used to examine the association between being a smoker at baseline and achieving at least 1 MCID on the SPADI at 4 weeks and 6 months. We used a backwards elimination procedure to construct the regression models. All potential predictor variables were entered into separate models predicting the outcome at each time point. Starting with all potential confounders, the variable with the largest *P* value was removed. If the removal resulted in a 10% change in the estimated odds ratio (OR) of the smoking variable, the potential confounder was retained in the model. Each variable was handled in this fashion until only potential confounders and the smoking variable were retained.[48]

Results

Table 1 displays the descriptive characteristics of the sample. Of the 98 participants (31 female) in the study, 17 were current smokers. The average age of the sample was 40.8 years (SD=12.0) with smokers being approximately 8 years younger than nonsmokers. The average baseline disability, pain, and fear avoidance beliefs

physical activity subscale were similar between current smokers and nonsmokers. The mean fear avoidance beliefs work subscale was higher for current smokers. Comorbid conditions, whether the participant followed the treatment protocol and treatment groups displayed by smoking status are also reported in Table 1.

Potential variables for inclusion in the final models are listed in Table 2. The results of the final multivariate logistic regression indicated that after controlling for covariates, smoking was significantly associated with the MCID at 4 weeks (Table 3) but not at 6 months (Table 4). Interpretation of the OR indicate that in patients receiving care for shoulder impingement, those that were smokers at baseline assessment had 0.16 times the log odds of achieving one MCID at 4 weeks compared to those who did not smoke. Although smoking was not associated with obtaining a MCID at 6 months, following the study protocol (receiving the treatment initially randomized to without ever crossing over during the follow-up period) and baseline SPADI were associated with that result. After controlling for covariates, those that crossed over treatments had 0.17 times the log odds of achieving one MCID at 6 months compared to those that only received the treatment they were initially randomized to. Likewise, those patients that presented with a higher baseline total SPADI score were more likely achieve one MCID on the SPADI at 6 months; for every one point increase in the baseline SPADI score, the log odds of achieving one MCID increased by 1.05.

Only 44 (45%) of the subjects in this cohort had received an MRI at the time of enrollment. Therefore, imaging results were not entered as a potential predictor into the model. However, of those that did have an MRI, 11 (25%) had labral tears, 23 (52%) had rotator cuff tears, 5 (11%) had biceps tendon pathology, and 37 (76%) had ACJ OA. Only 6 of the 17 subjects that smoked had an MRI.

Comment

Although smoking has been declining, it continues to be the leading cause of preventable deaths in the United States,[18] and rates of smoking are higher in the US military than in civilian counterparts.[19,20] It has a strong association with chronic disease and overall health prognosis. Among military veterans, smoking is linked to chronic pain and veterans who smoke are more likely to receive prescription opiates, and also more likely to abuse them.[49] For many of these reasons, and likely others still to be explored, smoking is associated with delayed recovery from an injury, and is an independent risk factor for poor prognosis in a variety of other musculoskeletal conditions.[50] Therefore, it is not surprising to expect an adverse effect on recovery from shoulder conditions as well.

The results from the clinical trial comparing the effectiveness of physical therapy and corticosteroid injection treatments for the shoulder demonstrated significant improvements from baseline of 50% after 4 weeks, which was maintained out to one year.[42] In the short term (4 weeks), smoking had a stronger negative influence on recovery than the type of treatment received. It may be that the deleterious effects of smoking play a stronger role during the initial injury phase, or active treatment phase, which in our study was about 3 weeks. In the short term, just as or more important than the actual treatment choice may be the ability to identify and address factors associated with a poor prognosis. Smoking could be one of these. Our study was the first to assess the effect of smoking on the short and long term recovery of patients

Table 1. Descriptive Characteristic of Sample at Baseline

	All Patients (N=98)	Smoker (n=17)	Nonsmoker (n=81)
Patient Variables			
Mean age in years (SD)	40.8 (12.0)	34.1 (11.7)	42.2 (11.6)
Female	31 (31.6)	4 (23.5)	27 (33.3)
Military Beneficiary Category			
Active Duty Service Member	52 (53.1)	12 (70.6)	40 (49.4)
National Guard or Reservist	8 (8.2)	2 (11.8)	64 (79.0)
Family Member/Dependent	18 (18.4)	2 (11.8)	16 (19.8)
Retired Service Member	20 (920.4)	1 (5.9)	19 (23.5)
Mean Body Mass Index (SD)	28.5 (4.5)	27.4 (4.4)	28.7 (4.5)
Mean Duration of Symptoms (SD)	175.1 (340.7)	185 (213.0)	172.5 (366.7)
Mean SPADI	45.5 (16.6)	46.5 (15.3)	45.3 (16.8)
Mean NPRS	3.6 (2.4)	3.8 (2.3)	3.5 (2.4)
Mean FABQ Work	11.9 (9.9)	17.2 (9.4)	10.9 (9.6)
Mean FABQ-PA	15.2 (4.9)	16.4 (5.0)	14.9 (4.9)
Hand Dominance Involvement	53 (55.2)	8 (47.1)	45 (57.0)
Pain Affects Sleep	90 (92)	14 (82.4)	76 (95.0)
Co-morbid Mental Health Condition	15 (15.3)	4 (23.5)	11 (13.6)
Co-morbid Cardiovascular Condition	21 (21.4)	2 (11.8)	19 (23.5)
Followed Protocol	80 (81.6)	16 (94.1)	64 (79.0)
Treatment Group			
Physical Therapy	46 (46.9)	11 (64.7)	35 (43.2)
Corticosteroid Injection	52 (53.1)	6 (35)	46 (56.8)

Note: Values are counts (percentages) unless otherwise indicated.
FABQ Work indicates Fear Avoidance Belief Questionnaire Work Subscale. FABQ-PA indicates Fear Avoidance Belief Questionnaire Work Physical Activity Subscale. NPRS indicates Numeric Pain Rating Scale. SPADI indicates Shoulder Pain and Disability Index.

receiving treatment for subacromial pain syndrome in the MHS.

Table 2. Variables Retained for Multiple Regression Modeling.

Smoker
Age
Gender
BMI
Hand Dominance
Treatment Group
On Protocol
Comorbid Mental Health Diagnosis
Comorbid Cardiovascular Diagnosis
Pain Effects Sleep
Symptom Duration
Baseline Pain
Baseline FABQ-PA
Baseline FABQ-W
Baseline SPADI

FABQ-W indicates Fear Avoidance Belief Questionnaire Work Subscale.
SPADI indicates Shoulder Pain and Disability Index.
FABQ-PA indicates Fear Avoidance Belief Questionnaire Work Physical Activity Subscale.

Table 3. Multivariate Adjusted Model for One-month Follow-up.

Variable	β	*P* value	aOR (95% CI)
Smoker	-1.856	.010*	0.16 (0.38-0.64)*
Treatment Group	0.721	.18	2.06 (0.72-5.92)
Pain Affects Sleep	-1.73	.171	0.18 (0.02-2.11)
FABQ-W	-0.02	.407	0.98 (0.93-1.03)

*Indicates significant value.
FABQ-W indicates Fear Avoidance Belief Questionnaire Work Subscale. aOR indicates adjusted Odds Ratio.

Table 4. Multivariate Adjusted Model For Reaching MCID at 6 Months.

Variable	β	*P* value	aOR (95% CI)
Smoker	-1.173	.097	0.31 (0.08-1.24)
Followed Protocol	-1.791	.045*	0.17 (0.30-0.96)
Age	0.019	.414	1.02 (0.97-1.07)
Comorbid Mental Health	2.002	.12	7.45 (0.52-95.83)
Baseline SPADI	0.048	.016*	1.05 (1.01-1.09)

*Indicates significant value.
MCID indicates Minimally Clinically Important Difference. SPADI indicates Shoulder Pain and Disability Index. aOR indicates adjusted Odds Ratio. MCID indicates Minimal Clinically Important Difference.

Smoking plays a detrimental role in musculoskeletal disorders through several proposed mechanisms, many of which are independent from other variables. Age-related loss of muscle mass (sarcopenia) and strength is significantly affected by smoking.[50] Impaired muscle metabolism, increased inflammation due to oxidative stress, and overexpression of sarcopenia-related genes have been observed in muscle tissue of chronic smokers.[50] Muscle weakness and impairment is also strongly associated with shoulder impingement and rotator cuff tendinopathies.[51,52] Our findings support findings from prior work. Bodin and colleagues found smoking to be an important risk factor for developing a rotator cuff tear confirmed via arthroscopic surgery.[53] The amount of smoking was positively correlated with the severity of the tear found. Nearly half of our patient cohort (44) had received an MRI prior to enrollment in the study, and of those, 52% had a rotator cuff tear. Only 6 of the 17 smokers had an MRI, but the majority of those with an MRI (83%) had a partial or full-thickness tear. However, 50% in the nonsmoking group also had a partial or full-thickness tear. There is also a higher risk for developing muscle pain in chronic smokers, and subacromial pain syndrome is primarily a muscle disorder.[50] In our cohort, baseline pain was not significantly different between smokers and nonsmokers, but as less smokers reached a clinically meaningful change at 4 weeks, the smoking may have explained the greater persistence of symptoms in this group.

Six months after treatment, smoking was no longer associated with poor outcome. With the passage of time, and in the absence of treatment (which did not last more than 3 weeks), there may have been time for additional factors to also influence prognosis. Because we did not reassess smoking status at 6 months, it is possible that some of the patients had ceased smoking during that time. It may also be that the deleterious effects of smoking are best expressed during active treatment, when pain modulation and restoring muscle function is the key focus.

Laslett and colleagues also found that greater pain and disability at baseline was a predictor of excellent outcomes in primary care shoulder pain patients.[54] Similarly, subjects with a higher disability at baseline were more likely to achieve a clinically important difference at 4 weeks and 6 months, regardless of treatment. While our inclusion criteria required a minimum of 20% (100% is maximum disability) on the SPADI to help prevent a ceiling effect, the greater improvements may reflect that these patients had more room to improve.

Educating patients on the dangers of smoking continues to be a strong public health initiative. This is especially important in the MHS, where smoking has been identified as a risk factor for musculoskeletal injury and greater occurrence of pain.[23-25,49,55] The extent to which this education affects the prognosis of musculoskeletal injuries is not well known. However, providers in the MHS should understand that the injurious effects of smoking extend beyond some of the more traditionally known sequelae such as lung cancer. In fact, the latest US Surgeon General report published by the Centers for Disease Control and Prevention did not focus on any relationships with musculoskeletal conditions, but rather the influence of smoking on respiratory diseases, reproduction, diabetes, cardiovascular health, and cancer.[56] Because musculoskeletal injuries are the primary source of disability for the US military, responsible for annual healthcare costs of $500 million and resulting in more than 25 million limited-duty days per year,[3,4] providers in the MHS should include discussions with their patients related to the effects of smoking on musculoskeletal injury. An

informative and shared decision approach when managing patients with shoulder conditions should incorporate education related to smoking habits and prognosis. This risk factor is not only associated with general medical health conditions, but it also may delay recovery and limit the benefit of treatment for shoulder injuries. Incorporating smoking education into the management of these patients could positively effect the high prevalence of patients with persistent shoulder pain. Future studies should focus on the effect of smoking education and cessation programs on functional outcomes for subacromial pain and other musculoskeletal injuries, as well as track longitudinally how smoking habits may change over the course of an injury.

Limitations

This study did not analyze the effect of smoking intensity (1 to 2 cigarettes vs 2 packs a day), which may improve the accuracy of the association with prognosis. Smoking history was only collected at baseline upon enrollment in the study and not reevaluated at the 6-month follow-up. It is possible that smoking patterns could have changed during the period, and if enough patients had given up smoking during that time, it may help explain why the risk of not recovering was there at 4 weeks, but not at 6 months.

Conclusion

Smoking was associated with a lack of clinically significant improvement in pain and function in patients with shoulder impingement syndrome, regardless of treatment received. Smoking habits should be accounted for in all future trials evaluating treatments for shoulder conditions, and a more robust sampling of potentially associated risk factors of poor prognosis are also needed to create better risk prediction algorithms. Providers in the MHS should consider this risk factor when managing patients with shoulder pain, and also musculoskeletal injury-related content to their smoking education programs.

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Real Time Interrater Reliability of a Novel Musculoskeletal Readiness Screening Tool

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Abstract

Military service members receive regular screenings for a variety of health conditions, but a field-expedient and military-specific screening tool that identifies an individual's risk for injury has not yet been identified. The purpose of this study is to describe the conduct of a novel musculoskeletal readiness screening tool (MRST) and evaluate the real-time interrater reliability of the MRST when scored by raters with differing levels of medical experience.

Materials/Methods: This study included a convenience sample of 40 active duty military participants (30 male, 10 female, mean age 29.3±6.9 years) without any current musculoskeletal injury or pain at the time of enrollment. The MRST consisted of 5 physical performance tests and one self-report question as follows: (1) weight-bearing lunge (WBL), (2) overhead squat, (3) closed kinetic chain upper extremity stability test (CKCUEST), (4) eyes closed forward step down, (5) repeated tuck jump, and (6) individual perceived level of risk for MSK injury. Three raters (a board certified physical therapist with 15 years of experience, a physical therapy student with less than one year didactic training, and a physical therapy technician with approximately 10 years of experience) independently scored each event as 0, 1, or 2 based on the quality of the participant's performance. This scoring system allows for a cumulative score ranging from 0 to 12, with lower scores thought to indicate higher risk for future injury. Descriptive, reliability, and chance-corrected agreement statistics were calculated using IBM SPSS. This study was approved by the Brooke Army Medical Center Institutional Review Board at Fort Sam Houston, Texas.

Results: The mean composite MRST score for all graders was 7.79±1.41. Among all 3 raters the overall reliability was moderate (ICC (2,1)=0.75 (0.62, 0.85)). Chance-corrected agreement values for the individual events ranged from slight to almost perfect as follows: WBL (κ=0.33-0.44), overhead squat (κ=0.57-0.65), CKCUEST (κ=0.89-1.0), eyes-closed forward step down (κ=0.10-0.42), repeated tuck jump (κ=0.39-0.61), individual perceived level of risk for MSK injury (κ=1.0).

Conclusions: The MRST showed moderate interrater reliability for the overall composite score with varied levels of agreement for individual events scores. Future research should investigate test-retest reliability and interrater reliability among medical personnel from different disciplines.

Musculoskeletal (MSK) injuries have steadily been on the rise and present a significant challenge to both military medical readiness and the military healthcare system.[1-3] Musculoskeletal injuries accounted for more than 3 million ambulatory care visits in 2014 for all active component service members.[4] They are the number one reason for medical discharge from the US Army and the most common cause of noncombat injuries reported during deployment.[5,6] At a time of military force reduction, medical readiness optimization is essential to the sustainment of successful worldwide military operations.[7]

While the military places a large focus on medical readiness through periodic health assessments, no standardized assessment for evaluating MSK readiness exists at this time. Multiple studies suggest that previous injury predisposes individuals to future injury.[8-11] Additional research suggest that faulty movement patterns may be associated with higher risk for injury,[12,13] although assessments to date have been fairly subjective and there is currently no consensus on what movements should be assessed. A lower level of optimism has also been found to be related to a higher likelihood of injury occurrence, which suggests that an individual's level of concern for injury should be considered in addition to physical performance measures.[14,15]

There are several MSK screening tools, such as the Functional Movement Screen (FMS)[9,13] (Functional Movement Systems, Inc., Chatham, VA) and the Y-Balance

Test,[12,16] that assess movement patterns and identify functional limitations and asymmetries. However, these tools are often used in elite athletic populations[9,13] rather than typical military service members, and research findings to date are mixed on the predictive capacity of these screening tools.[8,17,18] Additionally, these tools generally require time, equipment, and trained personnel in order to ensure proper administration, all of which may be in limited supply in any given military medical environment.

A musculoskeletal readiness screening tool (MRST) that can assess a broad spectrum of movement patterns commonly encountered by a majority of military service members is necessary.[19] Furthermore, this tool must be configured in such a way that it can be readily completed in any environment, performed using minimal equipment, and reliably assessed by a broad range of healthcare personnel. The MRST in this study was adapted from a previously reported screening tool intended to be used to assist medical providers with return to duty decisions.[20] A majority of the events from the previous screening tool were modified or replaced in this study in order to increase the level of challenge and decrease the time and equipment required for administration. Additionally, the authors selected the events and evaluative criteria for the MRST in this study in order to create a tool that would: (1) screen upper and lower extremity strength and mobility, core stability, and tolerance for upper and lower extremity plyometric activity, (2) evaluate participants using standardized scoring criteria regardless of gender, and (3) be general enough to apply to all military service members regardless of branch of service and occupational specialty. Because health screening in the military is performed by providers of varying levels of MSK expertise (eg, from unit medics to hospital physical therapists), it is necessary that a screening tool be reliable between providers of differing levels of MSK training. Therefore, the primary objective of this study was to describe and assess real-time interrater reliability of the MRST between raters of differing levels of medical training and experience.

Methods

Participants

A convenience sample of 40 participants was recruited over a 3-month period. All participants were active duty US military personnel stationed at Joint Base San Antonio, TX. A large majority of the participants were enrolled as students in some type of temporary medical training program during the data collection period. The Institutional Review Board at Brooke Army Medical Center, Fort Sam Houston, TX, approved this protocol and the rights of the participants were protected.

After consenting, participants completed a screening questionnaire consisting of basic demographic information, including age, sex, height, weight, past medical history, branch of service, and military occupation. To be considered eligible, participants had to meet the following inclusion criteria: active duty military service members ranging in age from 18 to 50 years; in no pain (0/10) at the time of enrollment; and read and speak English well enough to understand the informed consent documents, as well as instructions given by researchers. Exclusion criteria included the following: current musculoskeletal injury of any kind or signs or symptoms thereof; medical condition(s) that preclude rigorous physical activity; known pregnancy; physical restrictions that would preclude performance of MRST events; or any orthopedic surgery within the last 6 months.

Real-time interrater reliability was investigated using 3 raters, each representing varying levels of MSK education and training. The raters included the principal investigator (Rater 1) who was a licensed physical therapist and a board-certified clinical specialist with 15 years of clinical and functional movement screening experience, a doctoral physical therapy student (Rater 2) in the first year of academic preparation, and an enlisted physical therapy technician (Rater 3) with approximately 10 years of clinical experience. Raters 2 and 3 had minimal prior functional movement screening experience. This combination of raters was chosen because it is consistent with many military physical therapy clinic-staffing models.

Experimental Approach

This study was a single cohort study, with all participants following the same initial assessment protocol. All raters received approximately 5 hours of training to ensure standardized performance of duties related to the protocol. The raters were blinded to one another's results and data was not made available to any rater until all data collection was completed.

Procedures

The MRST consisted of 6 events executed in the following order: weight-bearing lunge event (WBL), overhead squat (OHS), closed kinetic chain upper extremity stability test (CKCUEST), forward step down with eyes closed (FSD), repeated tuck jump (RTJ), and a question regarding the individual's perceived risk for future musculoskeletal injury (QUEST). Each event was graded as a 0, 1, or 2, resulting in a cumulative score ranging from 0 to 12, with higher scores presumed to indicate a greater level of psychological and musculoskeletal readiness. For all events, with the exception of QUEST, a score of 2 in a single event indicated performance to standard as defined in the scoring rubrics. A score of 1 indicated

substandard performance, and a score of 0 was recorded if a participant demonstrated bilateral dysfunction and/or noted pain with the event. The participants were not informed about the scoring criteria for each event prior to testing. All participants received a standardized set of instructions for each MRST event that was followed by a live demonstration performed by an investigator not serving as a rater. Each of 3 raters used a similar viewpoint to simultaneously score the MRST events.

Weight-bearing Lunge (Figure 1). This event has been reported in several studies[21,22] as a method to assess ankle joint mobility. It was performed while wearing socks without shoes. Participants started from a staggered stance position with their feet slightly less than shoulder width apart. The longest toe of the trail foot was placed in line with the heel of the forward foot when viewed from the side. The participant was permitted to place 2 digits per hand against the wall as a balance aid only.[22] The longest toe of the forward foot was required to touch the edge of the tape marking the 10 cm distance. Participants were instructed to lunge directly forward with the intent of touching the kneecap to the wall, ensuring that the forward heel stayed on the ground throughout the movement.[21,22] If obvious compensatory movement of the hip, pelvis, or knee was noted, the trial could be repeated. One to 2 practice trials were permitted to ensure proper performance. If multiple trials were performed on this or any subsequent event, the last performed trial was the one graded by each of the 3 raters. The same procedure was then completed on the opposite lower extremity. All raters for this event used a lateral viewpoint. This event has demonstrated excellent intrarater and interrater reliability.[21,23] There is some evidence to suggest that it is predictive of lower extremity injuries in Australian football players,[24] and that less than 12 cm of motion may be considered restricted.[25,26] The standard of 10 cm distance was used in this study. Scoring criteria for this event and all subsequently described events performed in the MRST are listed in Table 1.

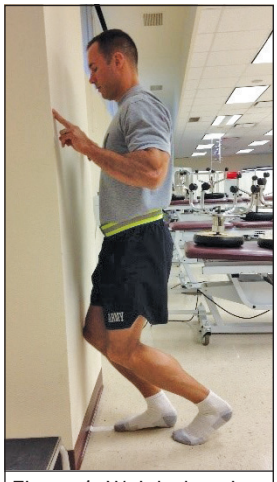
Figure 1. Weight-bearing lunge.

Overhead Squat (Figure 2). This event was a modified version of the deep squat performed as a part of the FMS[27] and similar to the overhead deep squat performed as part of the Selective Functional Movement Assessment.[28] Participants left their shoes off for this event and were instructed to lift the arms overhead in the manner shown in Figure 2 and keep them in this position throughout the duration of the movement. The participant's feet were placed in a comfortable position that was approximately at shoulder width. Neutral foot rotation and foot flat contact with the floor was expected throughout the duration of the movement.[27,28] Participants were instructed to squat until their thighs were at least parallel with the floor. The movement could be repeated up to 3 times, at the discretion of the raters, in order to determine an accurate score. All raters for this event started with an anterior viewpoint and then moved to a lateral view. This event has demonstrated acceptable chance-corrected agreement when evaluated by experienced raters[29] and has been shown to be predictive of injury risk in at least one study.[30]

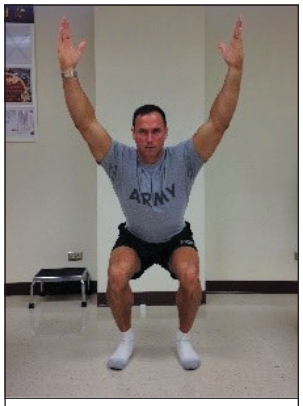

Figure 2. Overhead squat.

Closed Kinetic Chain Upper Extremity Stability Test (Figure 3). This event provided a dynamic challenge primarily to the core and upper extremities. Participants put their shoes on and kept them on for the remainder of the screening. Prior to starting this event, participants were permitted to stretch for up to 30 seconds. Male participants began by assuming the starting position for a standard military push-up position and female participants used a modified push-up position (lower body weight-bearing occurred through the knees).[31,32]. Folded towels were provided in the modified position for increased comfort during the event. The feet (or knees for the modified position) were no further than 12 inches apart (feet were raised off the ground in the modified position). Their hands were placed 36 inches apart on the floor, as marked by white athletic tape. The initial movement consisted of reaching toward the weight-bearing hand with the free hand to contact the tape or a part of the weight-bearing hand directly over the tape, before returning to the starting position. Hand contacts occurred alternately and each contact was counted as


Figure 3. Closed kinetic chain upper extremity stability test (male).

one repetition.[31] The stated goal was to complete 20 repetitions within 15 seconds. Participants were required to have at least one hand on the floor and maintain their trunk and legs alignment throughout the duration of the event.[32] Participants were instructed to stop when 15 seconds had elapsed or 20 correct repetitions were completed, whichever came first. The viewpoint of this event for all raters was anterior and only a single 15-second trial was completed. This event has demonstrated excellent reliability in both healthy and injured populations.[32] In one study, it was highly predictive of shoulder injuries in football players when using a cut-off score of 21 touches.[33] The standard used in this study was reduced to 20 given the increased variability in upper body and core strength found within a given military population.

Forward Step Down with Eyes Closed (Figure 4). This event was previously reported[20] and demonstrated moderate chance-corrected agreement. The event was modified from a low-light condition to an eyes-closed condition in order to increase generalizability. Agreement for rating quality of movement during the forward step down task under normal lighting conditions has been previously reported as fair to good.[34,35] Given that injury risk is potentially elevated during nighttime operations,[36] and landing mechanics are unfavorably altered during drop landings with visual compromise,[37] the purpose of this event was to grossly simulate disembarking from a vehicle during operational low-light conditions. This assessment is similar to the typical step-down functional assessment routinely performed in the clinical setting but with the addition of 2 textbooks held at the height of the umbilicus as a challenge to anterior balance and with the eyes closed. Participants began this event with both feet on an 8-inch step. The participant was given 2 hardcover textbooks, weighing 13 pounds collectively, and instructed to hold the books with the elbows bent to 90 degrees without allowing the books to contact the body. The instructor directed the participants to then close their eyes and step down one leg at a time. Participants were instructed not to open their eyes until completing the step down. The event was then completed by performing the same movement, but initiating the step-down with their opposite leg. The viewpoint for this event for all raters was anterior.

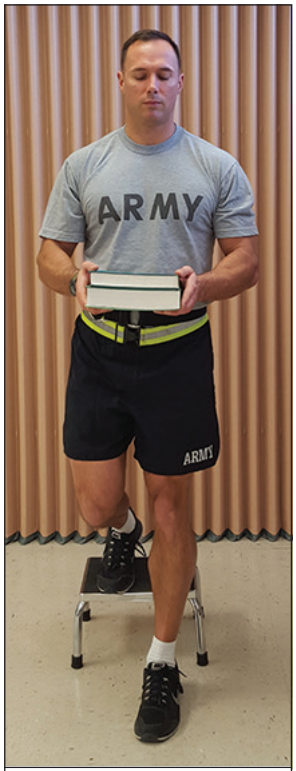

Figure 4. Forward step down with eyes closed test.

Repeated Tuck Jump (Figure 5). This event consisted of 3 tuck jumps completed in rapid sequence. Although there is minimal evidence regarding reliability and validity, it provided a substantial lower extremity plyometric challenge and is similar to the tuck jump exercise prescribed as part of the Army Physical Readiness Training program.[38] The starting position was an upright straddle stance, and participants were instructed to begin jumping when they felt prepared to do so. The stated goal was for the thighs to achieve at least a 45° angle from the vertical plane. The hands were not permitted to grasp the knees in an effort to draw the thighs closer to the trunk. Each participant was reminded to rapidly initiate the next jump after attempting to make a soft landing in the original starting position.[39] When a significant delay occurred between jumps, the event was repeated. If any participant experienced a sharp pain, they were instructed to stop jumping immediately. The viewpoint for this event for all raters was anterior.

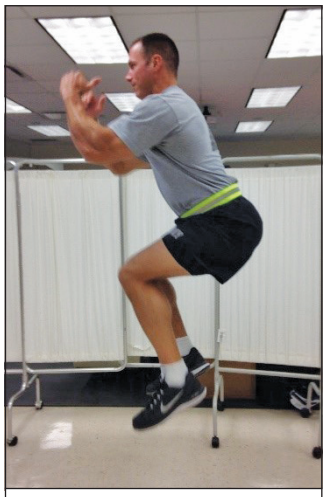
Figure 5. Repeated stationary tuck jump.

Individual Perceived Level of Risk for Musculoskeletal Injury. The goal of this event is to assess psychological confidence in return-to-duty capability and perceived risk of injury or reinjury.[14,15,40,41] Participants were asked to describe their personal concern for developing a musculoskeletal injury within the next 6 months. The previously reported[20] format used a simple verbal question with 3 possible answers.

Statistical Analysis

All data were analyzed using IBM SPSS Version 22. Descriptive statistics were performed to describe the demographic characteristics of the sample. Means and standard deviations were computed for continuous data and frequency distributions were analyzed for categorical data. It was estimated that data from 40 participants would be required to have adequate precision of interrater reliability (ICC with 95% CI) estimates. Intraclass correlation coefficient (ICC 2, 1) and associated

Table 1. MRST Scoring Criteria.	
Weight Bearing Lunge (WBL)	
2	Bilateral ability to touch the wall with the kneecap without pain
1	Unilateral ability to touch the wall with the kneecap without pain
0	Pain associated with the movement and/or bilateral inability to touch the wall with the kneecap
Overhead Squat (OHS)	
2	All of the following checkpoints are met: trunk parallel with tibia or toward vertical, arms in line with trunk, thighs at least parallel to floor, knees aligned over feet, and pain-free[27]
1	Failure to meet all of the checkpoints above and no pain present
0	Failure to meet all of the checkpoints above and/or pain present
Closed Kinetic Chain Upper Extremity Stability Test (CKCUEST)	
2	Perform 20 repetitions to standard without pain
1	Perform less than 20 repetitions to standard without pain
0	Pain during or after the event
Forward Step Down with Eyes Closed (FSD)	
2	No lower extremity frontal plane deviation, eyes remain closed, no pain experience during movement, and no gross or obvious loss of motor control
1	Any lower extremity frontal plane deviation, loud foot landing indicating lack of control, eyes open, or loss of motor control, and pain-free
0	Pain during or after the event
Repeated Tuck Jump (RTJ)	
2	Performs 3 successive jumps meeting all checkpoints: thighs at least 45 degrees compared to vertical plane, soft fore-foot to mid-foot landing, no frontal plane deviation, and pain-free during all phases of movement
1	Does not meet all checkpoints above without pain
0	Pain during or after event
Perceived Level of Risk for Musculoskeletal Injury (QUEST)[20(p17)]	
2	No concern for injury
1	Mild to moderate concern for injury
0	Significant concern for injury

confidence intervals were calculated to estimate interrater reliability. The interpretation of the ICCs was consistent with the method described by Portney and Watkins.[42] Unweighted Cohen's kappa values were used to estimate chance-corrected agreement of individual events and the results were interpreted per the guidelines reported by Landis and Koch.[43] Weighted Cohen's kappa was not used because having a 2 point difference between raters in a given event was unlikely given that in 4 of 6 tests, the only possibility by which a participant could receive a score of zero is if they reported pain. Also, the probability of rater disagreement when scoring the QUEST was considered extremely low.

Results

Consent was obtained from 40 participants (30 male, 10 female) with a mean age of 29.3±6.2 years that met the screening criteria to participate in the study. The mean height and weight of the sample was 175.26±8.63 cm and 77.56±13.52 kg respectively. The MRST composite score and individual event score means for each rater are reported in Tables 2 and 3, respectively.

Table 2. MRST Composite Scores.		
Rater	**Mean** (95% **CI**)	**SD**
All	7.79 (6.40, 9.18)	1.41
1	7.70	1.51
2	7.60	1.28
3	8.08	1.46

Table 3. MRST Individual Event Mean Scores (SD).			
Event	**RATER 1**	**RATER 2**	**RATER 3**
WBL	0.38 (0.63)	0.60 (0.74)	0.83 (0.87)
OHS	1.23 (0.53)	1.13 (0.46)	1.25 (0.49)
CKC	1.35 (0.48)	1.30 (0.46)	1.35 (0.48)
FSD	1.88 (0.33)	1.80 (0.41)	1.83 (0.38)
RTJ	1.23 (0.48)	1.13 (0.40)	1.18 (0.45)
QUEST	1.65 (0.53)	1.65 (0.53)	1.65 (0.53)

Interrater reliability estimates of the composite scores are presented in Table 4.

The ICC values for MRST composite scores ranged from 0.68 to 0.82. The level of chance-corrected agreement and percentage agreement is reported in Table 5. Substantial to almost perfect level of agreement was found with the OHS, CKCUEST, and QUEST amongst all raters with the exception of a moderate agreement in the OHS between the student clinician and the ancillary clinical staff member. All other events (WBL, FSD, and RTJ) had fair to moderate level of agreement with the exception of only a slight agreement in the FSD between the student clinician and the ancillary clinical staff member.

Comment

The results of this study indicated that the MRST composite scores for all raters had moderate overall interrater reliability and could potentially be applied consistently by individuals with varying degrees of MSK training. Chance corrected agreement of the individual events varied from slight to almost perfect, but was generally consistent with respect to percentage agreement. While

Table 4. MRST Composite Score Reliability.			
Composite Comparison	**ICC** (2,1)	95% **CI**	**Level of Reliability**
All Raters	0.75	0.62, 0.85	Moderate
Rater 1/3	0.82	0.65, 0.91	Good
Rater 1/2	0.76	0.58, 0.86	Good
Rater 2/3	0.68	0.43, 0.82	Moderate

some events, such as the QUEST and CKCUEST had almost perfect agreement across all raters, other events, such as the WBL and the FSD, did not achieve above a moderate level of agreement between any pair of raters. The variability in these results may be due to the complexity of the event, testing protocol, or interpretation of scoring criteria.

Although scores were generally consistent across the different raters, agreement was lowest between the 2 less experienced providers (Rater 2 and Rater 3). This may suggest that the level of MSK training does affect screening reliability to some extent. Alternatively, this finding may be attributable to the experienced clinician's direct involvement with the student rater's education and the ancillary staff member's continuing education. Therefore, the interrater reliability between these 2 sets of raters might be expected to be better than the interrater reliability between the student clinician and the ancillary staff member.

Some reliability studies for the WBL event by other researchers[21,44] have reported an excellent level of agreement between raters. However, the testing protocol for these studies differed in that the subject's heel was held to the ground throughout their attempt to touch the wall. In the current study, the participant's heel was not held stationary; it was at the discretion of the raters to determine if they observed any degree of heel lift. Additionally, the aforementioned studies did not penalize participants for proximal compensatory movements of the knee while the MRST grading criteria did. Essentially, the MRST leaves more room for rater interpretation in scoring the weight-bearing lunge test. Applying external stabilization at the heel could be considered in future studies to potentially eliminate the need to agree on this scoring criterion.

Multiple reliability studies have been performed on assessing a squat movement, but many of these studies were performed using a video recorder.[45-47] One study performed a real-time interrater reliability of the FMS.[48] This study looked at the interrater reliability between 2 raters and reported a perfect 1.0 kappa on the squat event. Although only one rater was FMS certified, both had similar levels of experience as certified strength and conditioning specialists. Having fewer raters along with having raters of more similar experience could account for the higher kappa value.

Park et al[35] reported good agreement for the FSD assessment. This event resulted in the lowest reliability between raters in the current study, with kappa values ranging from only a slight to moderate agreement. Reliability was likely affected by a number of differences in the grading criteria between the 2 studies. Park's study based their kappa values on agreement within a specific range. While raters in that study may have agreed that a particular movement was rated as good, this rating was based on a range of scores. Conversely, the current MRST study's kappa value was based on agreement on the exact score. Additionally, participants in the current MRST study were required to perform the maneuver with their eyes closed while holding 2 textbooks in their arms. This increased load may have influenced the difficulty of movement for the subjects and therefore increased potential for error in the way raters scored the participants. Despite achieving 72.5% to 85.0% agreement between all rating pairs for this event, all participants scored either a 1 or 2. The kappa value was expected to decrease because agreement is more likely to happen by chance when the scores become dichotomous. Given the low level of impact and minimal physical exertion required for this event, pain is unlikely to occur in a healthy population. Modification of the scoring criteria for a score of 0 that does not involve the presence of pain could be considered in future studies.

The evidence regarding reliability of real time jump assessments is limited. One study[49] assessed the

Table 5. MRST Individual Event Scoring Agreement.

Rater Comparisons by Event	Percentage Agreement	Kappa	Level of Agreement
Weight Bearing Lunge (WBL)			
Rater 1/2	67.50	0.39	Fair
Rater 1/3	60.00	0.33	Fair
Rater 2/3	65.00	0.44	Moderate
Overhead Squat (OHS)			
Rater 1/2	85.00	0.65	Substantial
Rater 1/3	82.50	0.61	Substantial
Rater 2/3	82.50	0.57	Moderate
Closed Kinetic Chain Upper Extremity Stability Test (CKCUEST)			
Rater 1/2	95.00	0.89	Almost Perfect
Rater 1/3	100.00	1.00	Almost Perfect
Rater 2/3	95.00	0.89	Almost Perfect
Forward Step Down with Eyes Closed (FSD)			
Rater 1/2	82.50	0.36	Fair
Rater 1/3	85.00	0.42	Moderate
Rater 2/3	72.50	0.10	Slight
Repeated Tuck Jump (RTJ)			
Rater 1/2	80.00	0.45	Moderate
Rater 1/3	85.00	0.61	Substantial
Rater 2/3	80.00	0.39	Fair
Individual Perceived Level of Risk for Musculoskeletal Injury (QUEST)			
Rater 1/2	100.00	1.00	Almost Perfect
Rater 1/3	100.00	1.00	Almost Perfect
Rater 2/3	100.00	1.00	Almost Perfect

jump-landing technique in real time and reported interrater reliability ranged from ICC values of 0.72-0.81. Unlike the current MRST study, researchers graded jump performance based on 10 characteristics of a single jump. The 3-point grading system of the MRST did not assess what types of deficiencies existed, only that one or more existed. Therefore, in order to achieve a maximum score for the RTJ in this study, all checkpoints must have been met. Since the MRST is intended to be both an individual and large-group screening tool conducted by a variety of personnel, it is initially more important for the screening to identify that an individual is at increased risk for injury, rather than a specific error.

The most technically demanding assessments in the MRST were the OHS, FSD, and the RTJ. These events are more dynamic in nature and required the simultaneous assessments of multiple areas. The lowest kappa values observed in those events existed between the raters with least experience. More experienced clinicians may be able to distinguish the subtle movement deviations that less experienced personnel might not observe. Also, the viewpoints for each rater was standardized, but they were not identical, so there is a possibility that slight differences in viewpoint could have affected rater agreement. Similar results were seen in a study where real time assessments were performed.[48] The authors of the study stated that the observation location of the rater might have been an integral factor in the low level of interrater reliability for one specific event. This indicates the need for more training and/or more specificity in the scoring instructions to achieve a more reliable assessment in those with less clinical movement screening experience.

A potential limitation in generalization of this study is the amount of training that the raters received prior to data collection. Although standardized grading criteria were provided for each event, a number of different interpretations can be made based on the grading criteria used. The ability to decide between 2 grading criteria when more subtle dysfunctions are present can be challenging and improvement would be expected with subsequent practice. Additionally, all participants were recruited from the same area and the majority were students in a medical training program of some type, so their level of physical activity may not be representative of a wider population. Therefore, the deficiencies identified in their performance may not be indicative of a more diverse military population.

Future reliability studies are needed to assess interrater and test-retest reliability of the MRST in more diverse military populations using raters from multiple medical and training disciplines that are responsible for assessing MSK injury risk. They should include a more specific training protocol for its raters and possibly slight modifications to the scoring criteria for the WBL and/or FSD events.

Conclusion

When applied by raters in the field of physical therapy, the MRST demonstrated moderate interrater reliability for the overall composite score with varied levels of agreement for individual events scores. Future research should investigate test-retest reliability and interrater reliability among personnel from multiple disciplines.

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Cognitive Behavioral Therapy for Insomnia Treatment in a Military Deployed Operational Setting Utilizing Enlisted Combat Medics: A Quality and Process Improvement Project

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ABSTRACT

Insomnia disorder is a prevalent condition especially among the American military, affecting up to 50% of service members. It is shown to affect military performance. Guidelines recommend the use of nonpharmacologic approaches as initial treatment of insomnia. Cognitive behavioral therapy informed insomnia treatment (CBT-I) has the greatest evidence, however it requires specialized training. While deployed in the Middle East in support of US military operations, we faced a resource challenge while caring for service members with insomnia. In order to meet the needs of the population, we created a checklist based CBT-I informed treatment to enable our health extenders, including combat medics and behavioral health specialists. Following institutional review board determination of this project as nonresearch, we implemented this as a Quality Improvement/Process Improvement Project (QI/PI). Here we describe the 4 phases of this QI/PI and our outcomes. This process can be easily reproduced in either the deployed or garrison setting with minimum efforts and resources, enabling delivery of high quality, evidence-and guidelines-based treatment while using combat medics and behavioral health specialists to their maximum potential.

Insomnia disorder is defined in the *Diagnostic and Statistical Manual of Mental Disorders*[1] as dissatisfaction with sleep quantity or quality related to difficulty initiating or maintaining sleep or early morning waking with inability to return to sleep. These symptoms result in distress and dysfunction with additional criteria of occurring at least 3 nights per week, lasting over 3 months. The period of the existence of symptoms is important to distinguish it from normal transient symptoms that are considered normal human experience. An important criterion is the requirement of having adequate opportunity to sleep. Given insomnia is a diagnostic criterion in various psychiatric disorder,[1] insomnia disorder requires absence of other sleep-wake disorders and ruling out explanation of symptoms by other coexisting mental disorders.

Despite the rigid diagnostic criteria, insomnia disorder is still prevalent, estimated to affect 6 to 10% of adults.[2] The prevalence of insomnia in the military is reported to be 50%.[3] The association of insomnia with health is well established. Sleep is frequently disturbed in posttraumatic stress disorder and traumatic brain injury,[4] the 2 signature health concerns from Global War on Terror. Additionally, there are concerns of insomnia affecting military operations. For example, Williams et al found that active duty Soldiers perceive 50% of their mistakes attributed to insomnia.[5] Their study also revealed that half of pilots surveyed reported falling asleep in the cockpit. While the presence of insomnia is concerning for Soldier performance, there is some evidence of improvement in military performance when interventions are made to improve sleep. In one study,[6] a comparison of 2 units was made, allowing the intervention unit accommodation of adolescent phase-delayed sleep regimen. Results showed improved marksmanship, sleep quality, mood, reduced sleep fatigue, and increased sleep duration.[6]

The prevalence of insomnia and perceived concern for reduced functioning is apparent in high prevalence (up to 20%) of hypnotic use among Soldiers.[4] There are obvious arguments against to the use of hypnotics in the military setting, such as potential impairment of psychomotor skills, sedation, and other adverse effects. Long-term use is also associated with concern for possible dementia and fractures.[7-9] Based on the risk and benefit appraisals, alternative treatments to pharmacotherapy have been evaluated. The greatest evidence comes from treatment strategies based on cognitive behavioral therapy (CBT) informed interventions. While there are heterogenous techniques and variations, these are often referred to as CBT-insomnia (CBT-I). At present,

CBT-I is the recommended initial treatment for adults with chronic insomnia disorder.[10]

CBT-insomnia typically has a combination of psychoeducation, cognitive (restructuring dysfunctional beliefs), and behavioral (stimulant control, sleep restriction, etc) aspects. The psychoeducation component aims to increase sleep literacy of the patient. It attempts to increase basic understanding of normal and abnormal sleep, mainly designed to help achieve acceptance from the patient while also targeting attitudinal competency. The cognitive component, in our opinion, is the most technical aspect of CBT-I, requiring significant expertise and experience. It aims to identify dysfunctional beliefs held by the patient that negatively affects their expectations and perceptions of their sleep. Once these dysfunctional beliefs are identified, the next step is to challenge and introduce doubts into these thoughts via the process of cognitive restructuring. Most clinicians have a significant behavioral component to their CBT-I interventions. These may include stimulant control, sleep restriction, and sleep deprivation to help increase sleep inertia and improve sleep efficiency. There might also be some component of progressive relaxation techniques to reduce anticipative anxiety and tension. The overarching goal is to optimally synchronize the sleep's Process C and Process S, a 2-process model of sleep regulation which is beyond the scope of this paper but can be reviewed elsewhere.[11]

Given the technical competency required to deliver CBT-I, it is typically conducted by behavioral health practitioners. In a deployed setting, however, availability of trained personnel (psychologists, social workers, psychiatrists) is the limiting factor. We experienced these same constraints with only 2 therapists and a single psychiatrist caring for a population of approximately 9,400 service members at a remote location. Herein we describe a novel approach to enable enlisted healthcare extenders (behavioral health specialists and combat medics) to deliver CBT- I treatment using a PI/QI strategy based on typical Plan, Do, Study, Act (PDSA) cycles. We describe the PDSA cycles of our project and report our significant outcomes. A similar approach can be used by deployed healthcare teams such as combat operational stress teams (or equivalent) to help extend the first-line, evidence-based therapy for service members with insomnia.

Materials and Methods

The Institutional Review Board for the deployed location in the Middle East reviewed and approved our PI/QI project for nonresearch determination. During the plan phase, teaching and CBT-I protocol deliverables were prepared by author R.A. Service members received treatment during the "Do" phase of the project. Outcomes as outlined below were reviewed and analyzed during the "Study" phase. Finally, feedback from patient outcome measures, enlisted combat medics, and behavioral health specialists were implemented into the original treatment protocol and delivery methods.

Plan

Author R.A. is formally trained in CBT-I and uses various methods and strategies in his clinical practice. However, during the development phase, literature search of the MEDLINE database was undertaken to find the most optimal combination of techniques using cognitive, behavioral, and psychoeducational strategies. No studies were found with head-to-head comparison among any of these strategies. There are standardized treatment protocols,[12] however, these were considered not ideal for 2 main reasons: (1) they are copyrighted protocols and were cost-prohibitive; (2) the workbooks are designed for experienced therapists and not practical for healthcare extenders such as combat medics.

Given this, we developed our own protocol with greatest emphasis on behavioral techniques and psychoeducation and a smaller cognitive component. The protocol was designed to enable someone with minimal training to deliver the cognitive, behavioral, and psychoeducation of CBT-I. Training of the treating medics relied on use of a checklist. This ensured no steps or components were missed and every patient received a standardized treatment.

Protocol

The protocol consisted of a "provider packet" and "patient packet." The provider packet contained an initial sleep intake, initial sleep prescription, initial checklist, constructive worry sheet, dysfunctional beliefs challenge scripts, follow-up checklist, follow-up intake and prescription form, provider psychoeducation slides, and sleep log form. All of these items were standalone documents made available electronically to the students.

The patient packet contained initial sleep intake, initial sleep prescription, constructive worry sheet, sleep log form, and patient psychoeducation slides. All of these documents were standalone documents made available electronically to the students to print as a packet for a given patient as needed.

Training on Using Sleep Protocol

A single, 3-hour training workshop was conducted to educate combat medics and behavioral health specialists on the use of the sleep protocol. Both of these military occupational specialties (MOS) in the US Army fall under the "68 series." The combat medics (MOS 68W) receive

training on supporting basic life functions with knowledge of medical care under fire and trauma care. The behavioral health specialists (MOS 68X) receive training on providing psychological first aid under the supervision of a behavioral health specialist. Neither of these 2 specialties have any training in CBT-I. The workshop audience consisted mainly of behavioral health specialists and combat medics assigned to an armor brigade. Following the training, a survey of pre- and posttraining confidence and satisfaction metrics were assessed.

PowerPoint slides were used to begin the workshop, providing an overview of both provider and patient packets. The first hour was spent on didactics which targeted understanding the Process C and Process S model of sleep regulation[11] and its role in sleep maintenance, normal sleep physiology, evidence for CBT-I, and understanding cognitions and behaviors and their effect on sleep and development of insomnia. For the second and third hour, cases were used to illustrate specific competencies necessary to effectively deliver the protocol. Training focused on assessment of sleep behavior using the initial sleep intake form, and skill to write initial and follow-up sleep prescription using provided forms within the provider packet. The students also learned to use the Dysfunctional Belief Challenge Scripts for cognitive restructuring. Additionally, students learned to assess and identify need for referral if there are concerns for organic sleep problems or psychiatric disorders. Finally, students were given templates for documentation of their encounters in the electronic health record and obtaining supervision from a supervising therapist.

The training underscored the accurate, exact, and unwavering use of the checklist. For example, the first item on the checklist is "Initial Intake Form completed." The initial intake form consisted of demographics, specific sleep questions to allow the provider to easily calculate sleep efficiency, review of systems to look for organic causes of insomnia, sleep satisfaction questions, a Patient Health Questionnaire-2,[13] suicide screening question, and a Generalized Anxiety Disorder Questionnaire-2.[14] Finally, in order to enable and operationalize a novice provider in tackling the most difficult part of CBT-I, identifying and challenging cognitive distortions and dysfunctional beliefs, the Dysfunctional Beliefs and Attitudes about Sleep (DBAS) was used. This scale was originally a 30-item questionnaire that was later validated in its shortened form as DBAS-16.[15]

Process

Patients were entered into treatment by one of 2 distinct routes. One route involved patients presenting to the brigade aid station with pure sleep complaints with no additional psychiatric symptoms. Those patients were offered CBT-I, receiving treatment in a private room inside the aid station. The intake form was completed using the checklist, then screened for evidence of depression, anxiety, or organic sleep problems. If any of the conditions were positive, the treating medic was instructed to refer those patients to a credentialed provider. However, medics were instructed to immediately escort anyone with acute suicidality to the behavioral health providers. The other route for treatment was through the behavioral health clinic. During routine intake for behavioral health treatment, patients citing sleep difficulties were offered CBT-I treatment in addition to other psychiatric services. The treatment was delivered inside the behavioral health clinic by either a trained behavioral health specialist (MOS 68X) or trained medic (MOS 68W) as the clinic had a shortage of behavioral health specialists.

The initial checklist component was psychoeducation. The provider used his or her "provider psychoeducation slides" while the patient followed with their "patient psychoeducation slides." Both were identical slides on basic physiology, dysfunctional beliefs and behaviors about sleep, introduction to CBT-I concepts, and evidence for this modality. The provider version contained boxes with text and providers were instructed to read those verbatim as they lead the patient through the 12 slides.

The second component on the checklist focused on behavioral interventions. The provider was tasked to calculate the sleep efficiency and provide the patient with exact wake-up time and earliest bed-time. The idea was to reduce time in bed awake (improving sleep efficiency) and the associated frustration with forcing oneself to fall asleep, as well as sleep deprivation to enhance sleep inertia. The initial sleep prescription form took information from the intake form. For practical reasons, sleep logs were optional and all treatment decisions were based on self-reported times averaged over a week. The initial sleep prescription took baseline self-reported total sleep time (adding sleep at night and any additional naps), and added one hour to this time. This was total permitted time in bed. For example, if someone reported sleeping on average 5 hours per night, but spent 8 hours in bed, then their sleep efficiency is 63% ($5/8 \times 100$). Using this example, the patient was asked about best daily wake-up time. They were required to wake up at this specific time for the next week even if they were not working. Patients were encouraged to take physical training or morning military formations into account. If, for example, the patient were to settle on daily wake-up time of 5 AM, then, based on the above example, they were permitted to go to sleep no earlier than 11 PM (5 hours plus one additional hour for a total of

6 hours permitted in bed). It was stressed that they must only go to bed after 11 PM and only if they are sleepy. Regardless of what time they finally went to bed, they were still required to wake up at the agreed-upon daily wake-up time. Next, rules for sleep that are listed on the same initial sleep prescription form were reviewed. It emphasizes behaviors of stimulant control and sleep hygiene that highlights behavioral concepts.

Finally, the DBAS-16 from the initial intake form was reviewed. The providers were instructed to read verbatim the scripts related to DBAS-16 items that score 6 or more (Dysfunctional Belief Challenge Scripts Packet). This cutoff of 6 or more out of 10 on the Likert scale is informed by the validation data from the initial study[15] on DBAS-16. Identifying and challenging cognitive distortions require a significant amount of clinical expertise to do well. Therefore, the Dysfunctional Belief Challenge Scripts Packet was designed by the authors to challenge all 16 of the dysfunctional beliefs on the scale. The use of the scale permitted identification of the majority of these beliefs. It also then permitted the provider to select the ones he or she would challenge. Any question with 6 or more points was selected. For example, if a patient was high (scoring 6 or more) on questions 3, 5, and 15, the provider would first read the introduction statement verbatim: "I am going to talk to you about some common trends of maladaptive thoughts and beliefs that we notice among those people who suffer from sleep problems. These thoughts and beliefs can worsen their sleep problems. I would like to highlight some of those for you by reading them aloud and then providing you some explanations. I am selecting these because you scored high on these." Next, the provider would read the question and then our provided "challenge script" for that particular question. The cognitive component of this protocol was only addressed at intake. They were, however, given the constructive worry sheet to use on their own if needed. It entailed a column for what their worry might be and a column for potential actions they plan to take to address that concern. The patients were given a sleep log form that they could choose to complete.

At follow-up, the "Follow-up Sleep Intake and Prescription" form was used to record sleep data to calculate sleep efficiency, and self-reported sleep satisfaction. This form also provided a decision-tree for the provider:

- If Sleep Efficiency is 85% or greater, add 30 minutes (earliest bedtime is 30 minutes sooner but wake-up time stays the same).
- If Sleep Efficiency is 65% or less, subtract 30 minutes (earliest bedtime is 30 minutes later but wake-up time stays the same).
- If Sleep Efficiency is 66% to 84%, keep the same schedule, follow-up in a week.

The plan was to have a patient seen for 3 sessions, including the intake session. All intake and follow-up data was recorded in an electronic medical chart. Cases were supervised on an as-needed basis by author B.W. She also conducted a chart review for each case for safety and accuracy.

Study

An Excel spreadsheet was maintained to account for all outcomes. A total of 25 service members underwent at least one session. The outcomes are discussed later in the Results section. The IBM SPSS application was used for the statistical analysis. Comparisons were done using nonparametric methods due to the small number of subjects in order to avoid false assumptions of normality.

Act

Chart review by B.W. was conducted throughout the deployment to ensure safety and accuracy. Feedback was

Table 1. Demographics and Baseline Data for Patients Undergoing Treatment for Insomnia.

Demographics and Baseline Data	Values	SD
N (Intake)	25	
Mean Age (years)	23.8	5.513
Male (n=23)	92%	
Rank, E1-E4 (n=21)	84%	
Number of Sessions Attended by Each Patient (n=number of patients attending that many sessions)		
1 (n=7)	28%	
2 (n=5)	20%	
3 (n=7)	28%	
4 (n=4)	16%	
5 (n=2)	8%	
Average Number of Sessions	2.56	1.294
Average Length of Insomnia (months)	13.96	9.813
Type of Insomnia		
Combined (n=21)	84%	
Initial (n=3)	12%	
Terminal (n=1)	4%	
Baseline Sleep Duration (hours)	5.12	1.716
Baseline Time in Bed (hours)	8.28	1.926
Baseline Sleep Efficiency*	61.80%	
Desired Sleep Duration (hours)	7.4	0.766
Average Number of Sleep Disruptions/Night	2.84	1.491
Average Number of Naps	0.9	1.291
Racing Thoughts on Pillow Present	72%	
Average Daily Caffeine Intake (drinks)	1.32	0.476
Prior Hypnotic Use (n=15)	60%	
Current Hypnotic Use (n=5)	20%	

*Defined as baseline sleep duration/baseline time in bed×100.

elicited about improvement to the Dysfunctional Belief Challenge Scripts Packet where it was noted that the language was too academic and inappropriate for the typical level of education of participants.

Results

Baseline data and demographics are presented in Table 1. Training evaluation by the medics and behavioral health specialists showed significant satisfaction, perceived improvement in skill, and confidence in the treatment of insomnia using newly learned CBT based insomnia treatment skills (Table 2). A total of 25 patients underwent intake for CBT based treatment for insomnia during a 2-month period prior to the redeployment of the unit from the theater. A total of 64 sessions were delivered, averaging 2.56 sessions per patient. Outcome measures were calculated for intake (Session 1), Session 2 and Session 3, with total of 15 patients having data for all 3 sessions.

Table 2. Post-Training Survey assessing perceived satisfaction and effectiveness of training by learners.*

	Min	Max	Mean	SE	SD
Effective goal communications	4	5	4.70	0.153	0.483
Effective learning climate	4	5	4.70	0.153	0.483
Instructor knowledgeable	4	5	4.90	0.100	0.316
Didactics important	4	5	4.90	0.100	0.316
Workshop important	2	5	4.50	0.342	1.080
Handouts important	4	5	4.90	0.100	0.316
PRIOR to this training, CONFIDENCE level	1	4	2.10	0.314	0.994
AFTER this training, CONFIDENCE level	3	5	4.40	0.221	0.699
PRIOR to this training, SKILLS level	1	4	2.10	0.314	0.994
AFTER this training, SKILLS level	3	5	4.20	0.200	0.632
Likelihood of using training	3	5	4.40	0.267	0.843
Likelihood of implementing training	3	5	4.30	0.300	0.949
Likelihood of recommending this to patients	4	5	4.80	0.133	0.422
Likelihood of recommending this to other medical providers	3	5	4.50	0.224	0.707
This training should be provided to all medics in Advanced Individual Training	1	5	4.10	0.433	1.370
Overall satisfaction with training	4	5	4.80	0.133	0.422

Min indicates minimum; Max indicates maximum.
*Values from Likert scale: 1=least; 5=most.

Outcome Measures

Learner's Training Evaluation

A training evaluation survey was completed (N=10, 30%) upon completion of the training workshop. Overall, there was positive response on postinstructional evaluation (Table 2). Using Wilcoxon Signed-Ranks Test, the pre- versus posttraining perceived skill (z=-2.871; $P<.01$) and confidence (z=-2.844; $P<.01$) levels to treat insomnia significantly improved.

Sleep Efficiency

Mean sleep efficiency significantly improved (Figure 1). A nonparametric Friedman's test of differences among repeated measures for sleep efficiency was conducted and rendered a χ^2 value of 19.54 which was significant ($P<.01$). Post-hoc Wilcoxon Signed-Ranks Test with Bonferroni correction indicated that posttest ranks were statistically significantly higher for Session 2 (z=-3.68; $P<.01$) and Session 3 (z=-3.11; $P<.002$) at follow-up when compared to Session 1. The change in ranks was nonsignificant between Session 2 and Session 3 (z=-0.08; $P<.94$).

Time Asleep

Total self-reported average sleep duration at intake was 4 hours, 32 minutes; Session 2 was 4 hours, 53 minutes and Session 3 was 5 hours and 11 minutes. However, nonparametric Friedman's test of differences among repeated measures for self-reported sleep duration was conducted and rendered a χ^2 value of 3.268 which was nonsignificant ($P=.195$).

Total Time in Bed

Average total time spent in bed (including both awake and asleep) was 8 hours and 4 minutes at intake. It significantly decreased to (Session 2) 5 hours, 46 minutes, and (Session 3) 6 hours and 5 minutes. Significance was measured using nonparametric Friedman's test of differences among repeated measures, rendering a χ^2 value of 14.68 which was significant ($P<.01$). A post-hoc Wilcoxon Signed-Ranks Test with Bonferroni correction indicated that post-test ranks were statistically significantly lower for Session 2 (z=-3.43; $P<.01$) and Session 3 (z=-2.68; $P<.007$) in comparison to baseline intake values (Session 1). The change in ranks was nonsignificant between Session 2 and Session 3 (z=-1.59; $P=.11$).

Perceived Sleep Satisfaction

Subjective satisfaction with duration (Figure 2) and quality (Figure 3) of sleep was measured on a Likert scale with 5 as maximum satisfaction. The baseline (intake) mean satisfaction for perceived sleep *duration* was 1.36, SD 0.57 (N=25), Session 2 mean was 1.94, SD 0.64 (N=18), and Session 3 mean was 2.57, SD 1.01 (N=14). A nonparametric Friedman's test of differences among repeated measures for intake, Session 2 and Session 3 (N=14) was conducted and rendered a χ^2 value of 16.77 which was significant ($P<.01$). A post-hoc Wilcoxon Signed-Ranks Test with Bonferroni correction indicated that posttest ranks were statistically significantly higher for Session 2 (z=-2.97; $P<.01$) and Session 3

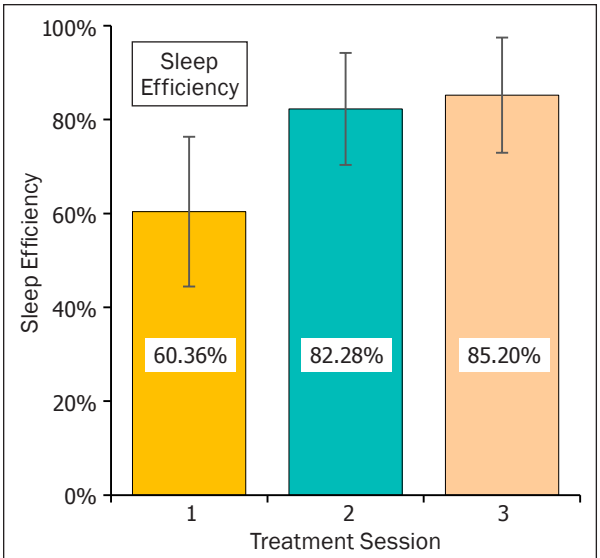

Figure 1. Sleep efficiency (mean) results demonstrate significant continuous improvement from treatment session 1 through sessions 2 and 3.

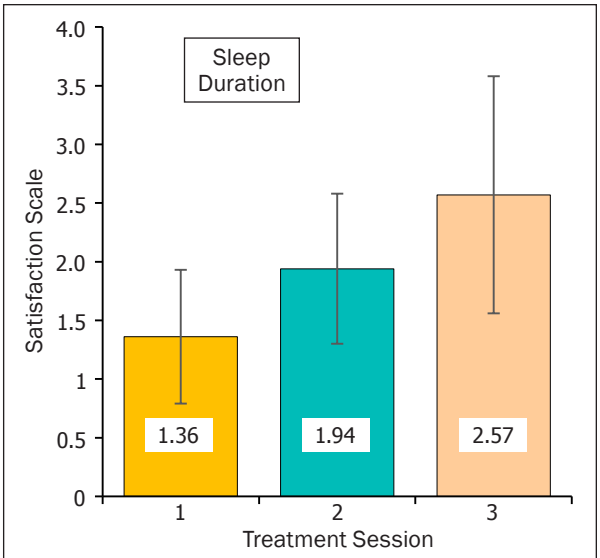

Figure 2. Sleep duration satisfaction results demonstrate significant continuous improvement from treatment session 1 through sessions 2 and 3.

(z=-3.03; $P<.002$) follow-up in comparison to baseline. The change in ranks was nonsignificant between Session 2 and Session 3 (z=-2.13; $P<.03$).

The baseline (intake) mean for satisfaction for perceived sleep *quality* was 1.40, SD 0.577 (N=25), Session 2 mean was 2.17, SD 1.15 (N=18), and Session 3 mean was 2.93, SD 1.07 (N=14). A nonparametric Friedman's test of differences among repeated measures for intake, Session 2 and Session 3 (N=14) was conducted and rendered a χ^2 value of 19.41 which was significant ($P<.001$). A post-hoc Wilcoxon Signed-Ranks Test with Bonferroni correction indicated that post-test ranks were statistically significantly higher for Session 2 (z=-2.75; $P<.001$) and Session 3 (z=-3.15; $P<.002$) follow-up in comparison to baseline. The change in ranks was also significant between Session 2 and Session 3 (z=-3.05; $P<.002$).

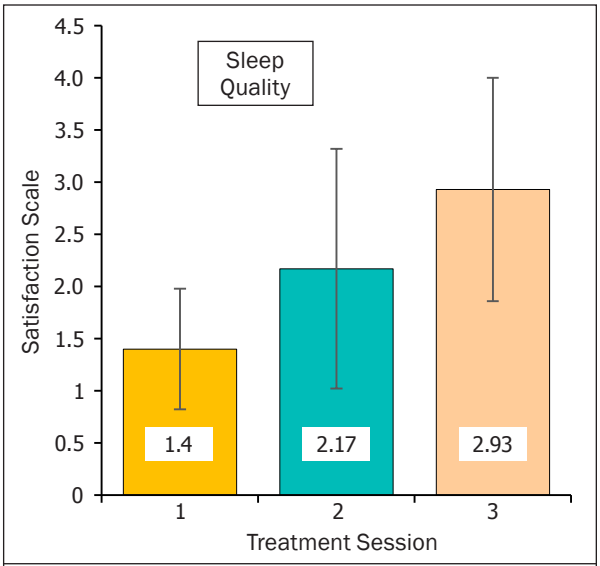

Figure 3. Sleep quality satisfaction results demonstrate significant continuous improvement from treatment session 1 through sessions 2 and 3.

Process Measures

The checklist served as a process measure to ensure the medics applied the methods of behavioral sleep treatment accurately. All cases seen were reviewed by the authors with focus on calculation of sleep efficiency and sleep prescription. On average, these were performed correctly 86% of the time. Only minor errors related to conversion of minutes were seen.

Balancing Measures

No sleep deprivation related events were reported. Of the 25 Soldiers who underwent intake for CBT-I, 18 followed-up for a second session. None of these, including those that were lost to follow-up, were involved in behavioral incidents, including acute psychiatric exacerbation or need for medical evacuation. None required acute referral for hypnotic therapy.

Comment

We faced the clinical challenge of delivering safe and effective nonpharmacological treatment for Soldiers suffering from insomnia in a limited resource environment. Cognitive behavioral therapy based insomnia treatment has been shown to be an effective treatment.[16] Hence, the root cause of this situation was insufficient providers who could deliver CBT based insomnia treatment

without relying on hypnotics. Hypnotics pose safety concerns. During the 4.5-month period of deployment, author R.A. observed one Soldier with priapism and another with drug-drug interaction,[17] both of which were likely due to their use of hypnotic medications.

We used formal QI/PI concepts to overcome the clinical obstacles in treatment delivery. We were effectively able to train medics in CBT based insomnia treatment (Table 2). The operationalization of this treatment, which otherwise requires a significant amount of training and experience, was made possible by a checklist procedural approach to treatment delivery. The protocolization of the techniques was likely the most important tool for challenging dysfunctional beliefs of those suffering from insomnia. The use of DBAS-16 as a rapid diagnostic tool in identification of such cognitions, followed by verbatim cognitive restructuring scripts, permitted us to easily enable the medics to challenge such dysfunctional beliefs. Additionally, the protocol with checklistled sleep prescriptions enabled the medics to rapidly approach sleep efficiency-based decisions with an easy to use algorithmic approach.

This was not intended to be a research study, but rather operationalizing evidence-based CBT treatment for insomnia by healthcare extenders (medics) that has not been done in the past, especially in the operational environment. The project illustrates one potential answer to manpower constraints by utilizing readily available medical personnel. The nonparametric tests showed significant improvements in both sleep efficiency (and related total time spent in bed), as well as satisfaction with the quality and quantity of sleep. Interestingly, these improvements occurred very rapidly after just a single session. Data analysis for both sleep efficiency and satisfaction showed significant improvements from intake's first session to the second session. Further post-hoc analysis showed that a third session maintained the significance from the intake. Interestingly, although there was not a statistically significant increase in the actual sleep duration, both satisfaction with sleep quality and duration improved. This supports the perceptual nature of the insomnia experience.

Given its success in the operational setting, we plan to formally evaluate our checklist-based approach to insomnia treatment using combat medics with a control group to study the feasibility and efficacy of our protocol in nonoperational setting. Appropriate sleep is an important ingredient for both physical and psychological fitness on which mission success relies. Sleep can affect both of these domains, and broader delivery of CBT-I based sleep literacy as primary prevention and wellness strategy could be the next step with broader use of a similar, checklist-based approach to sleep education.

Conclusion

Insomnia is a major problem in the deployed environment. Safer alternatives to pharmacological treatment such as cognitive and behavioral based approaches require specialized skilled personnel that are not readily available. This limited resource environment can be mitigated by using healthcare extenders such as combat medics, behavioral health specialists, or equivalent personnel. Our QI/PI project provides a road map that could be replicated early into a deployment or other resource-constrained environments to effectively deliver cognitive and behavioral treatment for Soldiers with minimal effort and supervision.

Acknowledgment

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Sandfly Fever in Afghanistan–A Sometimes Overlooked Disease of Military Importance: A Case Series and Review of the Literature

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Abstract

Sandfly fever, sometimes known as pappataci fever or Phlebotomus fever, is a vector transmitted viral illness with a history of affecting naïve military formations that travel through or fight in areas in which the infection is endemic. We present a series of 4 hospitalized cases of sandfly fever (2 presumptive, 2 laboratory confirmed) that were admitted to a Role 3 hospital in Afghanistan for evaluation and treatment following medical evacuation from a forward area for marked fevers and malaise. Laboratory evaluation of these cases was significant for leukopenia and thrombocytopenia, consistent with historical descriptions of sandfly fever. In the correct geographic and clinical setting, the finding of mild leukopenia among a cluster of febrile patients should prompt the clinician to at least consider a diagnosis of sandfly fever. A cluster investigation conducted by preventive medicine personnel identified numerous other presumed cases of sandfly fever in this forward special operations camp. Response efforts emphasized enforcement of standard vector-borne disease control measures by operational leadership in order to limit effect on tactical operations. We review historical instances of sandfly fever affecting military operations, and present a review of clinical presentation, transmission, management, and prevention.

Sandfly fever, sometimes known as pappataci fever or Phlebotomus fever, is a vector transmitted viral illness with a history of affecting naïve military formations that travel through or fight in areas where the infection is endemic.[1-3] We present a series of 4 hospitalized cases (2 presumptive, 2 laboratory confirmed) of sandfly fever (SFF) that were admitted to a Role 3 hospital in Afghanistan for evaluation and treatment following medical evacuation from a forward area for marked fevers and malaise.

Case Series

The following 4 cases occurred over a 2-week time period during midsummer in a malaria-endemic region of eastern Afghanistan. Through interviews and later investigations, we estimate that at least 3 dozen similar cases presented to special operations forces (SOF) medics during this period. However, the 4 patients discussed in the following case studies required medical evacuation to our referral hospital given their more marked symptoms. All patients were active duty male Army Soldiers who presented from the same region of eastern Afghanistan. All endorsed sleeping outdoors on the ground, bathing in local streams, and eating local foods. All endorsed repeated insect bites from a variety of insects. All endorsed limited use of necessary personal protective equipment to protect exposed skin. All reported strict compliance with doxycycline 100 mg by mouth daily for malarial chemoprophylaxis.

Patient A

Patient A was a 26-year-old active duty male Army Soldier who presented to a SOF medic with 48 hours of subjective fevers, myalgias, headache, and neck stiffness. He was initially treated by the SOF medic with acetaminophen and intravenous fluids. The patient also received a 2-day oral course of amoxicillin/clavulanic acid for apparent empiric treatment of community acquired pneumonia. Despite these interventions, the patient had no significant improvement in symptoms. He was transferred to our Role 3 referral hospital for further care.

Upon presentation to the hospital, Patient A was afebrile, but endorsed documented fevers as high as 103°F earlier in the day. He denied cough, dyspnea, abdominal pain, diarrhea, dysuria, or rash. His examination was largely unremarkable except for a positive jolt accentuation test, indicating possible meningeal irritation. A noncontrast CT head and chest radiograph were both unremarkable. Due to concern for meningitis, a lumbar puncture was performed which demonstrated zero leukocytes, a total protein of 58 mg/dL (normal 12-60 mg/dL), and glucose of 73 mg/dL (normal 40-70 mg/dL) with a negative cerebrospinal fluid gram stain. His complete blood count

(CBC) was significant for a leukopenia to 2,700 white blood cells (WBCs) per mm^3 (normal 4,500-11,000 per mm^3). A mild thrombocytopenia of 137,000 per mm^3 (normal 150,000-450,000 per mm^3) was also noted. His serum creatinine was mildly elevated at 1.40 mg/dL (normal 0.80-1.50 mg/dL). A hepatic function panel and urinalysis were unremarkable. His prothrombin time (PT) and his activated partial thromboplastin time (APTT) were both mildly elevated at 14.4 seconds (normal 8-12 seconds) and 64.9 seconds (normal 20.6-38.6 seconds), respectively. Thick and thin smears for malaria showed no parasites. A mononuclear spot ("monospot") test was negative. Blood cultures drawn at the time of admission showed no growth after 5 days.

After an extensive review of other diagnostic considerations as detailed later in the Investigation section, Patient A was presumptively diagnosed with SFF, and treated with bed rest, acetaminophen, and intravenous hydration. He was discharged after 48 hours of inpatient monitoring following improvement in his clinical symptoms.

Patient B

Patient B was a 19-year-old active duty male Army Soldier who presented to a SOF medic with 48 hours of subjective fevers, myalgias, and a sore throat. He was initially treated by the SOF medic with intravenous fluids and acetaminophen for 24 hours without improvement in symptoms, prompting medical evacuation for further workup and management.

Upon presentation to the Role 3 hospital, he was afebrile, but noted a fever of 103°F earlier in the day. He denied headaches, cough, dyspnea, abdominal pain, diarrhea, dysuria, or rash. His physical examination was remarkable for diffuse, noninflamed insect bites on his lower extremities. Complete blood count was remarkable for a WBC count of 4,500 per mm^3 and a platelet count of 122,000 per $mm.^3$ Serum creatinine, hepatic function panel, and urinalysis were unremarkable. The patient's PT and APTT were mildly elevated at 13.2 seconds and 43.5 seconds, respectively. A rapid antigen detection test for streptococcal pharyngitis ("rapid strep" test) and monospot test were both negative. Thick and thin smears for malaria showed no parasites. The day following admission, the patient's WBC count dropped to 2,900 per $mm.^3$ A chest radiograph was unremarkable.

Patient B was presumptively diagnosed with SFF and treated with symptomatic management. This included intravenous hydration, ibuprofen, and acetaminophen for 48 hours as an inpatient until his fever defervesced. He was discharged in improved condition.

Patient C

Patient C was a 21-year-old active duty male Army Soldier who presented to a SOF medic with 24 hours of diffuse myalgias, subjective fevers, fatigue, and a mild sore throat. A SOF medic treated Patient C with acetaminophen and intravenous hydration initially, but worsening symptoms, including a confirmed fever of 104°F, prompted the decision for medical evacuation.

Upon presentation to the Role 3 hospital, the patient was afebrile and hemodynamically stable. He denied headaches, cough, dyspnea, chest pain, abdominal pain, diarrhea, dysuria, or rashes. His physical exam was unremarkable except for numerous insect bites on his lower extremities. Complete blood count was significant for leukopenia with a WBC count of 2,300 per mm^3 and thrombocytopenia to 131,000 platelets per $mm.^3$ He had an elevated APTT of 52.5 seconds. His renal function panel and hepatic panel were both unremarkable. Both monospot and rapid strep tests were negative. A respiratory viral polymerase chain reaction (PCR) panel was unremarkable. Human immunodeficiency virus (HIV) antibody testing was negative. Thick and thin smears for malaria showed no parasites. Blood cultures showed no growth after 5 days. An erythrocyte sedimentation rate was 5 mm/hour (normal 0-15 mm/hour). His chest radiograph was unremarkable. A rickettsial panel was sent out of country for testing, but became unacceptable for testing during transit. Coxiella burnetii (Q fever) serology was sent out of country for testing, and eventually returned negative. A serum sample was sent to the Centers for Disease Control and Prevention (CDC) Division of Vector-Borne Diseases, Arboviral Diseases Branch, in Fort Collins, Colorado, specifically to examine for evidence of SFF exposure.

During his hospitalization, Patient C had a peak temperature of 103°F. He was treated with intravenous hydration, ibuprofen, and acetaminophen. On the recommendation of infectious disease teleconsultants, the patient was prescribed a 7-day course of doxycycline 100 mg by mouth twice daily for empiric treatment of a potentially undiagnosed rickettsial illness while we awaited the results of further confirmatory testing. Patient C improved over the next 24 hours and was discharged. A week later, a repeat CBC demonstrated resolution of his leukopenia and thrombocytopenia.

Patient D

Patient D was a 31-year-old active duty male Army Soldier who presented to a SOF medic with 48 hours of fevers, diffuse myalgias, sore throat, and intermittent headaches. He received intravenous fluids and acetaminophen by a SOF medic, but persistent symptoms

forced medical evacuation to the Role 3 hospital for further care.

Upon presentation to the hospital, Patient D had a temperature of 100.2°F. He denied cough, shortness of breath, abdominal pain, diarrhea, dysuria, and rash. Physical examination was significant for cervical lymphadenopathy without pharyngeal exudate or erythema. He was noted to have multiple lower extremity insect bites with associated pruritus. Comprehensive physical examination was otherwise unremarkable. Complete blood count analysis was significant for leukopenia with a WBC count of 2,300 per mm^3 and a mildly decreased platelet count of 133,000 per $mm.^3$ Renal function panel, hepatic function panel, and urinalysis were all unremarkable. A chest radiograph was unremarkable. He had a negative monospot test, rapid strep test, respiratory viral PCR panel, and HIV antibody. Thick and thin smears for malaria were negative for parasites. Blood cultures showed no growth at 5 days. An erythrocyte sedimentation rate was 5 mm/hour. A rickettsial panel was again sent out of country for testing, but became unacceptable for testing during transit. Coxiella burnetii (Q fever) serology was sent out of country for testing, and eventually returned negative. A serum sample was sent to the CDC Arboviral Diseases Branch in Fort Collins, Colorado, specifically to examine for evidence of SFF exposure.

Patient D improved within the next 48 hours and was discharged in improved condition. He was also discharged with instructions to complete a 7-day course of doxycycline 100 mg by mouth twice daily for empiric treatment of a potentially undiagnosed rickettsial illness. A follow-up CBC performed one week after discharge demonstrated resolution of his leukopenia and thrombocytopenia.

Investigation

During the admissions of the initial 2 patients (A and B) reported above, the SOF medical leadership and Role 3 hospital clinicians developed a working clinical diagnosis of SFF based on review of possible infectious disease threats in the area, clinical findings, and laboratory findings.[4] Particularly relevant was the presence of leukopenia and mild thrombocytopenia noted in all the above cases as had been described by other US military physicians 70 years prior.[5] Additional diagnostic considerations included malaria, leptospirosis, Q fever, rickettsial diseases such as scrub typhus, and Crimean-Congo hemorrhagic fever. However, these possibilities were ruled out in many cases by patient history and clinical examination. In all cases, thick and thin smears and point of care rapid diagnostic test were negative for malaria. Additionally, the patients provided reliable histories of adherence to doxycycline for malarial chemoprophylaxis. This reported adherence to doxycycline helped to place leptospirosis and rickettsial diseases far lower on the list of differential diagnoses due to presumed prophylaxis against these illnesses provided by doxycycline use.

A working case definition of SFF was developed from these 4 patients. The case definition was defined broadly as a febrile, viral-like syndrome, lasting 72 to 96 hours, without other overt clinical signs of malarial, rickettsial, or viral hemorrhagic complications occurring in the setting of known exposure to sand flies. The decision was then made to send preventive medicine (PM) personnel forward to assess the living conditions of the camp (Camp A) from which the above cases presented. During this mission, the PM detachment collected samples of arthropod vectors in that area and interviewed personnel still living at the camp site for other potential clues.

Camp A was a special operations camp located in a remote valley of eastern Afghanistan. Camp A and the immediate surrounding area housed between 20 to 50 US military personnel along with 15 to 20 partner nation force personnel. The population varied significantly from day to day and week to week as US military personnel rotated into and out of Camp A frequently. Although multiple other camps were located within roughly a 10-kilometer radius of Camp A, the above described cases originated solely from Camp A, suggesting that some aspect of the specific living conditions, sanitation, or arthropod vectors at Camp A were to blame for this cluster of illnesses. Of note, Camp A had only recently been established as an expeditionary location from which to advance operations. As a result, Camp A lacked significant infrastructure. Disruption of soil was required in order to build and reinforce defensive fighting positions and create a secure, functioning camp.

Preventive medicine personnel found that approximately 50% to 60% of US military personnel living at Camp A described a syndrome of 48 to 96 hours of fever, malaise, headache, and neck stiffness. A formal attack rate was not determined; however, a rough estimate was an attack rate of more than 60% of personnel who had lived at Camp A for more than 7 days based on the aforementioned SFF case definition. Using this case definition as a guide, the Camp A SOF medic closely monitored service members reporting fever and malaise, treating those patients with fluid resuscitation and rest when conditions allowed. Medical evacuation was then reserved for patients with fevers exceeding 103° F, refractory symptoms resulting in nonmission capable status, and for patients with symptoms unexplained by

the SFF working diagnosis. All other cases of febrile illness remained at Camp A, slowly improved over a period of 72 to 96 hours, and then were gradually returned to full duty by the Camp A SOF medic. In total, this febrile syndrome is estimated to have attacked 30 to 40 personnel to varying degrees on Camp A. The estimate produced marked concern of operational commanders at multiple levels that the continuation and spread of this syndrome would cause local military operations to essentially halt until all personnel had fully recovered from their illness.

Preventive medicine personnel found rudimentary field hygiene conditions at Camp A. Human waste disposal was managed with feces collection bags which were then burned for disposal. Bottled water was used for consumption. Food was occasionally procured from the local economy in order to allow engagement with local officials. However, the majority of food consumed were military Meals, Ready-to-Eat rations. Service members were noted to frequently bathe in a nearby river. Domestic animals including goats, donkeys, cats, and canines were frequently in close proximity to Camp A. Area vector control measures were not in place. Service members frequently worked during the day without wearing uniform blouses, and were not observed to apply insect repellant to exposed skin. Bed nets were used infrequently, and service members frequently slept outside. Nearly all interviewed members admitted to receiving frequent bites from flying insects.

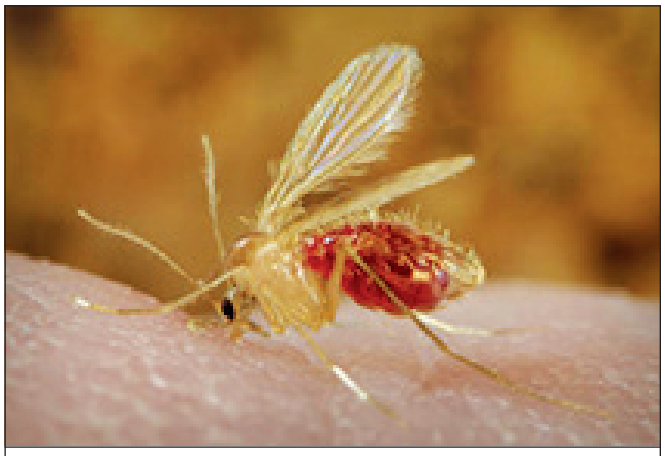
Preventive medicine personnel collected samples of local sandflies and mosquitoes, and submitted these specimens to the US Army Public Health Command-Europe for analysis. Results returned approximately one month later confirmed the presence of the SFF virus in sandflies collected at Camp A. Almost simultaneously, results of human blood samples drawn from Patient C and Patient D returned from the CDC Arboviral Diseases Branch with a positive plaque reduction neutralization test indicating prior infection with a sandfly fever virus, most likely Sicilian serocomplex.

Comment

Sandfly fever virus is transmitted through the bite of an infected phlebotomine sandfly (genus *Phlebotomus*) shown in the Figure. The SFF virus is a member of the *Phlebovirus* genus of the Bunyaviridae family.[6] Three serotypes are generally recognized: Toscana, Naples, and Sicilian. Naples and Sicilian serotypes cause the typical influenza-like febrile illness that has been traditionally described as sandfly fever, and was most likely witnessed in our cases, whereas Toscana serotype has been associated with neurovirulence and encephalitis.[6]

The geographic distribution of the virus is centered around the Mediterranean basin, with notable extension into parts of Europe and Central Asia.[1] Military formations ranging from Greece to Pakistan have been troubled by the development of SFF outbreaks in recent years.[7,8] Sandfly fever has been known to be endemic in Afghanistan for many years, but was most notably identified during the 1980s Soviet occupation of Afghanistan when SFF was known to attack significant proportions of Soviet troops based in eastern Afghanistan.[9-11] British troops also suffered from so-called "Helmand fever" during their most recent experience in southern Afghanistan. In many cases, Helmand fever was later determined to be SFF.[12,13] Sandfly fever is described by the US National Center for Medical Intelligence as potentially affecting up to 50% of small groups of susceptible troops in areas with large populations of infected sandflies if adequate and appropriate precautionary measures are not taken.[14] In the above case series and investigation, we estimate that roughly 50% of the personnel at Camp A were affected at some point during their tenure at Camp A or shortly after their return. This resulted in a significant reduction of unit combat effectiveness; forcing leaders at multiple levels from tactical to strategic to consider withdrawal from Camp A and the surrounding valley area, simply in hopes to maintain combat power.

As noted in our patients, clinically significant SFF develops after a 2 to 6 day incubation period following the bite of an infected sandfly.[5] This clinical presentation of classical SFF has been described as the abrupt onset of fever and malaise. In historical studies, 65% of affected patients had a temperature over 102°F, and roughly 8% of affected patients had a temperature between 104°F and 104.5°F.[5] In the cases described above, SOF medics



Phlebotomus papatasi sandfly, the vector of sandfly fever. Courtesy of Centers for Disease Control and Prevention, Public Health Image Library (https://phil.cdc.gov/phil/details_linked.asp?pid=10277).

developed an unwritten operating procedure to attempt to limit the number of medical evacuations from Camp A by establishing a fever over 103°F as the deciding factor for evacuation to at least Role 2 care or higher. The described fever typically lasts for 72 hours before spontaneous resolution, hence SFF is sometimes referred to as "3 days fever."[1] Headache, photophobia, and neck stiffness are frequently present as well, which may lead assessing clinicians to believe an infectious meningitis is present. Indeed, our initial hospitalized case underwent lumbar puncture upon arrival at the Role 3 facility for concern of meningitis. Physical examination has been reported to be remarkable for a marked flushed appearance of the face and neck which may resemble a sunburn.[5] Despite complaints of neck stiffness, nuchal rigidity and meningeal signs are not to be expected.[5] The remainder of the physical examination is generally normal as seen in our hospitalized patients.

Our cases were most likely Sicilian serotype SFF which typically manifests as a self-limited, otherwise benign illness, but it should be noted that Toscana serotype SFF can manifest neurovirulence with a prolonged meningoencephalitis picture.[15] On rare occasions, a more pronounced meningoencephalitis presentation has occurred with Sicilian serotype SFF. In 2004, Lesho and colleagues[6] reported a case of severe encephalitis secondary to Sicilian serotype SFF in a US Army officer serving during the early stages of Operation Iraqi Freedom. This case resulted in status epilepticus, a prolonged course of intubation for airway protection, and reported residual neurocognitive defects 3 months after initial presentation.

Laboratory evaluation should include complete blood count, renal/metabolic panel, hepatic profile panel, and coagulation profile at a minimum. Lumbar puncture with cerebrospinal fluid collection and analysis may be also necessary early on to exclude the diagnosis of bacterial meningitis. The most notable laboratory finding for our cases treated at a Role 3 facility was leukopenia. In the correct geographic and clinical setting, the finding of mild leukopenia among a cluster of febrile patients should prompt the clinician to at least consider a diagnosis of SFF. Additional frequent laboratory findings include thrombocytopenia, and elevated levels of aspartate aminotransferase and alanine aminotransferase.[16] However, in this small sample of cases, thrombocytopenia and liver enzyme elevation was not marked as shown in the Table.

Clinicians should also consider laboratory evaluation for other tropical infectious diseases associated with the location in which the affected patient was traveling. In our cases, the treating Role 3 clinicians initially performed laboratory evaluation for malaria in all cases. For Patients C and D, the evaluation expanded to include testing for mononucleosis, HIV, Q fever, and rickettsial disease. Unfortunately at our location, only malaria testing (thick and thin smears, and rapid diagnostic tests) was available with expeditious turnaround time. Thus, while serologic testing for the above infections was considered, the treating team had to rely primarily on exam and patient history to exclude the presence of a specific disease. For example, several clinicians noted the markedly similarity of these case presentations with that of dengue fever.[17] However, dengue fever is not endemic to Afghanistan and was easily excluded as a possibility with this information. This once again highlights the need for SOF medical providers to remain proficient in the identification of, and initial treatment for, the infectious disease threats present in the regions in which the troops they support are operating.

In general, treatment for SFF is supportive, involving convalescence, and fluid resuscitation as needed over an approximately 72-hour period. On rare occasions, SFF infections manifesting as encephalitis may require supportive care in a critical care setting. Leukopenia appeared to persist for 5 to 7 days following fever defervescence in our hospitalized patients. Return to full

Laboratory Values of Cases.

Hospital Day	White Cell Count	Hemoglobin	Platelet Count	AST	ALT
Patient A					
1	2,700	13.7	137,000	35	48
2	2,000	13.7	118,000	35	48
3	2,400	13.8	114,000		
6	2,600	16.1	120,000		
Patient B					
1	4,500	14.6	122,000	53	69
2	2,900	13.5	107,000	46	61
5	3,100	16.5	121,000		
Patient C					
1	2,300	14.2	131,000	28	30
2	1,900	14.7	126,000	41	44
3	1,900	14.3	105,000	54	44
8	4,200	16.5	165,000		
Patient D					
1	2,300	13.0	133,000	31	45
2	2,200	12.9	129,000	33	46
3	2,900	14.4	148,000	41	55
8	4,900	15.8	198,000		

Reference Ranges
White Cell Count; 4,500-11,000/mm^3
Hemoglobin; 12.0-16.0 g/dL
Platelet Count; 150,000-450,000/mm^3
AST indicates aspartate aminotransferase; 9-32 U/Liter
ALT indicates alanine aminotransferase; 7-30 U/Liter

duty may be impaired for as much as 14 to 30 days after initial presentation.[1] This could be crippling to military operations for military units with a significant proportion of affected troops.[2] This effect would be even more dramatic among small special operations teams.

The easiest and most effective method of protection from sandfly bites is through proper use of personal protective measures.[18] This includes the proper wear of loosely fitted permethrin-treated uniforms or clothing, and the use of insect repellents containing 30% to 40% N,N-Diethyl-meta-toluamide (DEET) on any exposed skin. Due to the nocturnal nature of sandflies, people are most likely to be attacked while they are sleeping. Unfortunately, these are also the times when proper uniform wear and insect repellent usage are least likely to be followed. Use of permethrin treated bed nets with a small mesh size, both indoors and outdoors, also serves as a protective barrier to prevent sandfly biting. In addition, sandflies are known weak fliers and tend to target exposed skin on the lower half of a human's body. Sleeping on elevated surfaces (3 feet or higher) from expected sandfly habitats will reduce the likelihood of being bitten during rest periods.[19] Following the field investigation by preventive medicine personnel described earlier, and subsequent recommendations to strictly enforce these personal protective measures, tactical leaders began to appreciate that only by enforcing these protective measures would cases cease or at least occur less frequently. In the 2 months that followed, no additional SFF cases from Camp A were evacuated to the Role 3 hospital. We attributed this reduction in cases to a continued emphasis on personal protective measures by leaders at all levels.

If sandfly populations are abundant enough to be a burden, chemical treatment should be considered to manage the number of insects in the area.[19] Residual pesticides can be applied to most surfaces and effectively kill sandflies. The following areas should be targeted: rocky outcroppings, HESCO barriers (HESCO Bastion Ltd, Leeds, UK), sandbags, rock walls, termite mounds, animal burrows, cracks in floors/walls, any loose soil, soil at the base of walls and trees, rubbish, and fecal waste. We assess that the disruption of soil associated with the creation of Camp A likely contributed to a marked increase in sandfly activity in the area, resulting in numerous bites for unsuspecting service members.

Conclusion

Sandfly fever has historically been considered a disease of military importance due to its ability to quickly incapacitate naïve military formations in areas where the virus is endemic. Unfortunately, we found this to be true during combat operations on a special operations camp in Afghanistan. We also learned that SFF can be easily overlooked as a disease of military importance as it is relatively unknown among many American and European military physicians, and serologic testing is unlikely to be available to confirm or deny. We encourage military physicians and SOF medical providers working in areas surrounding the Mediterranean, and extending east into Asia through Turkey, Iran, Afghanistan, and Pakistan to become familiar with SFF and consider SFF in the differential diagnosis of markedly febrile patients.

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Smoking and Periodontal Disease

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Destructive periodontitis can neither initiate nor progress in the complete absence of a select group of etiologic bacteria. In both chronic and aggressive forms of periodontitis, bacteria appear necessary for initiation of inflammatory periodontal tissue destruction, but mere presence of bacteria is insufficient for disease manifestation.[1,2] In fact, the bacteria most associated with periodontitis can also be isolated in small measure from clinically healthy sites and patients.[3,4] Evidence suggests a relatively small number of factors identify patients at high risk for periodontal destruction when causative bacteria are present.[1,5,6] One of the strongest and most widely studied risk factors for periodontitis is cigarette smoking. Indeed, smoking is estimated to account for fully half of the cases of periodontitis in the United States, and among patients who smoke one pack per day, smoking may account for an astounding 83% of cases.[7]

The biologic basis for the deleterious effect of smoking on the periodontium is largely understood. Some authors have reported that smoking shifts the counts and percentages of the bacterial species present toward a more pathogenic mixture, although other investigators found similar bacterial colonization among smokers and nonsmokers.[8-12] In any case, the possible effect of smoking on the attendant pathogenic ecosystem is probably not the primary mechanism responsible for the majority of the observed tissue destruction. Smoking is known to impair the function of the neutrophil, the key cell in an effective periodontal defense.[13,14] Periodontists have long recognized that any hematological or genetic malady that precludes an effective neutrophil response consistently produces severe, often devastating, periodontal destruction.[15] Likewise, in patients with localized aggressive periodontitis, neutrophils exhibit reduced chemotaxis and various other functional abnormalities.[16] Smoking also induces endothelial dysfunction, a situation with the potential to further hamper the neutrophil response in periodontal tissue.[17] In smokers, clinical signs of periodontitis such as bleeding on probing may be suppressed despite advanced underlying bone and connective tissue destruction.[18,19]

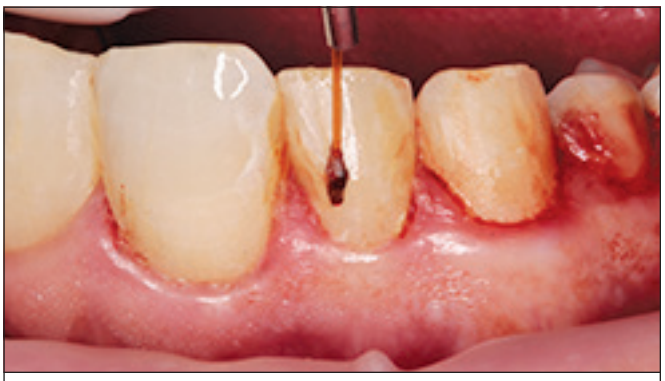
Smokers are not only more susceptible to destructive periodontal disease; they are also much more difficult to treat. Researchers have repeatedly shown that smokers with periodontitis respond less favorably to both nonsurgical and surgical therapy.[20-22] A classic, long-term study conducted in a university setting suggested that most of the periodontal breakdown that occurs following surgical treatment of periodontitis tends to cluster within patients who smoke.[23-25] For many of the specific procedures performed in periodontics, studies directly comparing smokers to nonsmokers appear in the literature. For example, Miller reported 100% correlation between heavy smoking and failure to achieve complete root coverage using free gingival grafts.[26] The often quoted study by Erley et al[27] demonstrated comparatively inferior outcomes in smokers treated with subepithelial connective tissue grafts for root coverage. Numerous studies also show that smoking is particularly unfavorable when bone or periodontal regeneration is attempted.[28-31]

Most chronic periodontitis patients respond favorably to conventional surgical therapy and lose few teeth long-term, given an appropriate maintenance interval after surgery and a proper personal oral hygiene regimen.[23,32] However, a relatively small proportion of patients experience disease progression despite sound surgical therapy, frequent professional maintenance, and excellent plaque control.[25,32] Many such patients exhibit one or more systemic factors predisposing toward periodontal destruction. Thus, it is incumbent upon clinicians to first identify systemic risk factors like smoking and modify such influences to the extent possible prior to initiating periodontal therapy. Moreover, high-risk patients should be treated and monitored differently than low-risk patients. Smokers respond less favorably to all types of periodontal therapy, experience more sites with periodontal breakdown during the maintenance phase, and have more postoperative complications compared with nonsmokers.[20-25] On the other hand, "watchful waiting" in patients with identified systemic risk factors will often lead to clinically significant disease progression and tooth loss. In perspective, patients with untreated periodontitis appear to lose teeth at a rate 3 times higher compared with patients who receive surgical treatment and maintenance, often leading to expensive and time-consuming approaches to tooth replacement.[33] Accordingly, clinicians should treat high-risk patients aggressively, but not necessarily invasively.

The current Army initiative to offer Nd:YAG laser periodontal therapy, shown in the Figure, to Soldiers is

helpful to clinicians managing high-risk periodontitis patients, including those who smoke. The laser protocol allows clinicians to treat smokers using a definitive modality, without relegating the patient to a nonsurgical program or "compromise periodontal maintenance."[34] Army clinicians can use the laser for smokers with limited risk to the patient, and the treatment itself is minimally invasive compared with conventional surgical techniques. In vitro and ex vivo experimental models have shown bactericidal activity for some species after indirect (noncontact) Nd:YAG laser treatment.[35-42] Bacterial kill appears to increase proportionally with power applied.[35] Depending upon experimental conditions, Nd:YAG laser output appears to produce clinically relevant bacterial kill of some species through dentin thicknesses of at least 1 mm.[40-42] In periodontal therapy, it is plausible that pulsed Nd:YAG laser irradiation may kill bacteria in privileged sites such as furcations and root surface irregularities where mechanical removal of bacteria is incomplete. However, this hypothesis has not been tested. Unpublished data suggests Nd:YAG laser periodontal therapy is capable of reducing putative periodontal pathogens below detectable levels immediately following therapy.[43] If confirmed, this finding would be very compelling. Although the host response to bacteria is critical in periodontitis pathogenesis, the specific colonizing bacteria remain relevant. For example, when *Porphyromonas gingivalis* and *Tannerella forsythia* are present in the subgingival plaque, a patient is more likely to develop chronic periodontitis, more likely to progress to advanced periodontal disease, and less likely to experience a successful treatment outcome.[3] Two proof-of-principle studies in humans indicate that a specific laser-based protocol is capable of improving clinical parameters and producing new bone, cementum, and periodontal ligament on previously diseased root surfaces.[44-46] One study conducted in a private practice setting suggests gains made through laser periodontal therapy are stable over at least 6 years of follow-up.[47]

Smoking alters the vascular and immunologic responses to the bacteria that initiate periodontal disease and may negatively affect the composition of the microflora present. Regardless of the treatment modality used, it is abundantly clear that nonsmokers respond much more favorably to periodontal therapy compared with smokers. For any periodontitis patient, optimal therapeutic response must include smoking cessation.[48,49] Laser periodontal therapy may be of clinical interest in the treatment of smokers because this modality offers ability to intervene early in a minimally invasive fashion.



An Nd:YAG laser being used to remove pocket epithelium in a periodontitis patient. In response to pathogenic bacteria and the ensuing inflammatory response, the normal junctional epithelium proliferates laterally and apically. Etiologic bacteria avoid the host immune response by invading epithelial cells, which then serve as a bacterial reservoir. Removal of this epithelium improves access for root debridement and purportedly denies pathogenic bacteria a niche sequestered from the immune response.

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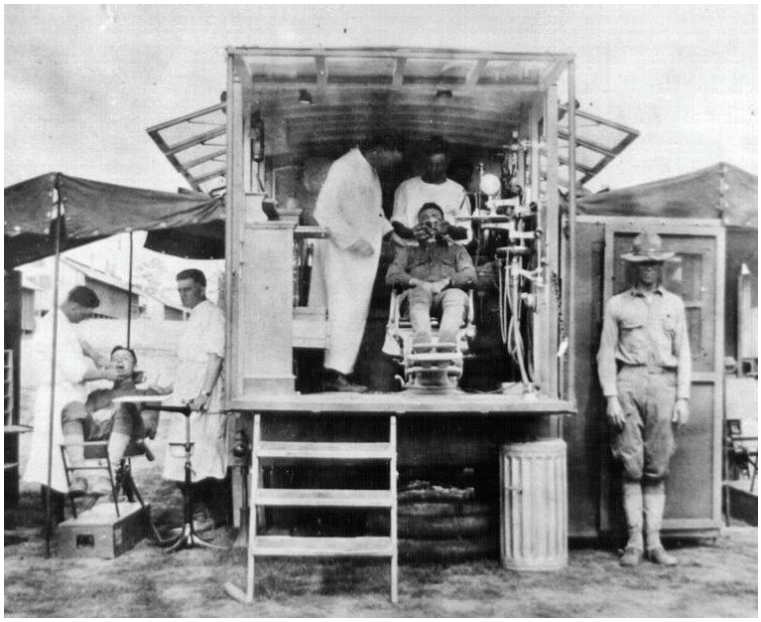

Army truck-mounted field dental clinic, circa 1917.

Core Temperature Responses of Military Working Dogs During Training Activities and Exercise Walks

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Abstract

Heat strain is common in military working dogs (MWDs), but can be mitigated by limiting duration of activity to avoid overheating and allowing sufficient time for recovery. To determine work/rest times for MWDs, temperature responses during training must be characterized. This study measured body core temperature of 48 MWDs at Lackland Air Force Base, San Antonio, TX. Twenty-four MWDs in training for patrol and detection activities participated under a range of ambient temperatures in August (27°C-32°C), October (22°C-26°C) and March (approximately 13°C). These MWDs swallowed a telemetric thermometer pill to measure continuous gastrointestinal tract temperature (Tgi). Twenty-four kennel MWDs participated in July (25°C-29°C). In these dogs rectal temperature (Tre) was measured manually during a standard exercise walk. For the MWDs in training, Tgi before the first activity was 38.5±0.5°C (mean±SD) and final Tgi was 39.8±0.6°C after sessions that lasted 13.1±4.9 minutes (5.4 to 26.3 minutes). Peak Tgi, 0.4±0.4°C above final Tgi, occurred 8 to 12 minutes into recovery. Before beginning a second activity 40 to 165 minutes later, Tgi was within 0.5°C of initial values for 80% of dogs. For the kennel MWDs, Tre was 39.0±0.8°C (37.7°C to 40.7°C) at the start and 40.1±0.6°C at the end of the 21.3±2.8 minute walk. The continuous increase in core temperature during activity of both groups of MWDs indicates that limiting exercise duration is important for minimizing risk of overheating in MWDs. The observation of continued increase in Tgi to a peak after exercise ends suggests that for MWDs suspected of overheating temperature should be monitored for at least 15 minutes postexercise to ensure recovery.

Hot environments can be challenging for military working dog (MWD) teams who must balance mission requirements against increased heat strain and risk of heat injury. Heat stroke was the third most common cause of death in MWDs during conflicts in Iraq and Afghanistan, affecting 9 MWDs, and was the most common cause of death from nonbattle injury.[1] Outside of combat, heat injury is the second most common reason (behind behavioral causes) for discharge from duty of younger (less than 5 years of age) MWDs.[2] Not all canines are suited for work in the heat. Factors that could contribute to heat intolerance include physical characteristics (thick fur, obesity), medical conditions (cardiovascular or neurological abnormalities, laryngeal paralysis), and unfavorable structure of the upper airway (nares, nasal turbinate, soft palate).[3] Despite these potential issues, over 1,500 MWDs in service in the Department of Defense (DoD) successfully perform their missions.

One strategy to avoid excessive heat strain is to use work/rest cycles, both to limit the extent and duration of elevated core temperature (Tc) and to allow adequate recovery between successive bouts of work. Although a Tc of 42°C (108°F) may suggest heat illness in a dog exposed to heat alone,[4] during heavy exercise Tc can reach this level even with very short duration work (10 minutes) under relatively mild (24°C, 75°F) environmental conditions.[5-8] However, a Tc of 43°C (109°F) may be fatal[9]; therefore, knowing how quickly temperature increases during work, what temperature is reached, and how readily recovery occurs are important for judging what duration of work is appropriate and how long a recovery is necessary to minimize risk of heat injury.

While several studies have documented thermoregulatory responses of dogs during treadmill running,[5,6,10,11] only a few have reported Tc during activities performed outside of laboratory settings. Field studies have included both standardized tasks, such as covering a measured distance, and sport performance, such as retrieving, where work intensity varies among dogs. The most rapid increase in Tc reported was in racing greyhounds who reached 41°C after a 400 m sprint lasting only 30 seconds.[12] Sled dogs reached a Tc of approximately 41°C to

over 42°C when pulling carts over distances from 3 to 6 km.[13] Three studies reported Tc during exercise in Labrador retrievers. A Tc of 40.4±0.6°C was reached in a 20 minute, 3.2 km conditioning run[14]; a Tc of 41.8±0.3°C was reached after 10 minutes of repeated retrieves[7]; and during field trials Tc reached 40.7±0.2°C, with one dog's Tc as high as 42.2°C.[15] None of these studies included the types of activities performed during MWD training.

The purpose of this study was to characterize Tc responses in MWDs during training at Lackland Air Force Base, San Antonio, TX. The results of this study will improve understanding of heat storage during exercise and recovery of MWDs, and provide a basis for evaluating interventions or guidance for working in hot conditions.

Methods

The 341st Training Squadron at Lackland Air Force Base procures and trains MWDs for patrol and detection activities, spending approximately 60 days on each type of training.[16] At any time, 140-150 MWDs are undergoing this training. Once certified, MWD teams support military operations and their capabilities are used to enhance the effectiveness of the unit. The training includes the following skills:

- Obedience: Respond to cues of Sit, Down, Heel, Stay
- Obstacle Course: Negotiate obstacles under control
- Controlled Aggression: Pursue, bite and hold, respond to cues of Out, Heel, Stay
- Building Search: Detect a person, narcotics, or explosives hidden inside a building
- Vehicle Search: Detect narcotics or explosives hidden on a vehicle
- Scouting: Locate a person by scent, sight, or sound
- Gunfire: Remain calm and attentive while weapons are fired

Also at Lackland AFB are MWDs awaiting training, those in the DoD breeding program, and Transportation Security Administration canines. These dogs are walked twice a week on a standard route around the kennel grounds.

A total of 48 MWDs participated in this study, which was approved by the Department of Defense MWD Veterinary Service Institutional Animal Care and Use Committee. Twenty-four MWDs in training were tested over 2 consecutive days to obtain measurements during a variety of activities. Six were tested on each of 4 occasions: August and October 2014, March and August 2015. Another 24 MWDs that were not currently in training ("kennel MWDs") were tested in July 2015 during a single exercise walk around the kennel grounds.

Testing for MWDs in training was scheduled for different times of the year to obtain data over a range of ambient temperatures (approximately 15°C to 30°C). Under these conditions, Tc can be maintained within a normal range at rest,[10,17] but increase with exercise. Two data collections occurred in August due to instrument failure during recovery measurements on the first occasion. Meteorological conditions, including ambient temperature, relative humidity (RH), solar radiation, and wind speed were measured (WeatherHawk 500 Series weather station, Campbell Scientific, Inc, Logan, UT) in the same place and at the same time as the MWD activities. Average meteorological conditions during the testing are shown in the Table.

MWDs in Training

Of the 24 MWDs participating in the training portion of this study, 14 were Belgian Malinois and 10 were German Shepherd Dogs. Four were female, all neutered; 20 were male, 3 neutered, the rest intact. Their age was 23±6 months (range 16-37 months), weight 32±3 kg (range 26-39 kg), height at withers 62±6 cm (range 53-84 cm) and length 78±5 cm (range 70-89 cm). All data are presented as mean±standard deviation.

Each morning the MWDs were picked up from the kennels and loaded onto a trailer where each dog was housed in an individual compartment ("dog box") for transport to the site where training was conducted. The trailers were equipped with air conditioners, but these were not used during any of the training sessions in this study. Dogs rested in their dog box while awaiting their turn to train, and returned to their box afterwards for

Average Meteorological Conditions.

	August 2014		**October** 2014			**March** 2015		**August** 2015		**July** 2015	
	0800	1100	0800	1100	1300	0800	1100	0800	1100	0700	1100
Temperature											
°C	27	32	20	25	27	13	14	24	31	25	29
°F	81	90	68	77	81	55	57	75	88	77	84
Relative Humidity	62%	46%	65%	49%	73%	76%	71%	77%	51%	83%	60%
Solar Radiation (W/m^2)	107	580	45	400	567	18	230	64	528	7	438
Wind Speed (m/s)	0.2	1.3	0.4	1.8	1.3	2.7	2.7	0.2	1.3	1.3	2.2

recovery. They performed between 1 to 3 sessions each day, comprised of a selection of activities from patrol or detection skills. The actual activities performed by the MWDs on each team depended on the particular skills the team was training at that time.

Body core temperature in these MWDs was represented by gastrointestinal temperature (Tgi), which was measured using an ingestible telemetric thermometer capsule (VitalSense, Phillips Respironics, Murrysville, PA). The capsule contains electronics that allow transmission of the temperature signal to a data logger worn on a vest around the dog's chest when the dog was working (Sensor Electronics Module (SEM), Equivital, Hidalgo Ltd., Cambridge, UK), or to a data logger placed just outside the dog box when the dog was resting in the trailer (VitalSense Monitor, Phillips Respironics, Murrysville, PA). The 2 data loggers are shown in Figure 1. The capsule transits the gastrointestinal (GI) tract and is excreted, typically after 12 to 36 hours. Ideally the capsule is ingested at least 4 hours before data collection begins to ensure the capsule is out of the dog's stomach and not affected by water ingestion.[18]

The telemetric thermometer capsule is advantageous due to the continuous temperature data provided without need for invasive measurement or interruption of activity. However, this method depends on appropriate timing of pill ingestion to avoid the influence of water consumption, and also on the successful transmission of the temperature signal to the data logger. In this study, capsules were administered the day before testing; however, some dogs excreted the capsule overnight and a new capsule was administered the morning of testing. In those cases, water consumption after the first training activity obscured initial recovery temperature. Overall, recovery temperatures were missed in 13 MWDs due to water consumption and in 11 cases where the MWD was resting at the back of the dog box out of range of the data logger. In August 2014, no recovery Tgi was obtained due to instrumentation failure, therefore this group was repeated in August 2015.

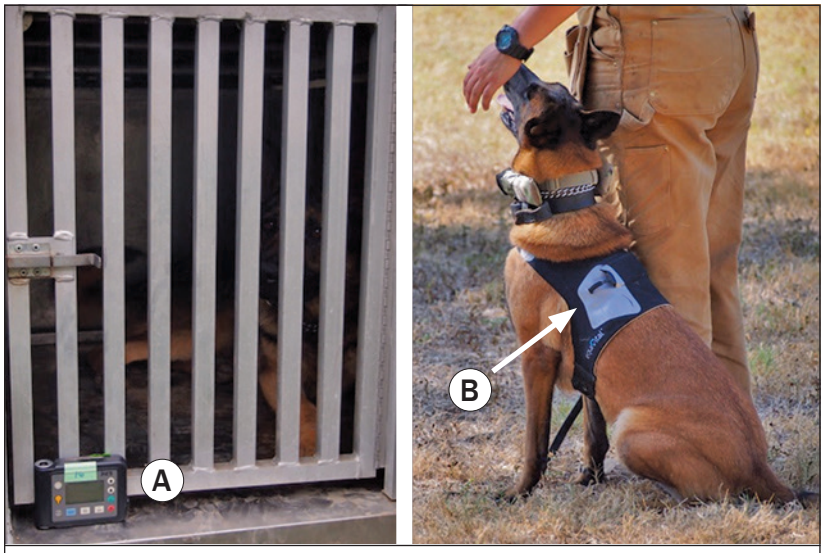

Figure 1. The Vital Sense Monitor (A) was used to record Tgi when the dog was resting on the trailer. The vest-mounted Sensor Electronics Module (B) recorded Tgi while the dog was engaged in training.

Kennel MWDs

Twenty-four MWDs participated in this part of the study which was conducted on a single occasion over 2 days during July 2015. This population consisted of 8 Belgian Malinois, 3 German Shepherd Dogs, 5 German Shorthair Pointers, 6 Labrador Retrievers, one Flat-coated Retriever, and one Dutch Shepherd. Sixteen were male (3 neutered), and 8 were female (2 neutered). Their age was 33±23 months (range 9-96 months), weight 29±5 kg (range 19-39 kg), height 59±4 cm (range 53-69 cm), and length 29±3 cm (range 61-91 cm).

This population represented a wider range of breed, age, and body condition than the MWDs in training, but the activity for the kennel MWDs was the same for all. The dogs were walked for about 20 minutes, covering a 750-800 m loop around the kennel facilities. Toward the middle or end of the walk (depending on the location of their kennel on the grounds), the dogs were taken into a climate-controlled (27°C, 59% RH) building for grooming that lasted up to 5 minutes. They were then returned to their kennels. Since data were only collected during a single walk for each dog and it was not possible to continue data collection into recovery, body core temperature was represented by rectal temperature (Tre) measured manually with a digital thermometer (Adtemp 422, American Diagnostic Corporation, Hauppauge, NY) before the walk, after the initial walk to the grooming building, at the end of grooming, and after return to the kennel. The dogs wore a muzzle for 30 seconds to one minute while the temperature was taken.

Results

MWDs in Training

Initial Tgi just before beginning the first activity was 38.6±0.5°C. All but 3 dogs had resting temperatures between 37.8°C and 38.9°C, which is within a normal range.[17] Two dogs, both of whom tended to spin in their kennels, had elevated Tgi (39.8°C and 39.3°C) before the first activity, but both

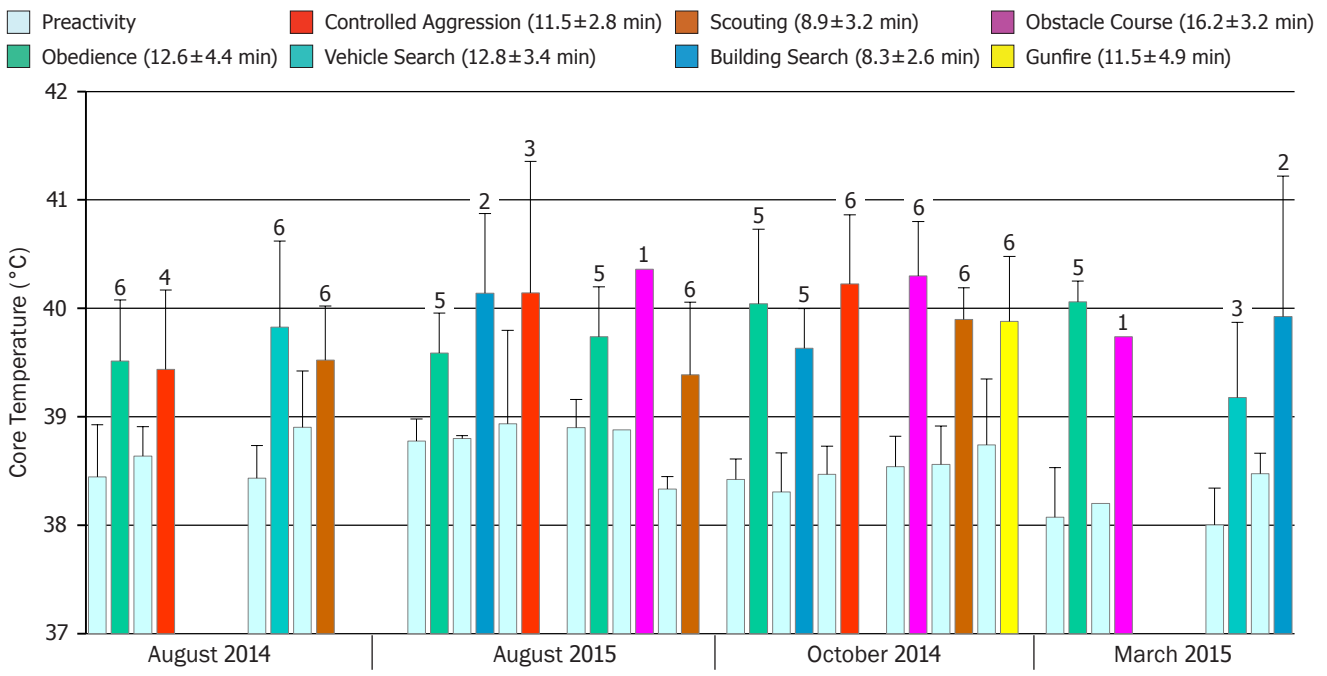

Figure 2. Initial and final temperatures (mean±SD) are shown for each group of MWDs and each activity. The number of participating MWDs is shown above each bar. The mean (±SD) duration time of each activity is shown in the legend.

returned to within normal range after recovery (38.6°C, 38.8°C, respectively). Both tended to spin less frequently as the training day progressed. One dog during the March session had a low Tgi (37.4°C) before the first activity.

Initial and final Tgi for each training activity are presented in Figure 2 for the 4 training groups. Data for one dog from October 2014 was not included in the data presented on this figure for Obedience and Building Search because his preactivity Tgi was outside even the wide range of normal body temperature presented by Vogelsang.[17] For all groups on both days, Tgi at the end of the first activity was 39.8±0.6°C, with a large range (38.4°C to 41.4°C) due to individual variability and varied intensity and duration of training. Successful performance is typically reinforced by presentation of a toy reward and game of tug, or, in the case of patrol activities, chasing a decoy and presentation of a bite sleeve and game of tug. These energetic games contribute to the overall metabolic intensity of a particular activity. The overall duration of training sessions was 11.6±5.0 minutes The average duration of each activity is shown in the legend of Figure 2. Figure 3 shows the individual Tgi responses during Obedience training. Since nearly all dogs performed this activity and it occurred as the first activity on a particular day, this provides a good illustration of the variability among dogs. The temperature responses of the dogs with initial Tgi outside of the normal range are shown in Figure 3.

Four dogs reached Tgi over 41°C during a single activity. In August 2014, one dog reached a Tgi of 41.3°C during Vehicle Search; in October 2014, one dog reached 41.2°C during Controlled Aggression and another dog reached 41.1°C during Obstacle Course; in August, 2015,

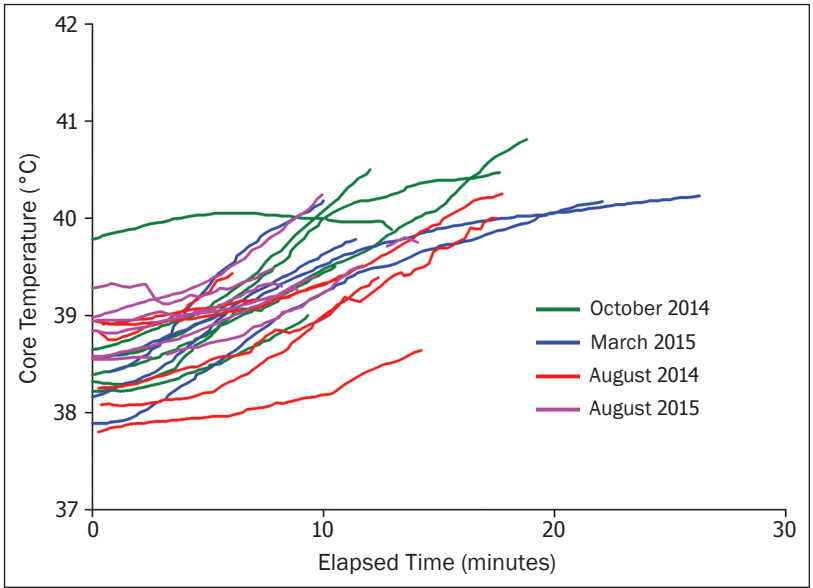

Figure 3. Core temperature response during obedience training. Data are presented for all 23 MWDs that participated in this activity.

one dog reached 41.4°C during Controlled Aggression. Neither of the MWDs with elevated Tgi before beginning the first activity reached Tgi over 41°C during training.

Peak Tgi typically occurred after the end of activity and the dog had returned to the trailer box for recovery. Figure 4 presents the Tgi response of a single MWD during the course of a training day where the activities performed were Obedience, Building Search, and Controlled Aggression. The red line indicates Tgi measurements during activity, the blue line indicates Tgi measured during recovery while the dog was resting in the trailer box. Note that peak Tgi occurred several minutes after exercise ceased. For the 36 cases where recovery data was obtained, peak Tgi was 0.4±0.4°C higher than Tgi at the end of activity, and occurred 10.2±10.6 minutes into recovery (typically during the first 8-12 minutes of recovery). The highest peak Tgi was 42.4°C, which occurred 8 minutes after the end of the activity. In only 2 cases was peak Tgi the same as the final Tgi measured during activity.

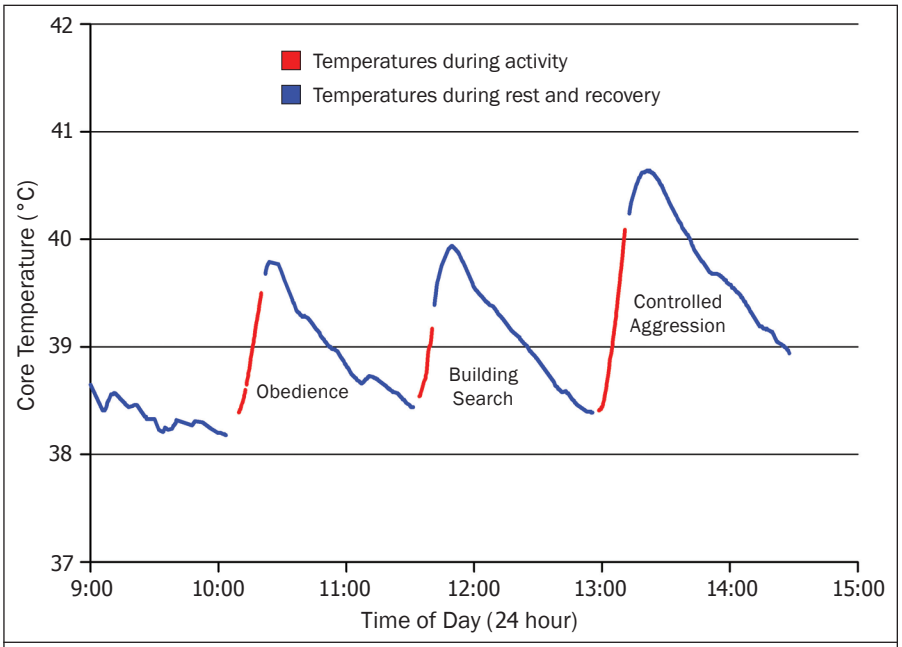

Figure 4. Example of MWD temperature response over the course of a day, consisting of 3 training sessions.

Three activities were conducted each day in the October group, 2 in each of the August groups, and only one activity was conducted each day in March. For the 18 MWDs who performed a second activity, 103.5±36.2 minutes elapsed since the end of the first activity. For most dogs, there was sufficient time for recovery, and Tgi at the start of the second activity was within 0.5°C of initial values for 80% of the dogs. For the 10 MWDs with continuous recovery data after the first activity (ie, not obscured by water ingestion or out of range of the data logger), Tgi returned to within 0.5°C of initial values in 44.1±12.6 minutes.

Kennel MWDs

The initial Tre measured in the Kennel MWDs was 39.0°C±0.8°C (37.7°C to 40.7°C). Eleven of these MWDs had an initial Tre that was higher than 39.2°C, which is considered the upper limit of normal.[17] These readings would not be considered true "resting" temperatures, as some dogs were active in their kennel, pacing or jumping in anticipation of the morning's activities.

Completing the approximately 800 m loop generally required about 15 minutes (not counting approximately 5 minutes for grooming), for an average speed of 0.9 m/s. Since the MWDs typically moved back and forth during the walk, they may have covered more distance at a somewhat faster pace. Temperatures for each phase of the walk are shown in Figure 5. After 11.4±3.3 minutes of walking, Tre was 39.9±0.6°C. The dogs stood quietly during grooming, then walking back to the kennel where final Tre was 40.1±0.6°C and total elapsed time was 21.3±2.8 minutes. One dog reached a temperature over 41°C during the first walk period (41.3°C after 12 minutes), but returned to 40.7°C by the end of the session.

Four Kennel MWDs were taken for veterinary care, based on the handlers' interpretation of signs and/or symptoms of heat strain, including strained breathing or labored panting, and general demeanor (either unusually anxious or subdued). Three of these dogs (a Labrador Retriever, a German Shepherd Dog, and a Belgian Malinois) had an initial Tre greater than 40°C. These events all occurred between 6:30 AM and 7:30 AM when trailers were arriving at the kennels to load other MWDs for training. This sudden increase in general activity around the kennel excites many of the dogs, some of whom repeatedly jump or spin in their kennels. For the Belgian Malinois, it was the fifth occasion of overheating. The fourth dog (Labrador Retriever) had a normal initial temperature, but Tre was elevated to 40.5°C by the end of the first walk period. For that dog, it was the second report of overheating. Medical treatment at the veterinary clinic for all 4 dogs included placing the dogs in a large open kennel, spraying them with water, and

placing a fan in front of the kennel to enhance evaporative and convective cooling. All recovered without need for further intervention. Only 2 other MWDs reached Tre greater than 40.5°C during the walks.

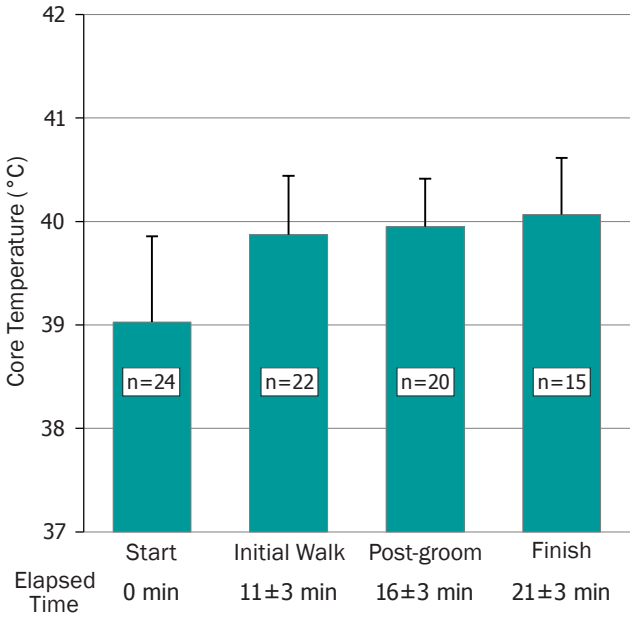

Figure 5. Core temperature for kennel MWDs and elapsed time are shown for the time points of measurements during their walk. The number of MWDs measured for each time point (n) is indicated in the data bar. Two MWDs were taken to the veterinary clinic just before and 2 others just after the initial walk. Final temperature was not measured in 5 MWDs whose kennels were located adjacent to the grooming area.

Comment

This is the first study to report core temperature in MWDs during training activities and kennel walks. While the data presented here are descriptive, they provide a baseline for future studies where comparisons may be made or interventions evaluated. An important finding in the present study was the continued increase in Tgi to a peak 8 to 12 minutes after exercise ended, shown for one dog in Figure 3. This delay in reaching peak Tgi may reflect both a transient lag in temperature response of the gastrointestinal tract due to decreased blood flow during exercise, compared to the temperatures of the working muscles and central blood,[18,19] and continued heat storage even after exercise ends.[20] Since rectal temperature is measured in MWDs suspected of overheating, this underscores the importance of measuring temperature not only when exercise is ceased, but also periodically during recovery until a decrease in temperature is observed. This practice may identify a need for additional cooling such as greater ventilation, or could potentially allow earlier identification of MWDs that require veterinary attention.

Although heat injury can occur at a body core temperature of 42°C with heat exposure alone,[4] temperatures this high have occurred during exercise in the heat without adverse effect.[5-8] Clearly, caution is advised at temperatures this high, particularly with longer duration exposure. A temperature of 43°C can be fatal.[9] Under the conditions in the present study, Tgi reached approximately 40°C at the end of a training session, with only 4 MWDs reaching a temperature over 41°C (two in August, two in October). For 2 of these dogs, this occurred on the last activity of the day. Before beginning the second activity of the day, Tgi had returned to within 0.5°C of initial Tgi for all but 4 MWDs in August data collections. This suggests that, under the conditions of this study, the duration of both training sessions and recovery periods were acceptable. Figure 3 shows the continuous increase in core temperature during Obedience and illustrates how limiting training duration could be effective for avoiding excessive heat strain. Under conditions of high heat stress, short sessions can reduce risk of overheating while still meeting mission requirements. Kennel MWDs also reached a Tre of about 40°C at the end of their walk, with only one dog reaching a Tre over 41°C, excluding 4 Kennel MWDs taken to the veterinary clinic before completing the walk. For the dogs taken to the veterinary clinic, whether the excitement of the kennel activity had contributed to their elevated temperatures or whether they were otherwise predisposed to overheating cannot be discerned from this study.

The temperatures achieved during this study are similar to what has been reported for other working dogs when the intensity and duration of work are considered. Angle and Gillette[14] reported Tgi of approximately 40.5±1.0°C in Labrador Retrievers at the end of a 20-minute run at 2.9 m/s, and Tgi of approximately 40.0±1.0°C after 12.5 minutes of work, comparable to findings in the present study. Matwichuk et al[7] reported a higher Tre of 41.8±0.3°C in Labrador Retrievers after 10 minutes of work. However, those dogs on average completed 44 retrieves about 40 m long, for a total distance (round trip) of 3,520 m at a speed nearly twice as fast as the dogs in the study of Angle and Gillette.[14] Phillips et al[13] reported Tre in sled dogs pulling a cart for 3.5 km at a pace of 4.7 to 6.7 m/s reached 39.9°C to 41.7°C, but when dogs ran for longer distances (16 km) without pulling a load, Tre was lower (39.5°C to 40.2°C). In that study, Tre reached a plateau after about 25 minutes for the dogs running longer distances.

None of these studies reported the delayed peak temperature observed in the present study. This may be due to the frequency of temperature measurements. For example, Matwichuk et al[7] found that Tre was the same after

5 minutes of recovery as it was at the end of exercise, and had decreased only to 41.6±0.3°C after 10 minutes. Likewise, Angle and Gillette reported little change in Tgi in the first 5 minutes of recovery.[14] Whether a peak in Tre had occurred within the first 5 minutes of recovery of either of these studies is unknown. For longer duration steady state exercise, a peak temperature during recovery may not be observed, since body temperature would likely have become more uniform.[18]

Limitations

For the MWDs in training, work intensity and duration varied among dogs, yet both are important factors for heat storage. This makes it difficult to compare among activities and among conditions, such as climate. At the same time, there are individual differences in temperature response, including the initial temperature of the dog. Kennel MWDs walked at the pace of their handler; therefore there was less variability among dogs for the physical work performed. However, nearly half had an initial Tre above a normal resting range. Behaviors exhibited in the kennels include repetitive leaping, spinning, and barking, particularly in the morning when the trailers arrived to pick up other MWDs for training. Three of the 4 Kennel MWDs taken for veterinary care had elevated initial Tre. Kennel MWDs also typically receive less exercise than the MWDs in training, and may therefore be less fit or heat acclimatized.

Summary

This study reports body core temperature responses to MWD training activities as well as standard kennel walks. The results of this study suggest that alternating periods of work with adequate recovery is an effective strategy for accomplishing mission-required training while avoiding excessive heat strain. Peak temperature may occur several minutes after work ends; therefore, Tre should be monitored during the first 15 minutes of rest to ensure recovery.

Acknowledgments

The research described in this report was conducted in compliance with the standards and practices set forth in the *Guide for the Care and Use of Laboratory Animals*: *Eighth Edition* issued by the Committee on Care and Use of Laboratory Animals of the Institute for Laboratory Animal Research, National Research Council, published by National Academies Press.

We are sincerely grateful to the teams of the 341st Training Squadron, the Department of Defense Military Working Dog School, as well as to the 48 MWDs who participated in this study. Our appreciation also goes to SSG John Camelo for his dedication to documenting the activities of the MWDs during this study.

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Effects of Technique-Focused Training in Conjunction with Physical Readiness Training on Army Physical Fitness Test Performance

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Abstract

The Army Physical Fitness Test (APFT) is a semiannual requirement. While conducting physical readiness training (PRT) is a requirement for all Soldiers, there is no requirement to train Soldiers on techniques that may help to optimize their performance on the APFT. A cohort of 34 officers that attended the Army Medical Department Basic Officer Leadership Course completed a technique-focused training program in conjunction with their required PRT program subsequent to failing one or more events on their initial APFT. The training consisted of a 30-minute video lesson and an individualized performance assessment completed by an Army physical therapist. Upon retest 10 days after the initial test, 27 (79.4%) participants passed the APFT with a mean improvement of 22.3 points on their overall APFT score. When evaluating change in performance by event based on failing the event initially, the observed improvement was an increase of over 9 push-ups, over 11 sit-ups, and nearly 2 minutes on the run event. The addition of a technique-focused training program to an existing PRT program can result in significant short-term improvement for those with substandard APFT performance.

The Army Physical Fitness Test (APFT) is a semiannual training requirement for all Soldiers of the US Army. It consists of 3 events: the 2 minute push-up event, the 2 minute sit-up event, and the timed 2-mile run event. Based on a Soldier's age and gender, a scoring scale is used to convert a raw event score (number of push-up repetitions correctly performed, number of sit-up repetitions correctly performed, or 2-mile run time) to a scaled event score that ranges from 0 to 100 points for each event. The 3 scaled scores are then summed for a combined score between 0 and 300 points. In order to pass the APFT, Soldiers are required to earn a minimum of 60 points on each event and a total of 180 points.

This combination of upper body and trunk anaerobic endurance events (push-ups and sit-ups) and a lower body aerobic endurance event (run) creates an efficient and relatively balanced assessment of overall physical fitness. While performance on the APFT is predominately determined by a Soldier's physical fitness level, technique on each event is also likely to contribute to an individual's score. Experience shows that seasoned Soldiers usually develop efficient technique strategies that optimize performance on the APFT. However, newer Soldiers that have not had significant prior exposure to these events, and the scoring standards for each, may find it challenging to develop a technique that allows them to achieve their personal best scores on the APFT. The training manual[1] that governs the execution of PRT is an excellent resource regarding the planning and conduct of a daily exercise regimen that will adequately address the strength, mobility, and endurance needs of the Soldier, but does not provide specific tips to optimize performance.

There is currently no required training for Soldiers upon entry into the military that would expose them to information regarding recommended techniques that can be used during the APFT. There are several reasons why a Soldier fails to earn a passing score on the APFT, such as fatigue, injury, inconsistent training regimen, poor nutrition, etc. The use of an exercise technique or motor control strategy that is not biomechanically, physiologically, or strategically sound could also adversely affect performance. Therefore, the purpose of this report is to assess the potential value of a technique-focused training program when administered by Army physical therapists to a group of Army Medical Command officers that failed to pass their initial APFT upon matriculation into the Basic Officer Leadership Course (BOLC).

Methods

Participants

From January 2015 through March 2016, 34 Army Medical Command officers who were enrolled in BOLC at Fort Sam Houston, Texas, participated in an APFT

performance improvement training program. Within one week of arrival at the course, all student officers are required to take a "record" APFT. Completion of an APFT performance improvement training program was mandated for any individual officer that failed one or more events on that APFT. Evaluation and approval of this performance improvement training program by the local Institutional Review Board was not required.

APFT Evaluations

The APFT was administered by BOLC cadre as a part of their normal BOLC schedule. All participants that failed the initial APFT were retested 10 days later by BOLC cadre as dictated by local Army Medical Department Center and School command policy. Grader assignments for the APFT were randomly selected by the command team and no attempt was made to ensure that an assigned grader for the initial APFT was the same grader for the retest.

Screening Intervention

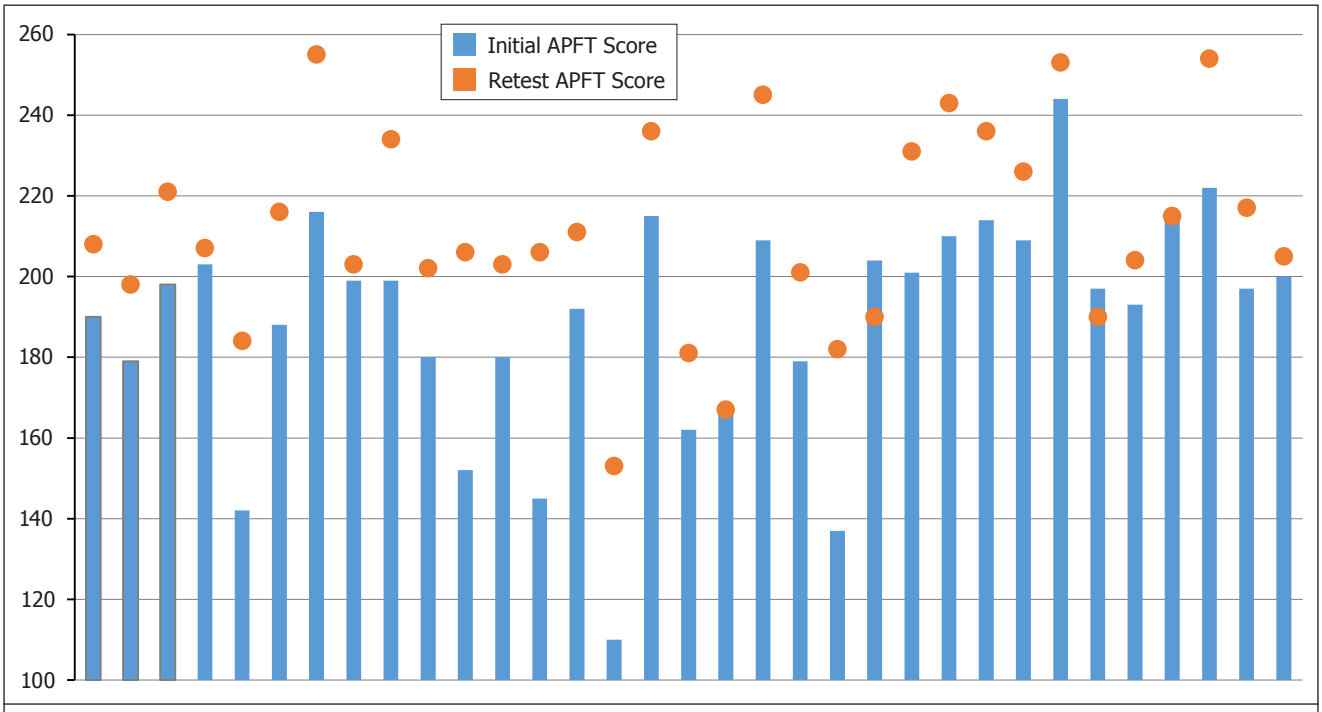
Regardless of which event(s) were failed, all officers participated in the special population PRT program per the associated regulation[1] under the supervision of their unit leadership. A typical one-week PRT training regimen is presented in Table 1, however, the specifics of the training regimen often varied based on the company leadership during the time of APFT failure. This group exercise regimen was performed 3 to 5 times a week for 60 to 75 minutes per session. A dynamic warm-up, known as the "preparation drill," consisted of 10 exercises and was conducted first for approximately 15 minutes. This was followed by drills aimed at improving anaerobic muscular strength and endurance, overall mobility, and aerobic conditioning lasting approximately 35 to 45 minutes. Each training session was concluded with a cool down static stretching activity known as the "recovery drill," lasting approximately 10 minutes.

Table 1. Typical 5-Day Physical Readiness Training Schedule.

Day	Warmup	Activities	Cooldown
1	Preparation drill (5 reps)	4 for the Core- (60 seconds) /conditioning drill #1 (5 reps)/push-up sit-up drill (4 reps x 30 sec)	Recovery drill (20 seconds)
2	Preparation drill (5 reps)	Push-up drill, sit-up drills, 1 mile split time training	Recovery drill (20 seconds)
3	Preparation drill (5 reps)	Military movement drill #2 (1 rep)/conditioning drill #2/release run by platoon	Recovery drill (20 seconds)
4	Preparation drill (5 reps)	Push-up drill, sit up drills, 1 mile split time training	Recovery drill (20 seconds)
5	Preparation drill (5 reps)	4 for the Core (60 Seconds); conditioning drill #1 (5 reps); climbing drill #1 (5 reps)	Recovery drill (20 seconds)

The officers were also required to attend an APFT performance assessment evaluation conducted by local Army physical therapists (PTs). This training was completed within 3 days of their initial APFT, in order to maximize training time and possible benefit prior to the next administration of the APFT. In preparation for this training, all officers were required to view a 30-minute video lesson that outlined common performance detractors observed during the conduct of an APFT. As previously described in an earlier study,[2] this training is available to holders of a Department of Defense common access card at the following web address: https://www.milsuite.mil/book/docs/DOC-189640 and has also been previously reported.

In total, 4 PTs conducted the live training on several training dates during the data collection period. All were board certified in orthopedic and/or sports physical therapy and all had been serving as active duty Army physical therapists for a minimum of 15 years. The live training program consisted of the following sequence: subjective APFT concerns, observation and analysis of the push-up and sit-up events, and observation and analysis of the running event. Each officer was first asked to confirm that they did not have a medical condition of any kind that precluded their ability to provide a good faith effort on the most recent APFT. If no, they were asked to rank order the APFT events from most to least challenging and to specifically state which events were failed and by how many points (if known). Lastly, before starting any physical activity, they were asked if they used any kind of strategy as to how they planned to execute each of the 3 events. Each officer was asked to perform 30 to 60 seconds of push-ups as they would do them on an APFT. The number of repetitions varied from officer to officer to allow for assessment of the pacing, breathing, position modifications, depth of movement, and rest positions used. No officers were required to perform push-up repetitions until muscle failure ensued. After a brief rest while feedback on push-up performance was provided, a similar approach was used to assess performance on the sit-up event. Again, after a brief rest while feedback on the sit-up event was provided, they completed a run analysis. The run analysis was performed on a commercial treadmill and was completed in less than 5 minutes. Officers were asked to begin by achieving a moderate walking pace for approximately 2 minutes and were then instructed to gradually increase the treadmill speed until they reached a pace commensurate with the pace used on the most recent APFT. The PT would first perform a real-time assessment focusing on any noteworthy visual or auditory findings that could potentially affect performance on the 2-mile run



Graphical comparison of initial and retest overall APFT scores (N=33).

event. Additionally, a smartphone was then used to take 6 to 8 second slow motion videos from both a posterior and lateral vantage point. This was done in order to assess more subtle motor control movement patterns in the frontal and sagittal planes and to provide visual and auditory feedback for the observed officer. Each officer was given an information sheet that reflected the findings specific to that individual, and recommendations from each of the 3 training events. For example, a common observation on the push-up event involves the dropping of the head during the down phase, which typically leads to inability to achieve the appropriate depth. As a possible correction, the recommendation to keep the head in neutral or slightly extended and leading the down phase with the chest may be given. Officers were encouraged to incorporate any recommendations made during this training event into their unit-led PRT training program, but there was no attempt to track use or compliance. The videos were deleted immediately after use and no data was retained by the physical therapist examiners.

Data Analysis

Upon completion of the APFT retest, de-identified APFT scores were collected by the unit leadership and provided to the primary author for analysis. Descriptive statistics were calculated to define the demographics of the cohort and their performance on the APFT. Inferential statistics (paired *t* test) were performed to determine individual event and overall APFT performance change observed from the initial APFT to the retest. All statistics were calculated using IBM SPSS Statistics 22 and alpha of 0.05.

Results

Descriptive statistics regarding the demographic data for the 34 participants (14 female, 20 male) in this program are presented in Table 2. Thirty-three participants completed the entire 3-event APFT, whereas one participant had a permanent profile precluding performance of the sit-up event and only completed the push-up and run events. The time of year for testing varied for participants, but the duration between APFT test dates was 10 days for all participants. Initial overall mean score on the APFT was 189.3±28.1 points, and 211.6±24.7 points for the APFT retest administered 10 days later. Individual test and retest scores are shown in the Figure. Upon retest, 27 of 34 (79.4%) participants were able to achieve a passing score on the APFT. The breakdown of numbers of failures by event on the initial APFT was 8, 14, and 22 for the push-up, sit-up, and run events respectively. Table 3 presents a summary of the mean number of repetitions completed or run times as appropriate for each of the events, as well as the overall APFT scores. Table 4 highlights the change in performance by event based on whether

Table 2. Descriptive Statistics (N=34)

	Range	Mean	SD
Age (years)	22-37	28.7	4.3
Height (inches)	62-76	68.2	3.4
Weight (pounds)	122-234	173.9	32.1
Body Mass Index	20.3-33.8	26.2	3.6

Table 3. Individual Event and Overall APFT Performance Results (N=34).

	Mean (95% CI)	SD	*P* value
Push-up Reps Initial	38.5	17.5	
Push-up Reps Retest	39.7	14.5	
Change in Push-up Reps	1.2 (-1.6,4.0)	8.1	.390
Sit-up Reps Initial	50.9	13.5	
Sit-up Reps Retest	56.6	11.5	
Change in Sit-up Reps	5.6(2.0,9.3)	10.3	.004*
Run Time Initial	19:01	2:22	
Run Time Retest	17:32	1:50	
Change in Run Time (seconds)	-89.5(-68,-110)	58.9	<.001*
APFT Total Score Initial	189.3	28.1	
APFT Total Score Retest	211.6	24.7	
Change in APFT Score	22.3(16.2,28.3)	17.0	<.001*

*Statistically significant improvement

Table 4. APFT Event Performance Comparison by Event Status (N=34).

	Failed Event	n	Mean	SD	*P* value
Change in Push-up Reps					
	NO	26	-1.2	7.0	.001*
	YES	8	9.1	6.0	
Change in Push-up Score					
	NO	26	-1.4	8.0	.001*
	YES	8	10.6	7.3	
Change in Sit-up Reps					
	NO	19	1.5	7.4	.006*
	YES	14	11.1	11.3	
Change in Sit-up Score					
	NO	19	1.7	7.9	.003*
	YES	14	13.1	12.7	
Change in Run Time (seconds)					
	NO	12	-39.5	22.7	<.001*
	YES	22	-116.7	54.6	
Change in Run Score					
	NO	12	5.2	3.8	<.001*
	YES	22	19.0	8.5	

*Statistically significant difference

or not the individual had failed that event on the initial APFT. The overall mean change score for the APFT of 22.3 points improved regardless of which event(s) were failed initially. There were statistically significant improvement for the entire cohort observed for the sit-up and run events. When quantifying mean improvements based on whether or not the event was initially failed as presented in Table 4, all events demonstrated statistically significant improvement with a cumulative improvement on the APFT of 42.7 points.

Comment

The results of this program suggest that significant short-term gains in performance can be made on the APFT when participants are provided a structured PRT program that is augmented with an individualized, technique-specific evaluation and training session. Improvement in each of the events comprising the APFT was observed, especially in the sit-up event and even greater in the run event. A mean improvement for the entire cohort of approximately 6 sit-ups and 90 seconds on the 2-mile run in 10 day period is noteworthy. Mean push-up performance, on the other hand, remained unchanged. This could indicate that technique is less important for push-up performance than for sit-ups and running. Alternatively, this finding could be due to the recommendations that Soldiers received on overall APFT strategy. Specifically, during their training sessions, individuals were encouraged to reduce the number of repetitions attempted on the push-up event if they passed that event initially. This strategy was employed to allow individuals to conserve energy for the subsequent 2 events for which they may have failed to achieve a passing score on the initial test. Therefore, an analysis of improvement based specifically on whether or not the event was initially failed may provide further insight. Based on the analysis in Table 4, we observed a mean improvement of over 9 push-up repetitions in the group that failed the push-up event initially. When the sit-up and run events were analyzed in a similar manner, we observed mean increases of over 11 sit-ups and nearly 2 minutes faster, respectively. This cumulative increase equated to an increase of 42.7 points on the overall APFT retest score.

This degree of change in a relatively short period of time would argue against the premise that the continued PRT alone they were required to perform was solely responsible for the observed improvements. Muscle hypertrophy and cardiopulmonary adaptations are 2 mechanisms by which APFT performance can be expected to improve.[3] It is unlikely that a significant degree of either occurred in the limited time between test dates. In contrast, changes in motor control patterns through neural adaptations can occur in a short period of time and subsequently result in improved performance.[4,5] For example, Frost et al[6] reported an immediate improvement on the Functional Movement Screen (7 tests representing various functional movements) score for a group of firefighters given immediate feedback regarding expected movement patterns on events graded as substandard. This study indicated that following feedback, participants were capable of optimizing movement, but were unaware of the best strategy to achieve a better score. Similarly, the participants in this study likely had a limited amount of experience with being evaluated on the 3 events of the APFT, potentially limiting their ability to develop an optimal movement strategy for each.

The advice given to the participants in this study was intended to result in improved biomechanical and motor control physiologic strategies.

Multiple limitations exist with the design of the cohort study. First, the sample size was small and there was no control or usual training group to compare what, if any, additive effect was provided by the individualized training session. Also, all participants were required to pass the APFT in order to graduate from BOLC and ultimately be allowed to begin their careers as branch qualified officers. Therefore, they were strongly motivated to improve their performance regardless of the training that they received.[7] Further, no attempt was made to account for any additional voluntary training the participants may have done between APFT testing dates. Due to personnel constraints, there was also no attempt to ensure that each participant had their APFTs graded by the same grader. The interrater and intrarater reliability of the push-up event was recently reported to range between 0.10-0.97 and 0.47-0.99 respectively.[8] This degree of variability in grading could have affected the outcome on this event. No such reliability data has been previously reported for the sit-up event. Minimal evidence does exist to support the interrater and intrarater reliability of a videotaped qualitative running assessment.[9] Lastly, given that the cohort initially scored poorly on the APFT and were specifically selected to receive this training based on their substandard performance, some regression toward the mean would be expected.[10]

Future studies should include a comparison group that does not receive individualized guidance regarding their performance. Also, this training method should be assessed in a regular Army unit with a more normal distribution of APFT scores.

Practical Applications

This study provides baseline evidence for the value of technique specific APFT performance feedback provided by a military physical therapist. Given that physical therapists are currently assigned in wide variety of positions throughout the military, there is potential for a larger scale implementation of this type of human performance optimization training program.

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Evidence-based Practice and Single-case Designs in Psychotherapy

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Like their private sector counterparts, Department of Defense (DoD) behavioral health providers rely on evidence-based practice and evidence-based treatment to guide development and delivery of care plans. Unfortunately, most of the evidenced-based treatment protocols involve civilian participants in nonmilitary environments, which makes the generalization of interventional strategies and treatment results to military personnel a challenge. "Treatment generalization" has been raised by a number of providers and organizations both within and outside of the DoD. Another concern is the lack of evaluation in the efficacy of treatment provided to military members and their families. This concern was recently presented in studies conducted by the Institute of Medicine (IOM) of the National Academies. Additional concerns raised by the IOM include (1) the cost of care, (2) the lack of use of established frameworks, and (3) length of treatment.[1,2]

Effectiveness of Psychotherapy

Broadly, the effectiveness of psychotherapy is indisputable[3-6]; however, the quality of psychotherapy is not as unambiguous because of dependency upon the therapist.[7] Clinical trials have detected differences in outcomes among therapists.[8-10] Even with the implementation of evidence-based practice and evidence-based treatment, desired treatment outcomes are not guaranteed since even well-accepted therapies can have harmful effects in some people.[11,12] For example, even though relaxation training has been demonstrated to be beneficial for most patients, relaxation training can induce panic attacks among a minority of patients.[13] Complicating the issue of implementing evidence-based practice is a 20-year lag between knowledge acquired from our best clinical research and the applied use of that knowledge in the mental health sectors.[14]

Single-Case Designs

Also known as single-subject and N-of-1 designs, single-case designs (SCDs) have rarely been taught to students or used by investigators in the behavioral sciences until recently. Consequently, many misconceptions exist about conducting SCDs and their value. However, most recently, in applied behavioral research and clinical settings, SCDs are being more widely and heavily applied.[16] Moreover, the increase in the use of SCDs has not been centered on the behavioral sciences. Instead, their use is occurring across a variety of medical and educational settings.

In fact, in some disciplines such as special education, the experimental literature has been dominated by single-subject investigations.[17-19] Other areas experiencing an increase in single-subject designs include emergency department medicine,[20] general medicine,[21] early childhood special education,[22] special education,[23,24] autism,[25] speech and language pathology,[26] aphasia,[27] special education,[28,29] students with disabilities,[24] behavioral problems,[30] natural disasters,[31] and self-management.[32] In the mental health field, a number of researchers have written on the use of single-subject designs in clinical use.[33-37] Although this list is extensive, it is by no means exhaustive.

What has led to the resurgence in the use of SCDs? The answer is as varied as the disciplines employing the designs. One answer derives from an area of psychology known as applied behavior analysis, which focuses on interventions in a number of settings. This area has firmly established the utility of the SCD.[38] Another answer derives from clinical social work where more and more practitioners have been charged with empirically demonstrating the effectiveness of their interventions.[39] In a clinical practice setting, the effectiveness of interventions can most readily be evaluated by SCDs. Additionally, given the fact that social workers are the largest providers of mental health services in the United States,[40] it is not surprising that, more and more, SCDs are being used in the delivery of mental health services.[41]

An additional source of support for single-case designs comes from the federal government via the US Department of Education Institute of Education Sciences (IES), which was established under the Education Sciences Reform Act of 2002. This Act provides funds to establish The What Works Clearinghouse (WWC). The WWC has

accepted that single-case designs can provide causal evidence of intervention effects.[42] Additionally, professional organizations such as the American Psychological Association (APA) recommend single-case designs alongside randomized control trials in their clinical evidence standards.[43] Furthermore, individual social workers have discussed the importance of single-case designs in clinical practice,[44-46] and the National Association Social Workers (NASW) Press has published a number of documents related to single-case designs for clinical practice.[47]

Cost Considerations

The cost of health care services and the lack of cost data analysis in health care and mental health services has long been a concern in healthcare.[48-49] These concerns may further strain the mental health system beyond its capacity.[50] Unfortunately the DoD is not immune to the escalating costs in rendering mental health care and is developing alternative treatment methods to reduce these costs.[51-54]

The use of SCDs allows for a quicker assessment of the costs involved in providing the services, which is extremely important given the dramatic shift from inpatient care to an increase use of ambulatory alternatives and outpatient care. In 1988 inpatient costs were 51% of total mental health care costs for enrollees in the fee-for-service medical plan; in 1990 inpatient care costs accounted for 44% of all payments; and in 1996 inpatient care costs accounted for only 20%.[55] This downward trend in costs continues today. Moreover, although the overall rate of outpatient psychotherapy use has not significantly changed over the last decade, the number of psychotherapy visits per patient has decreased.[56] This decrease is due to a number of factors including briefer models of therapy, improvement in psychotropic medications, changing practice patterns, practice guidelines and payment policies.[57-59]

The use of time series single-subject design permits the tracking of care (eg, number of sessions by diagnosis over time) thus allowing for the development of more accurate cost estimates for specific types of disorders. Additionally, time series single-subject design permits analyses of when the patient is making progress and when progress may not be cost effective. Applying single-subject designs enables case rates to be developed for outpatient mental health services, which can contribute to focused attention optimizing both the clinical result and the business result (eg, avoiding unnecessary services and waste). Moreover, this would assist in identifying providers who are efficient and receive desirable outcomes. Finally, it would assist the DoD in moving payment from volume to value.

Information technology lies at the intersection of SCD use, optimization of clinical outcomes, and realization of larger cost-related performance goals (such as cost minimization, cost avoidance, savings, and so on). As an enabler of clinical and patient needs, information technology has the potential to greatly enhance patient outcomes whether SCD is a factor or not; however, investments in information technology can be extremely costly, particularly if deployed in a manner that fails to understand the interdependent aspects of clinical care and patient outcomes. Porter asserts that information technology is a key enabler of value, particularly when providing the means to capture and aggregate data across time, providers, and patients,[60] which are core and essential ideas associated with SCD and evidence-based practice. Other research has pointed to a "symbiosis" between information technologies and SCD as relating to the ability to efficiently capture behavioral changes and demonstrate improvements in outcomes.[61]

Advancement in Statistical Methodologies

An additional source of support for the use of single-subject designs is the advancement in statistical procedures that evaluate the effectiveness of the treatment in single-system designs. A number of researchers have developed and applied various types of statistical procedures in analyzing single-case designs.[15,62-72] Most recently, Vannest et al[73] conducted a review of the statistical methods used to analyze single-case research in terms of determining effect size and the certainty of the decision. Their review weighted heavily on the research conducted by Parker and colleagues[74] and Parker et al.[75] In summary, Vannest and associates concluded that the "number and quality of statistical techniques for single case research has dramatically increased in the last decade."[73(p38)]

One of the more useful techniques for behavioral science researchers and especially practitioners providing therapy is the use of Improvement Rate Difference (IRD). Briefly, IRD is the difference in behavior between A, the baseline phase, and B, the intervention phase—understanding the difference between baseline and intervention phases is what clinicians strive to do on a daily basis. Another more useful statistical technique for therapists is what is referred to as the nonoverlap of all pairs (NAP).[76] This method of analysis provides information on the percentage of data (eg, therapy sessions) that shows improvement from one phase to another based on all pairwise comparisons across phases A and B. Although the NAP can be calculated by hand, the most efficient method is to use a statistical package such as NCSS (number crunching statistical system).[77] In addition to the development of the new statistical procedures, a number of researchers have applied statistical

procedures primarily developed in the business community to single-case designs. For example Davies et al[78] used funnel plots to explore variation in cancer mortality across primary care trust in southeast England. Mayer and associates[79] have applied funnel plots to surgery.

Statistical methods used to evaluate the effectiveness of treatment are naturally aligned with visual analysis, which has been the traditional means of detecting the effect of intervention.[80] The steps involved in visual analysis generally involve documentation of a stable baseline period, analysis of within phase data, analysis of between phase data, and integration of results across all phases. Within this analytic framework, researchers use typical statistical measures and concepts to examine data, which include levels (eg, means), within phase rate of change, variability, effect immediacy, overlap, and consistency across phases.[80] A straightforward approach to identify change involves use of ideas from statistical process control (SPC). For example, detection of variability between baseline to intervention phases can be achieved through creation of intervals (such as 2-standard deviations) surrounding mean values in order to identify statistically meaningful changes.[81]

Although SPC concepts were developed in the 1930s and have been hailed among the greatest contributions to the philosophy of science,[82-84] these methods have not featured prominently in healthcare research.[85] One of the interesting aspects of SPC is that the majority of users of the chart methodology over the last 70 years has been engineers, statisticians, and mathematicians, so it comes as a surprise that members of the behavioral science community find the methodology lacking in statistical validity, which is particularly interesting since the SPC process has been seen as a statistician's technique.[86] However, low adoption of SPC methods may be in part due to the lack of understanding on how to use SPC charts in analyzing single-case designs. For example, according to Orme and Cox,[87] the only method for constructing an SPC chart described in the social work literature is incorrect. Fortunately, this may not be the case today in view of the growth of articles that have been written to more fully explain the use and interpretation of SPC charts.[87-93] Additionally, many statistical software packages to which behavioral science researchers have access (eg, Minitab, SPSS, SAS) contain procedures that are capable of producing a variety of SPC charts.

Bolstering the case for the use and analysis of single-subject designs and the accompanying robust statistical procedures is the fact that numerous researchers have indicated that despite widespread belief, standard statistical methods are not robust when differences exist or when there is an association between random variables.[20,94-101] More specifically, even arbitrarily small departures from normality result in low power when distributions are normal. Heteroscedasticity can seriously lower the power of standard analysis of variances (ANOVA) and regression methods.[101] The practical result is many clinical studies would have achieved a level of significance if less traditional but more robust statistical procedures had been used.

Meta-analysis of Single Case Designs

Potentially the most important support for single-subject designs has been the progress in the development of meta-analysis statistical methodologies for single-subject designs. Traditionally evidenced-based treatments refer to interventions that have empirical support in their behalf. The evidence has been derived from rigorous tests that the treatments relative to various control or other treatment conditions produce therapeutic change.[16] Although there are a number of different approaches to rating evidence, one of the most widely used in the medical field has been developed by Melnyk and Fineout-Overholt.[102] This system has at the highest level evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs) or evidence-based clinical practice guidelines based on systematic reviews of randomized controlled trials. Although single-case designs technically will not meet the criteria of randomized controlled trials, the time-series design, including single-case designs as a special case, can be among the strongest nonrandomized experimental designs.[103]

This, coupled with recently developed meta-analysis statistical procedures, should increase the confidence in the findings derived by single-case design studies. To date, these recently developed statistical methodologies have used regression approaches, especially multilevel modeling and parametric and nonparametric effect-size estimation.[69] The results of this effort should make it possible for single-case design researchers to make significant contributions to the advancement of evidenced-based practice. As previously noted, although single case designs represent a special case of time-series designs and statistical methods for analyses of long time series designs are well developed, methods for short term analysis are not as well developed. However, this is changing and progress has been made in this area, and some of the methods that have been applied to long term time series designs are also applicable to the short time series designs. Improvements in methods associated with short-term analysis coupled with increased use of

these methods across clinical settings will be especially beneficial in psychotherapy where advances in psychotherapy interventions are reducing the time the patient actually spends in therapy.

Although statistical innovation in developing methodologies for single-case designs is progressing, one area impeding this progress is the overreliance on null hypothesis significance testing (NHST). According to Sharpe,[104] there are a number of reasons for the overreliance on NHST. One reason is the lack of awareness of developments in statistical theory and methods. Many researchers focus their attention on applied work and may not keep up with advances in statistical methodologies.[105,106] In his provocative article "How Many Discoveries Have Been Lost by Ignoring Modern Statistical Methods," Wilcox asserts that many psychological journals "are littered with nonsignificant results that would have been significant if a more modern method had been used."[101(p300)] Cummings et al[107] researched the 10 leading international journals that publish empirical research and indicated that there is little change in statistical procedures and that NHST continues to dominate. They also noted that the reporting of confidence intervals (CIs) was increasing, albeit slowly, and that CIs are seldom used for interpretation. This is especially interesting since the APA Task Force on Statistical Inference advocated for improved statistical practices, including reporting effect sizes and confidence intervals.[108]

Another reason for the lack of the application of statistical methodologies is the scarcity of personnel trained in quantitative methods, especially the newer more complex techniques.[109] Additionally, with few exceptions, the majority of textbooks in research and statistics focus on NHST with little or no attention paid to single-case designs or especially to statistical methods to evaluate single-system designs.[44]

Conclusion

Single-subject designed research has a rich tradition of providing evidence for the effectiveness of interventions applied to solving a diverse range of human problems.[15] Over the past decade, advances in this area have included new developments in research design, visual and statistical analyses, and methods for summarizing single-case interventions. In today's military environment, with the shortage of mental health personnel and the increase in workload, the need for evidenced-based practices, as well as efficacy in practice, has never been greater. The time for implementation of single-subject clinical research has come. Although the need for traditional research design and analysis remains, the reality of clinical practice is that patients are provided care on an individual basis. This care takes into account the individual differences of the patients as well as the providers. It is important to keep in mind that statistical and research design resistance to progress has not benefited the mental health field.[101]

Looking ahead, it is in the best interest of the DoD to integrate single-case designs as an evaluation tool for clinical mental health services.[45] The collection of the reliable data obtained from multiple providers throughout the DoD using single-case designs can produce a quality sample to further evaluate. The evaluation of these data through meta-analysis coupled with the use of effective statistical procedures can provide a broader understanding of the most beneficial and cost-effective treatments being provided, which is ultimately an efficient and effective way to create changes to policies based on empirically collected and analyzed data. The current circumstances of both the mental health field and the budget make this a prime opportunity to employ the use of single-case designs to become more efficient.[53]

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A Descriptive Analysis of Data from the Department of Defense Joint Trauma System Prehospital Trauma Registry

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Abstract

The active battlefield is an environment of chaos and confusion. Depending on the scale of combat, the chaos and confusion often extend into the prehospital combat setting with multiple personnel and units involved in the chain of care of casualties. The chaos of the prehospital combat setting has led to limitations in the availability of data for performance improvement and research. The Department of Defense (DoD) Joint Trauma System (JTS) Prehospital Trauma Registry (PHTR) was developed in conjunction with the updated Tactical Combat Casualty Care (TCCC) card and a TCCC after action report (AAR), and currently serves as the prehospital repository and module of the DoD Trauma Registry (DoDTR). We conducted a descriptive analysis of data from the DoDTR PHTR.

Methods: The JTS collected trauma-associated data which comprise the PHTR are consolidated from TCCC cards and TCCC AARs. Where possible (requires 2 patient identifiers), JTS linked data from the PHTR module to other modules in the DoDTR to maximize availability of prehospital data and gain additional information regarding clinical outcomes.

Results: From January 2013 through September 2014, there were 705 patients available for research, of which 94.8% (668/705) had data from TCCC AARs, 3.3% (23/705) had data from TCCC cards, and 2.0% (14/705) had data available from DoDTR collection forms. There were one or more of the following data points per subject: pulse rate (77.4%, n=546), blood pressure (75.9%, n=535), respiratory rate (76.5%, n=539), pulse oximetry (61.8%, n=436), mental status (96.0%, n=677) and pain score (24.5%, n=173). Only 42.4% (647/1,527) of vital sign metrics had an associated time stamp. Documented interventions included limb tourniquets, of which only 27.3% (113/414) had an associated documentation of application time. Only 27.0% (190/705) of patients in the PHTR could be linked to the DoDTR due to missing identifiers.

Conclusions: The PHTR data capture was suboptimal with many patients lacking documentation of vital signs and procedural details. Future efforts to improve prehospital data capture will require ownership and enforcement by unit leadership.

Background

War is ninety percent information.
Napoleon Bonaparte

During the recent conflicts in Afghanistan and Iraq, the United States has achieved the lowest recorded case fatality rates for combat casualties in the history of American warfare.[1-3] This accomplishment was primarily due to a reduction in prehospital or killed in action deaths, which in turn was due to improved prehospital treatment and transport of combat casualties. However, preventable death studies during these same conflicts identified additional room for improvement, particularly in the realm of prehospital mortality.[4-7] Optimizing outcomes for combat wounded who die in the prehospital setting has proved challenging, especially as resources directed toward this goal remain limited.

In 2004, the Department of Defense (DoD) initially created a Joint Theater Trauma System and Joint Theater Trauma Registry (JTTR) to conduct performance improvement on casualties who incurred traumatic injury in the US Central Command (CENTCOM) theater of combat.[8,9] The DoD subsequently established the Joint Trauma System (JTS) to provide centralized efforts for multiple theaters and commands worldwide. The DoD further centralized the JTTR to form the DoD Trauma Registry (DoDTR). A desired end-state for this registry was to collect and analyze combat casualty data from the point of injury and throughout the continuum of care. This registry was largely successful in capturing Role 3 (temporary full-capability hospital inside combat zone) and Role 4 (permanent full-capability hospital outside combat zone) data. However, it was initially less successful in capturing Role 2 (temporary limited-capability

forward-positioned hospital inside combat zone) and Role 1 (prehospital point of injury, casualty collection point, battalion aid station) data.

To achieve better capture data from Role 2 facilities, the JTS developed intake forms and a database for use by these facilities. There were no mandates or resources allocated to these efforts and Role 2 personnel ultimately collected these data as an additional volunteer duty. Data capture proved to be intermittent and inconsistent within and between facilities.[9,10] Although a subsequent mandate to capture these Role 2 data improved capture, the mandate was only partially effective as it lacked personnel resourcing and an enforcement mechanism to ensure adherence.

Modeled after successful efforts from the 75th Ranger Regiment,[7,11-14] the DoD JTS subsequently developed prehospital documentation tools and a prehospital trauma registry (PHTR) to facilitate the capture of prehospital data from Role 1 and 2 entities alike.[15-17] Using the tactical combat casualty care (TCCC) card adopted by the Committee on TCCC[18] and based on the 75th Ranger Regiment casualty card, the JTS worked with the Defense Health Agency to update, rename, and replace the DD Form 1380 Field Medical Card dated December 1991 with a new DD Form 1380 Tactical Combat Casualty Care Card dated June 2014. This new card sought to align prehospital documentation with current clinical practice guidelines, to facilitate the documentation of initial care provided by both nonmedical and medical first responders, and to standardize prehospital data collection to optimize performance improvement. The intent was to attach the card to the patient to convey vital prehospital information to providers at the next role of care, and to also preserve data for entry into a registry for individual and aggregate analysis and performance improvement.

The new DD Form 1380 TCCC card reflected modern day prehospital combat trauma practices, and followed a "MIST" (mechanism, injury, signs and symptoms, treatment) format. The JTS also developed a TCCC after action report (AAR) adapted and modified from the 75th Ranger Regiment as another opportunity to capture prehospital data. The TCCC AAR retained similar features of the TCCC card, except with additional detail. The TCCC AAR was to be completed as soon as feasible following a mission and submitted through the chain of care or directly to the JTS.

Development of the PHTR occurred in parallel with the TCCC card and TCCC AAR. The design of the PHTR sought to optimize data capture to facilitate prehospital performance improvement.[17] The Commander, US Forces-Afghanistan issued Fragmentary Order 13-139* in July 2013 which mandated the use of the TCCC card and the TCCC AAR for all combat casualties in Afghanistan. Simultaneously, the DoD established a prehospital directorate comprised of physicians, physician assistants, and combat medics with extensive prehospital experience who were also trained by the JTS to serve as consultants to build and sustain the PHTR. However, after more than a year of data collection and progress, as forces deployed to Afghanistan were reduced, the DoD withdrew JTS personnel resources from the combat theater. Prior to this withdrawal, 2 comprehensive reviews were conducted by senior military physicians and remain a source for prehospital combat trauma issues and recommendations.[19,20]

Goal of this Study

The purpose of this study was to provide a descriptive analysis of data within the DoD JTS PHTR.

Methods

The JTS collected prehospital TCCC cards and TCCC AARs for casualties injured during combat operations conducted in Afghanistan from January 2013 to September 2014. Joint Trauma System personnel entered these data into the PHTR. This study met US Army Institute of Surgical Research regulatory requirements (USAISR protocol H-16-013). We analyzed data considered to be "required" items on TCCC cards as listed on the front side of the card, shown in the Figure.

Prehospital Trauma Registry

The JTS PHTR is a data collection and analytic tool designed to provide near-real time feedback to commanders. As described by Kotwal and colleagues,[12] the primary purpose of this tool is to improve casualty visibility, augment command decision-making processes, and direct procurement of medical resources. Additionally, this tool seeks to reduce morbidity and mortality through performance improvement in the areas of primary prevention (tactics, techniques, and procedures), secondary prevention (personal protective equipment), and tertiary prevention (casualty response system and TCCC).[19] The CENTCOM JTS Prehospital Directorate collected TCCC cards and TCCC AARs, and transferred information from these documentation tools into the PHTR.[17]

Department of Defense Trauma Registry

The DoDTR, which evolved from the JTTR, is a centralized data repository for DoD trauma-related injuries. The DoDTR consolidates data and information about demographics, injury-producing incident, diagnosis,

*Internal military document not readily accessible by the general public.

treatment, and outcomes of injuries sustained by US and non-US military forces, and US and non-US civilian personnel, in wartime and peacetime from the point of injury to final disposition. When possible, the JTS personnel linked subjects from the PHTR to the DoDTR.

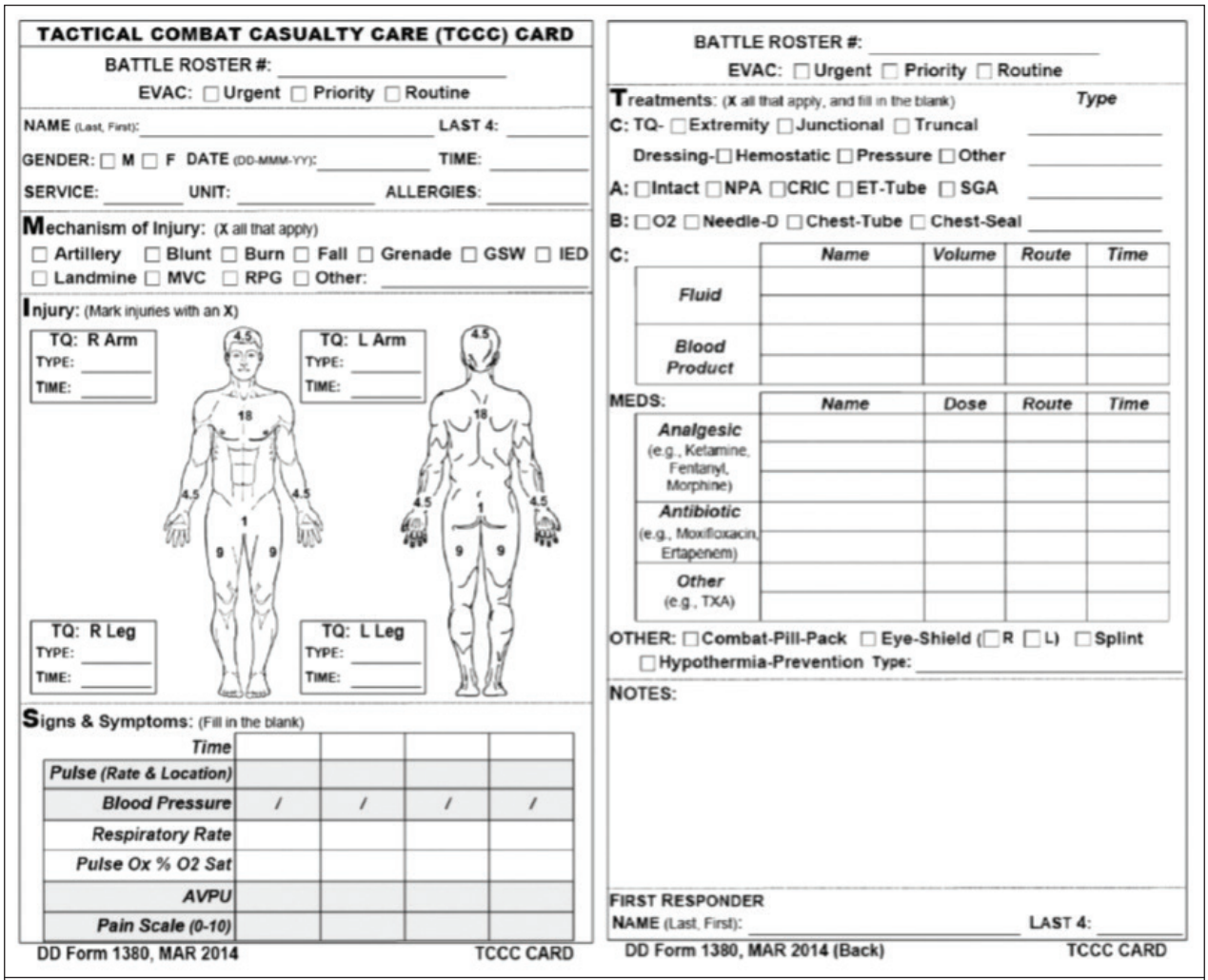
Data Analysis

We performed all statistical analysis using Microsoft Excel Version 10 and IBM SPSS Version 24. We used descriptive statistics to analyze PHTR data availability and completeness.

Results

From January 2013 through September 2014, 737 documented patient encounters were entered into the PHTR. Excluded from further study were 32 casualties who were either killed in action (24/32), dead on arrival (5/32), or an enemy prisoner of war (3/32). Of the 705 patients available for study, 94.6% (668/705) had data primarily from completed TCCC AARs, 3.3% (23/705) had data primarily from completed TCCC cards, and 2.0% (14/705) had data obtained primarily from DoDTR intake forms completed upon patient arrival at a Role 2 or Role 3 medical treatment facility.

Patient encounters were predominantly a result of battle injuries (91.2%, 643/705). As shown in the Table, most patients had documentation of mechanism of injury (100%, 705/705), military service (99.9%, 704/705), gender (98.2%, 692/705), and military unit (94.3%, 665/705). A full or partial set of prehospital vital signs was available for most patients. However, there was no documentation of prehospital vital signs for 13.7% (97/705) of patients. There were 1,527 full and partial prehospital vital sign sets recorded, including repeat measurements. Additionally, 42.4% (647/1527) of these vital signs had an associated time stamp. There were 501 documented instances of analgesia administration to 56.3% (397/705) of the study population. However, only 43.6% (173/397) of individuals who received analgesia also had



DD Form 1380, Tactical Combat Casualty Care Card.

a documented preanalgesia pain score. However, none of these individuals had a documented postanalgesia pain score. As a surrogate marker of data gaps, we identified documentation of 414 tourniquets. Of these, only 27.3% (113) included documentation of application time. Of the 705 patients in the PHTR during this period, 190 (27.0%) were linkable to the DoD Trauma Registry. The remaining 515 lacked the required 2 patient identifiers to link the patients between the 2 registries as the identifiers were either missing or inaccurate.

Documented items for the study population (N=705) recorded in the DoD Joint Trauma System Prehospital Trauma Registry.

Item	Number	Percentage N
Evacuation Status	661	93.8%
Gender	692	98.2%
Event Time	622	88.2%
Service	704	99.9%
Unit	665	94.3%
Allergies	209	29.6%
Mechanism of Injury	705	100%
≥1 Pulse Rate	546	77.4%
≥1 Blood Pressure*	535	75.9%
≥1 Respiratory Rate	539	76.5%
≥1 Pulse Oximetry	436	61.8%
≥1 AVPU†	677	96.0%
≥1 Pain Score	173	24.5%

*Blood pressures included both standard blood pressure measurements as well as estimated blood pressure measurements (ie, estimated 90 systolic by palpation of radial artery).
†APVU indicates alert, pain, verbal, unresponsive.

Comment

Documentation of care in the prehospital combat setting has proven to be challenging for US military forces during the conflicts in Afghanistan and Iraq.[21] The aim of the PHTR was to provide improved capture of data from the prehospital combat setting. In this analysis, we found that most subjects had demographic and evacuation information completed along with at least one vital sign. However, pain scores were not routinely available. We also found that most tourniquets placed did not have a documented placement time. It is plausible that documentation times occurred via another medium, such as directly onto the tourniquet or the patient. However, there was limited capture of those data into the PHTR.

Multiple articles have commented on the inadequacy and need for improved prehospital combat documentation and data capture.[1,3,4,7,9,12,14,16-26] However, there are limited published data that actually quantify prehospital combat documentation deficiencies.[14,17,24-26] This analysis was unique in that we identified and quantified these deficiencies in the documentation provided by US military prehospital personnel after the implementation of standardized TCCC cards and TCCC AARs in Afghanistan.

The results of this study demonstrate that TCCC card completion rates were low, with TCCC card data available for only 3.3% (23/705) of PHTR encounters from January 2013 through September 2014. This level of adherence and completion was less than the 7% to 14% previously reported.[17,23] The remaining 96.7% (682/705) of PHTR encounters arose from TCCC AARs and backfilling of data from DoDTR forms upon reaching a higher role of medical care (eg, forward surgical team or combat support hospital). The results of this study reaffirm the need for improved documentation practices by US military personnel in the prehospital combat setting. Improving care for casualties in the prehospital combat setting requires training to a standard. This standard is set through best practice clinical recommendations outlined by evidence-based guidelines such as TCCC. Validation, refinement, and optimization of these guidelines occur via analysis of data. Data are reliant on the documentation efforts of prehospital first responders. Thus, medical and nonmedical first responders must understand the importance of documentation and train to accomplish this vital task.

Suboptimal documentation practices likely stem from inadequate time and insufficient leader emphasis and enforcement. Many Soldiers may perceive documentation of care as relatively unimportant compared to care delivery, particularly for a lone medic treating combat casualties during a firefight. However, improving the treatment of future casualties, and reducing morbidity and mortality, relies on documentation and data collection. Although enemy actions, environmental conditions, and patient acuity can influence documentation practices, documentation nevertheless remains an important priority. Training is imperative, and US military leaders should consider implementing several measures to increase prehospital documentation efforts.

In concert with practices already implemented by United Kingdom military forces, both medical and nonmedical personnel in combatant units should train to record care on prehospital documentation tools. Combatant units already routinely assign recorders for documentation tasks such as collection of enemy information, site exploitation, logging of radio communication transmissions, and filling out 9-line medical evacuation requests. As the TCCC card is a relatively simple documentation tool, recorders can easily become proficient with its use without needed detailed medical training.

Additionally, air and ground prehospital patient transport personnel should briefly stay at the receiving military treatment facility after delivering patients to complete prehospital patient care records. This was the method used in a previous successful prospective investigation,[23] and also aided in the capture of data for retrospective studies.[3,16,27,28] Completion of prehospital documentation at a medical treatment facility should be a shared

responsibility, with a medical transport crewmember and a medical treatment facility emergency room staff member pre-identified for compliance assurance of documents before release of prehospital transport personnel for the next mission. As part of quality assurance, dedicated personnel should be available within theater to actively track missing data in a rapid and prospective manner.

The 2017 National Defense Authorization Act has placed an emphasis on improving and maintaining operational medical force readiness—specifically, standardization of TCCC and the development of a trauma care registry. As there is notable variability between TCCC courses taught within the DoD, this lack of standardization could be a significant contributor to the lack of prehospital documentation. Technology has contributed to increased survivability through direct patient care; however, it is currently lacking in respect to prehospital documentation. A hands-free interface that interacts with communication devices such as smart-phones could greatly enhance documentation in the prehospital setting.

Summary Recommendations

- All nonmedical personnel within units should undergo training to serve as medical recorder for the medic and medical officers to improve documentation quantity and quality while not detracting from the time available for healthcare delivery to combat casualties.
- Prehospital transport teams should provide prospective input into the registry, similar to the method used for DoDTR form completion. Prospective real-time quality assurance methods, including dedicated in-theater personnel, should be available to ensure timely and accurate completion of records.
- There should be a mandate and enforcement for completion of medical data collection across the DoD. Commanders should be held accountable for ensuring this task is completed. A near real-time feedback loop in theater would inform commanders on medical documentation adherence.
- Development of technology that allows for input of data with rapid movement of the data "forward" in the patient chain-of-care should be a priority.

Conclusions

The DoD recently updated prehospital documentation tools. The implemented changes sought to align documentation tools to identify compliance with TCCC guidelines, simplify documentation and to facilitate rapid documentation. The PHTR aimed to consolidate and analyze the data collected from these documentation tools. The PHTR data capture was suboptimal with many patients lacking documentation of vital signs and procedures. Future efforts to improve prehospital data capture will require ownership and enforcement by unit leadership.

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A 12-Month Descriptive Analysis of Emergency Intubations at Brooke Army Medical Center: A National Emergency Airway Registry Study

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Abstract

Emergency airway management is a critical skill for military healthcare providers. Our goal was to describe the Emergency Department (ED) intubations at Brooke Army Medical Center (BAMC) over a 12-month period.

Material and Methods: Physicians performing endotracheal intubations in the BAMC ED complete data collection forms for each intubation event as part of the National Emergency Airway Registry, including patient demographics, intubation techniques, success and failure rates, adverse events, and patient disposition. We cross-referenced these forms against the numbers of intubation events reported in the ED nursing daily reports to ensure capture of all intubations. Providers completed forms for every intubation within 6 weeks of the procedure. We analyzed data from March 28, 2016, to March 27, 2017.

Results: During the study period, providers performed 259 intubations in the BAMC ED. Reasons for intubation were related to trauma for 184 patients (71.0%) and medical conditions for 75 patients (29.0%). Overall, first-attempt success was 83.0%. Emergency medicine residents performed a majority of first attempts (95.0%). Most common devices chosen on first attempt were a video laryngoscope for 143 patients (55.2%) and a direct laryngoscope for 115 patients (44.4%). One patient underwent cricothyrotomy. The 2 most common induction agents were ketamine (59.8%; 95% CI, 55.2%-67.4%) and etomidate (19.3%; 95% CI, 14.7%-24.7%). The most common neuromuscular blocking agents were rocuronium (62.9%; 95% CI, 56.7%-68.8%) and succinylcholine (18.9%; 95% CI, 14.3%-24.2%).

Conclusion: In the BAMC ED, emergency intubation most commonly occurred for trauma indications using video laryngoscopy with a high first-pass success.

Endotracheal intubation is a critical skill for emergency physicians. While anesthesiologists have historically taken ownership of the procedure, emergency physicians are increasingly responsible for performing this intervention. Studies over the past 2 decades estimate the proportion of emergency department (ED) intubations performed by emergency physicians ranges from 89% to 95%.[1-3] This procedure is of particular importance to the military emergency physician as airway emergencies account for 9% of preventable deaths on the battlefield.[4] Adequate experience with this procedure in garrison will help to ensure physician readiness to execute this life-saving intervention in the deployed environment.

As the military's largest hospital and only level 1 trauma center, Brooke Army Medical Center (BAMC) is an ideal training platform to offer physicians such experience in intubation procedures. The size and scope of the capabilities and care responsibilities of BAMC are the result of the closure of the USAF Wilford Hall Medical Center and consolidation of its functions into BAMC as mandated by the Defense Base Closure and Realignment Commission decisions of 2005.[5] It is responsible for the care of active duty and retired military personnel and military beneficiaries, as well as sharing emergency medical care responsibilities with area civilian hospitals for nonmilitary trauma patients received from the surrounding communities.

In 2016, the BAMC ED initiated research-based surveillance of its intubation practices as part of the National Emergency Airway Registry (NEAR), a multicenter observational intubation registry coordinated through

Brigham and Women's Hospital in Boston, Massachusetts.[3,6] This article presents an overview of the data collected during the first 12-month period of study at BAMC. Our objective was to describe the intubation experiences, practices, and outcomes of the active duty physicians in this unique setting.

Materials and Methods

Study Design

We conducted a prospective observational study of intubations in the BAMC ED as part of the facility's participation in NEAR.[3,6] Data collection began on March 28, 2016. The Brooke Army Medical Center Institutional Review Board approved the study. The US Army Medical Research and Material Command approved the data sharing agreement with Brigham and Women's Hospital for participation in NEAR.

Setting

Brooke Army Medical Center is an urban tertiary care academic hospital and the only level 1 trauma center in the Department of Defense (DoD). The ED sees approximately 82,000 patients annually that includes active duty and retired military personnel, military beneficiaries, and nonmilitary trauma patients received from the surrounding communities. Brooke Army Medical Center is affiliated with the San Antonio Uniformed Services Health Education Consortium, the largest sponsoring institution for graduate medical education in the military and hence a major training platform for residents and fellows within the DoD. The ED hosts a 3-year emergency medicine training program with each class typically comprising 16 residents (48 residents total).

Selection of Patients

This study includes all patients intubated during the first 12-month period of data collection at BAMC for the NEAR registry during the period March 28, 2016 through March 27, 2017. All patients intubated in the ED were eligible for inclusion. There were no exclusion criteria.

Study Methodology

Intubating providers recorded data about each intubation using a data collection form. This form is standardized across all NEAR sites. Variables included patient demographics, indication for intubation, intubation device, pharmacologic agents, operator characteristics, intubation success or failure, and adverse events. When intubation was not successful with the first attempt we solicited data on additional attempts (up to 5 attempts total). All study variable definitions and data collection forms were in accordance with those established by NEAR.[3]

Providers recorded all such data as soon as possible. Providers then deposited completed forms in a secured file cabinet situated in the emergency department. Research assistants cross-referenced complete forms with daily nursing reports of intubations performed in the ED to ensure capture of forms on 100% of ED intubations. These assistants contacted the intubating providers as identified by the daily nursing reports via e-mail, phone, or in person to obtain missing forms.

We considered data missing for intubations performed during the study period if entered more than 6 weeks after the intubation attempt. Upon completion of data entry, we uploaded these data into a centralized web-based data management StudyTRAX Version 3.47.0011 database (ScienceTRAX, Macon, GA). Following upload, NEAR personnel based at Brigham and Women's Hospital reviewed all data using quality assurance algorithms to minimize occurrence of data entry errors. We retrieved missing data whenever possible by interview of the intubating provider or manual chart review.

Analysis

For the purposes of our analysis, we exported all data to IBM SPSS, Version 22. We used descriptive statistics to describe intubation indications, intubating provider characteristics, intubation methods and devices, drugs used, and patient outcomes. We calculated 95% confidence intervals (CI) for select outcomes. We did not perform a sample size estimate as our intent was to perform a descriptive analysis of the experience of all emergency intubations in our ED during a 12-month period. We did not perform inferential statistical testing.

Results

During the period of the study, physicians performed all 259 intubations in the BAMC ED as confirmed by daily nursing reports. The mean time from procedure to data entry was 0.2 days (95% CI, 0.1-0.5). The time from intubation to data entry was less than 24 hours for 249 (96.1%) of intubations. Data was captured for each of the other 10 procedures within 6 weeks of occurrence.

Indications for intubation were related to trauma for 184 patients (71.0%) and medical conditions for 75 patients (29.0%). As shown in Table 1, the most common trauma indications for intubation included polytrauma (22.3%) and head injury with hemorrhage (19.6%). The most common medical indications for intubation, shown in Table 2, included noningestion-related altered mental status (28%) and cardiac arrest (18.7%).

Physicians achieved first-attempt success in 215 patients (83.0%; 95% CI, 77.9%-87.4%). The detailed data is

Table 1. Trauma Indications for Intubation (n=184).

Indication	Number of Patients	% n	95% CI
Abdomen trauma	4	2.2	0.5%-4.3%
Burn/inhalation injury	16	8.7	4.9%-13.0%
Chest trauma	14	7.6	3.8%-12.0%
Combative/agitated	24	13.0	8.2%-17.9%
Facial trauma	8	4.3	1.6%-7.1%
Head injury without hemorrhage	14	7.6	4.3%-12.0%
Head injury with hemorrhage	36	19.6	14.1%-26.0%
Neck trauma	3	1.6	0%-3.8%
Polytrauma	41	22.3	16.3%-28.3%
Shock (hemorrhagic)	5	2.7	0.5%-4.9%
Shock (spinal trauma)	1	0.5	0%-1.6%
Traumatic arrest	18	9.8	5.9%-15.0%
Total	184	100.0	

presented in Table 3. One patient who sustained a gunshot wound to his face underwent a primary cricothyrotomy as the first method of endotracheal intubation. No patient required a cricothyrotomy as a result of a failed attempt at oral intubation. There were no significant differences in first-attempt intubation success percentages compared across alternative study variables.

Emergency medicine residents performed 246 of 259 first attempts (95.0%). Forty-six of the residents were in postgraduate year (PGY) 1, 166 were PGY 2, and 34 were PGY 3. Two hundred four (82.9%) first attempts performed by residents were successful. Of the 13 intubations not managed primarily by emergency medicine residents, 7 were performed by emergency medicine attending physicians and 6 by anesthesiology attending physicians.

Table 2. Medical Indications for Intubation (n=75).

Indication	Number of Patients	% n	95% CI
Airway obstruction*	2	2.7	0%-6.7%
Asthma	1	1.3	0%-4.0%
Cardiac arrest	14	18.7	9.4%-28.0%
Congestive heart failure	3	4.0	0%-9.3%
COPD	2	2.7	0%-6.7%
Gastrointestinal bleed	2	2.7	0%-6.7%
Intracranial hemorrhage	4	5.3	1.3%-12.0%
Myocardial infarction	2	2.7	0%-6.7%
Non-overdose mental status change	21	28.0	17.3%-38.7%
Overdose	6	8.0	2.7%-14.7%
Pneumonia	4	5.3	1.3%-10.7%
Seizure	5	6.7	1.3%-13.3%
Shock (cardiogenic)	2	2.7	0%-6.7%
Shock (sepsis)	4	5.3	1.3%-10.7%
Shock (distributive, not sepsis)	2	2.7	0%-6.7%
Stroke	1	1.3	0%-4.0%
Total	75	100.0	

*Not anaphylaxis or angioedema.
COPD indicates chronic obstructive pulmonary disease.

Direct laryngoscopy were used in first attempts for 115 patients (44.4%) and video laryngoscopy for 143 patients (55.2%). The most commonly used device for video laryngoscopy was the Glidescope (Verathon Inc., Bothell, WA), accounting for 137 of these attempts. First-pass success percentage was 73.0% (95% CI, 64.0%-80.9%) for direct laryngoscopy versus 90.9% (95% CI, 85.0%-94.7%) for video laryngoscopy. Induction agents most commonly used during first attempts included ketamine for 155 patients (59.8%; 95% CI, 55.2%-67.4%) and etomidate for 50 patients (19.3%; 95% CI, 14.7%-24.7%). For neuromuscular blocking agents, providers used rocuronium for 163 patients (62.9%; 95% CI 56.7%-68.8%) and succinylcholine for 49 patients (18.9%; 95% CI ,14.3%-24.2%).

Sixty-one of 259 (23.6%) patients intubated experienced 80 peri-intubation adverse events during the first attempt (Table 4). The most commonly reported adverse event included was hypoxia (59%) defined as an oxygen saturation less than 90%. The next most common peri-intubation adverse events were hypotension reported in 13 patients and cardiac arrest reported in 10 patients. The probability of adverse event was similar for second attempts (23.8%). We observed limited numbers of third (n=7), fourth (n=4), and fifth attempts (n=1), making it difficult to assess the risk of adverse events for these subsequent efforts.

Comment

Endotracheal intubation is a critical skill for military healthcare providers as part of combat casualty care in the deployed environment.[7-9] We report on 12 months of emergency airway management experiences at BAMC as part of its participation in the NEAR registry.[3] In total, we reported 259 intubations, of which 83.0% were successful upon first attempt. Emergency physicians performed most intubations for trauma indications. These data provide an overview of the stateside emergency airway management experience at the military's largest hospital and only level 1 trauma center.

The indications for a majority (71.0%) of intubations were related to trauma. This reflects the BAMC trauma program's treatment of civilian trauma patients.[10] Our results highlight the substantial proportion of our procedural experience arising from our participation in this program. By extension, these results highlight the importance

of our participation in this program in maintaining the medical readiness of our force.

To this point, our first-pass success percentage of 83.0% is identical to that reported for ED centers nationwide as part of the NEAR registry during 2002-2012.[3] This suggests a comparable level of skill between the military practitioners in our hospital compared to civilian counterparts. This finding is noteworthy given recognition of the importance of experience and patient volume for procedural competence.[11] Indeed, authors have voiced concerns regarding the potential lack of adequate exposure to sufficient procedure volume in domestic military treatment facilities for military healthcare providers to achieve and maintain clinical skills.[12,13] Our findings suggest that BAMC, together with off-service rotations at outside civilian hospitals, provide the emergency medicine trainees managing the majority of emergency airways at BAMC with adequate procedure volume to maintain airway management competence.

While 259 intubations in a 12-month period is substantial by the standards of a military treatment facility, it is a modest intubation volume by the standards of many civilian academic centers. Comparatively, a similar study observing all intubations performed during one calendar year at the University of California, Davis, Medical Center reported 610 intubations.[2] This represents an annual intubation gap of more than 350 procedures between BAMC and busy civilian academic centers. While our data suggest the volume at BAMC is adequate to train emergency physicians to the level of their civilian peers, the gap highlights the ongoing challenges faced by military healthcare providers to maintain procedural competence. This challenge is of particular concern at smaller military healthcare facilities seeing much lower patient volumes.

Emergency medicine residents managed 95% of first attempts which is a testament to the educational mission of the BAMC ED. By way of comparison, previous iterations of NEAR reported the proportion of ED intubations managed by emergency medicine residents ranging from 77% to 79%.[1,3] The residents play a pivotal role in managing airways for critically ill and injured patients presenting to BAMC. Maintaining this focus on resident airway management will be imperative moving forward to ensure the best possible training for military emergency medicine residents prior to deployment as attending physicians. Our results highlight that this focus does not come at the expense of clinical outcomes or patient safety.

There are several notable differences in the intubation practices in our cohort as compared to nationwide statistics reported in the NEAR registry.[3] First, a larger proportion of intubations in our cohort used video laryngoscopy—55.2% at BAMC versus approximately 10% in the NEAR registry. We suspect this largely reflects the different time periods examined; even within the earlier time period examined by the NEAR registry data (2002-2012), there was a clear trend towards increasing use of video laryngoscopy. We found a higher percentage of first-pass intubation success with video laryngoscopy (90.9%) as compared to direct laryngoscopy (73.0%). The literature reports conflicting findings regarding relative intubation success with direct versus video laryngoscopy.[14-16] Our finding of higher first-pass success with video laryngoscopy may reflect less experience among our intubating providers with direct laryngoscopy rather than the superiority of video technology.[17] Further research on this question using the

Table 3. First Attempt Intubation Characteristics and First-Attempt Successes (N=259).

Study Variable	Number of Patients (n)	Successful First Attempts		95% CI
		Number	% n	
Indications				
Medical	75	58	77.3	68.0%-86.7%
Trauma	184	157	85.3	79.9%-90.2%
First Attempt Operator				
EM1	46	34	73.9	60.9%-87.0%
EM2	166	141	84.9	79.5%-90.4%
EM3	34	29	85.3	73.5%-97.1%
EM attending	7	7	100.0	-
Anesthesia	6	4	66.7	-
First Attempt Device*				
Direct laryngoscopy	115	84	73.0	64.0%-80.9%
Video laryngoscopy	143	130	90.9	85.0%-94.7%
First Attempt Method				
Paralytic and sedative	211	184	87.2	82.5%-91.5%
Sedative only	5	4	80.0	-
Paralytic only	2	2	100.0	-
No medications	41	25	61.0	43.9%-75.6%
First Attempt Induction Agent				
Etomidate	50	41	82.0	72.0%-92.0%
Ketamine	155	138	89.0	83.9%-93.5%
Midazolam	2	1	50.0	-
Propofol	9	8	88.9	-
None	43	27	62.8	48.8%-76.7%
First Attempt Paralytic Agent				
Rocuronium	163	145	89.0	84.0%-93.3%
Succinylcholine	49	40	81.6	69.4%-91.8%
Vecuronium	1	1	100.0	-
None	46	29	63.0	47.8%-76.1%

*One patient underwent first-attempt cricothyrotomy.
EM indicates emergency medicine.

Table 4. First Attempt Peri-intubation Adverse Events Occurring in Patients (n=61).

Adverse Events	Number of Patients	% n*	95% CI
Airway trauma	2	3.3	0.3%-11.9%
Cardiac arrest	10	16.4	9.0%-27.8%
Dysrhythmia	3	4.9	1.1%-14.0%
Esophageal intubation (delayed recognition)	2	3.3	0.3%-11.9%
Esophageal intubation (immediate recognition)	2	3.3	0.3%-11.9%
Hypotension	13	21.3	12.8%-33.3%
Hypoxia	36	59.0	46.5%-70.5%
Main-stem intubation	5	8.2	3.2%-18.2%
Tachy-dysrhythmia	1	1.6	0.0%-9.6%
Vomiting	6	9.8	4.3%-20.2%

*Percentages do not total 100% as some patients experienced multiple adverse events.

broader NEAR registry will be of value to the military and emergency medicine communities. Should such research conclude superiority of video laryngoscopy, the literature would benefit from cost-effectiveness analyses of ensuring widespread availability of such devices for deployed personnel.[18]

Our study also reports a unique distribution of pharmacologic agents used for rapid sequence intubation (RSI). In our cohort, a far higher proportion of patients received ketamine for induction (59.8%) as compared to that reported by the historic NEAR registry (1.0%).[3] This finding could indicate a change in national trends as recent literature has suggested better outcomes with ketamine compared with more traditional induction agents (eg, etomidate) among trauma[19] and sepsis patients.[20] The increased use of ketamine in our population may also reflect intubating culture at BAMC given the frequent use of this medication by military physicians in the deployed environment and its recommended use for analgesia by the Tactical Combat Casualty Care guidelines.[21]

Similarly, our finding that physicians used rocuronium for 62.9% of patients and succinylcholine for only 18.9% of patients is different from what has been reported in previous NEAR reports[3] and non-NEAR facilities[22] where nearly three quarters of all RSIs involved succinylcholine. A growing literature suggests equivalent intubating conditions between these 2 agents when rocuronium is dosed at 1.0-1.2 mg/kg.[23] This makes rocuronium an attractive option, particularly given that succinylcholine is contraindicated for use in patients with diseases upregulating skeletal muscle acetylcholine receptors. Examples of such disease processes include spinal cord injuries and burns 72 hours or more from the time of injury.[24] Given that emergency medicine physicians may not necessarily be privy to the presence of these medical conditions when actively managing an airway emergency, it is understandable by the use of this agent is increasingly popular within the specialty of emergency medicine.[25]

This study has several limitations. As an observational study, we are unable to ascertain whether the apparent trends we observed (eg, higher first-pass success with video as compared to direct laryngoscopy) reflect correlation or causation. Moreover, given that it is a single center study, we have inadequate sample size to perform inferential analyses comparing first-pass success across alternative RSI regimens or intubation devices while controlling for potential confounders (eg, regression models, propensity matching). Moreover, given our reliance upon self-reported data, it is possible that biased responses skewed our results towards more favorable outcomes. In particular, reporting of some adverse events is more subjective than others and could be susceptible to under-reporting as a result of such reporting bias.

Another important limitation is that our results may have limited generalizability. The environment of BAMC is unique. As a military hospital, its experience may not be representative of the experience at civilian hospitals. Simultaneously, as the military's largest academic hospital and an urban tertiary care center, our data may not reflect the emergency airway management experience at smaller military treatment facilities or in the deployed environment. Nevertheless, generalizability was not our intent. Rather, we sought to describe the garrison experience for stateside military healthcare professionals at the epicenter of military medicine. In so doing, we intended to provide military trainees, educators, and leaders alike with a better understanding of the context in which military physicians practice and maintain readiness with regards to emergency airway management, a skill known to be critical for saving lives on the battlefield.[4]

It is our hope that these data related to endotracheal intubation will provide yet another building block to the growing literature exploring devices and training for the military related to airway management.[26-28] Future research with the NEAR registry will be useful for clarifying whether some of the trends observed in our study are generalizable to other settings (eg, the superiority of video to direct laryngoscopy for first-pass success). Future military research will benefit from additional airway registries at other military treatment facilities and the deployed environment to ascertain the unique characteristics of airway management in those settings.

In summary, this article reports the experience of emergency airway management at BAMC over a 12-month period. It highlights robust exposure to airway management opportunity for military healthcare providers at the military's largest emergency medicine residency. It further reports comparable outcomes in terms of intubation success as reported in the civilian literature. Taken together, these data highlight the substrate offered by this institution to maintain military health provider readiness and clinical competence to support the United States armed forces combat operations.

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An Evaluation of the Significance of Individual Endogenous Risk Factors and Medical and Orthopaedic Conditions on Physical Fitness in Military Executives

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Abstract

As part of occupational health promotion in the Bundeswehr (military services of the Federal Republic of Germany), top-ranking executives were offered a medical examination and training program. The participants were subjected to retrospective evaluation. The aim of this study was to determine to what extent risk factors for the development of internal and orthopaedic conditions are present in military executives and how these factors affect physical fitness. To collect their medical history, a total of 122 male subjects answered a questionnaire aimed at evaluating private and occupational stress factors. This process was followed by an internal and orthopaedic examination. A lactate performance test (treadmill or bicycle ergometry) was conducted. The results showed that the presence of hypertension correlates with reduced fitness. While orthopaedic conditions had no negative influence on executives' fitness, high body mass index and waist circumference, mental stress, and older age did. It is recommended that executives undergo professionally guided endurance and weight training on a regular basis in order to prevent the development of internal and orthopaedic conditions.

Military executives are faced with a different type of occupational stress than other employees. It is a known fact that executives are mainly confronted with mental challenges and, as a result, can also develop somatic pain, primarily in the cervical vertebral column and shoulders.[1] What is more, executives are an important target group in occupational health promotion,[2] and many companies have launched health promotion projects.[3] Executives are faced with less physical activity during working hours than other employees. At the same time, military executives are much more active during their leisure time than other military personnel.[4] In general, health behavior is influenced by, among other things, educational level, with those attaining higher educational levels showing a more health-conscious lifestyle.[5] Another study revealed that work-related travel and commuting activity correlate with a lower level of physical fitness in executives.[2] Particularly prominent risk factors for the development of cardiovascular disorders include high body mass index (BMI), low education level, smoking, excess weight, age, and male sex.[6] In addition, people in positions of high responsibility tend to develop nocturnal blood pressure peaks and acute heart disease.[6,7] Too little cardiopulmonary fitness can also cause the development of cardiovascular disease.[8] This can be verified with a lactate performance test.[9] The development of orthopaedic conditions, in particular back pain, is associated with insufficient trunk strength.[10] The aim of this study was to determine to what extent risk factors for the development of internal and orthopaedic conditions are present in military executives and how these factors affect physical fitness. The results of this retrospective observation study will lead to conclusions about how, as part of occupational health promotion, improvements can be made in the fields of physical fitness and disease prevention.

Material and Methods

Subjects

In total, 122 male subjects took part in the prevention program for executives during the study period. The average age was 54.6±4.2 years. The average BMI was 26.6±2.8 kg/m², and the average waist circumference was 95.9±8.2 cm. Prior to equipment-based testing, the subjects were given a standardised questionnaire on the following points: occupation, weekly working hours, alcohol consumption, smoking habits, commuting activity, exercise, mental stress, previous internal or orthopaedic disorders, and medications taken. This was followed by a nutritional analysis based on the *Freiburger Ernährungsprotokoll* (Freiburg Dietary Record). The subjects then provided a blood sample to determine the parameters glycated haemoglobin (HbA1c), blood count, alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT), γ-GT, sodium, potassium,

creatinine, urea, blood glucose, total cholesterol, HDL cholesterol, and LDL cholesterol.

Lactate Performance Test

For the performance test, 86 patients used a stationary bicycle (Ergometrics 900; ErgoLine; Baden-Württemberg, Germany) and 36 patients used a treadmill (ELG 70/200; Woodway; Waukesha WI. ECG; Spacelabs Healthcare, Hawthorne, CA). The choice of exercise equipment was based on whether subjects preferred running or other types of sports. For bicycle ergometry, a stress profile was chosen that was started at an individual level, with the intensity increasing by 50 watts every 3 minutes. For the treadmill ergometry, the stress profile was also started at an individual level and the speed increased by 1 km/h every 3 minutes. Measurement was discontinued when the patient became fatigued. Lactate levels were measured before the exercise, at the end of each 3-minute period of exercise, and during the recovery phase. Blood samples were taken from the ear. The earlobe was pricked with a lancet (safety lancet, prick depth 1.8 mm; Saarstedt; Nürnbrecht, Germany) and a drop of blood was collected by means of manual compression. The first drop of blood was discarded, and the second was collected in a capillary tube (heparin-coated end-to-end capillary; EKF; Magdeburg, Germany). This blood sample was stored in an analysis kit (glucose and lactate haemolysis solution; EKF; Magdeburg, Germany). Lactate concentration was then established using a spectrometer (Biosen S-Line; EKF; Magdeburg; Germany). The data obtained was evaluated using Winlactat software (V 4.6.3.21; Mesics GmbH; Münster, Germany). Performance or speed at 4 mmol/l lactate ($p_{4mmol\text{-}L}$, $v_{4mmol\text{-}L}$) and maximum performance or speed (p_{max}, v_{max}) were chosen as comparable parameters for evaluation.[11] Following an individual performance analysis, the subjects received sports medical advice.

Statistical Evaluation

A descriptive data analysis was conducted for all groups (establishment of minimum, maximum, mean, and median). Group rank sum comparison was conducted by means of the Kruskal-Wallis test. This was followed by a significance analysis using a χ^2 test. The significance level was set at $P>.05$. The Mann-Whitney U test was used to conduct pairwise comparisons. The significance level was determined at $P>.05$. For the correlation analysis, the correlation coefficient was determined in accordance with Pearson's r. The $P>.05$ value was specified as having a 2-tailed significance level. To determine the significance of individual factors affecting fitness, a multiple linear regression analysis was carried out. The coefficient of determination (R^2), the standardized (β) and nonstandardized (b) regression coefficients of the predictors together with the Pearson correlation coefficient (r) and squared semipartial correlation (sr^2) were reported. The statistical data analysis was carried out with IBM SPSS V 21.0 and the effect size was calculated with G*Power. According to Cohen, the effect size f^2 was interpreted as follows: $f^2=0.02$ minor effect, $f^2=0.15$ moderate effect, $f^2=0.35$ major effect.[12]

Results

Effect of Individual Determinants on Fitness

Age

To determine the effect of age on performance, the subjects were divided into two groups (Group 1, aged 55 years or less; Group 2, aged more than 55 years). As shown in Table 1, the bicycle cardiac stress test revealed that Group 1 was fitter than Group 2. The treadmill ergometry also showed this trend. Younger subjects were fitter than older subjects.

Body Mass Index

After establishing body mass index, the subjects were divided into 3 groups: Group 1, BMI<25 kg/m^2 (N=36); Group 2, BMI 25-30 kg/m^2 (N=73); Group 3, BMI>30 kg/m^2 (N=13). Within the 3 groups, the bicycle ergometry revealed no significant difference in performance at the 4 mmol lactate threshold and at maximum performance (Table 2).

The treadmill ergometry revealed no significant difference either, but the group with a BMI≤25 kg/m² tended to be fitter than the subjects with a BMI>25 kg/m² (Table 2). The physical fitness of executives decreased with increasing BMI, in particular on the treadmill.

Table 1. Overview of the performance of subjects by age group at the 4 mmol lactate threshold and at maximum performance in the bicycle ($p_{4mmol\text{-}L}$, p_{max}) in watts, and treadmill ($v_{4mmol\text{-}L}$, v_{max}) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol\text{-}L}$ W	p_{max} W	$v_{4mmol\text{-}L}$ km/h	v_{max} km/h
Group 1 (N=44/22) Subjects aged ≤55 years	175.0 (±36.3)	243.8 (±46.5)	11 (±1.6)	13.5 (±1.6)
Group 2 (N=42/14) Subjects aged >55 years	153.7 (±34.0)	200.7 (±44.6)	9.9 (±1.4)	12.3 (±1.1)
P	.003	.001	.053	.033

Body mass index was identified in the regression analysis as a predictor for physical activity. The model was significant: F=2.473 (P=.038) and the model equation correlated to R=0.338 with the criterion variable (R^2=0.114; R^2 adjusted=0.068; f^2=0.129; Power=0.99). The variance in physical activity was

Table 2. Overview of the performance of subjects by BMI group at the 4 mmol lactate threshold and at maximum performance in the bicycle ($p_{4mmol-L}$, p_{max}) in watts, and treadmill ($v_{4mmol-L}$, v_{max}) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	p_{max} W	$v_{4mmol-L}$ km/h	v_{max} km/h
Group 1 (N=20/16) BMI<25 kg/m^2	163.6 (±37.6)	237.7 (±52.9)	11 (±1.1)	13.1 (±1.3)
Group 2 (N=53/20) BMI=25 to 30 kg/m^2	163.8 (±37.0)	217.4 (±48.1)	10.2 (±1.8)	12.9 (±1.9)
Group 3 (N=13/0) BMI>30 kg/m^2	169.4 (±35.1)	221.7 (±53.9)	-	-
P	.853	.807	.08	.08

predicted to a significant extent by the variable BMI (ß=0.624; b=39.559; SE=2.487; *P*=.003; *r*=0.294; sr^2=0.294). Body mass index accounted for 7.8% of the variance in physical activity.

Waist Circumference

On the basis of the values measured, the subjects were divided into 3 groups: Group 1, up to 94 cm (N=46); Group 2, 94-102 cm (N=36); Group 3, <102 cm (N=24). Waist circumference was not recorded for 16 of the subjects.

The bicycle cardiac stress test revealed no significant difference between the groups at the 4 mmol lactate threshold (Table 3). However, a significant difference was established at maximum performance. Subjects with a small waist circumference were fitter (Table 3). Moreover, the subjects revealed a significantly lower heart rate at the individual anaerobic threshold (144/min (Group 1) vs 136/min (Groups 2 and 3); *P*=.026). The treadmill cardiac stress test also revealed a significant difference between the groups, which substantiates the result of the bicycle stress test (Table 3). Increased waist circumference in executives has a negative effect on physical fitness (*r*=-0.281; *P*=.015).

Nutrition

Subjects who provided information about their eating habits (N=107) were divided on the basis of their eating behavior into the following 4 groups: (1) isocaloric (balanced) (n=45); (2) hypercaloric (balanced) (n=12); (3) hypercaloric (imbalanced) (n=4); (4) hypocaloric (n=46).

Table 4 shows the average performance achieved. For the performance test, the statistical analysis showed no significant differences in the groups with the values for $p_{4mmol-L}$ or $v_{4mmol-L}$. There was no proof that nutrition had a significant effect on the fitness level of executives.

Smoking Habits

Subjects were asked about their nicotine consumption and were divided into 2 groups: smokers (N=17) and nonsmokers (N=105).

This study did not reveal any proof that smoking habits had a significant influence on the physical fitness of executives (Table 5). It turned out, however, that the majority of the executives were nonsmokers.

Physical Activity Outside of Working Hours

Nineteen of the subjects specified that they never engaged in any sports/exercise activity outside of working hours. Six persons did not provide any information about their physical activity. Executives who exercised regularly outside of working hours were more physically fit than those who did not (Table 6).

Effect of Health Conditions on The Physical Fitness of Executives

Diabetes Mellitus

Five of the 122 subjects in the study had diabetes mellitus. The study revealed no significant difference in physical fitness in comparison with the group that was not affected by the illness (data not shown).

Hypercholesterolemia

Fifty-eight of the 122 subjects had hypercholesterolemia. No significant difference in physical fitness was established between those affected and those not (data not shown).

Hyperuricemia

Of the 122 subjects, 17 had hyperuricemia. 14.4% of the senior officers (n=8) and 12.1% of the generals (n=8) were affected. No significant difference in

Table 3. Overview of the performance of subjects by waist circumference measurement at the 4 mmol lactate threshold and at maximum performance in the bicycle ($p_{4mmol-L}$, p_{max}) in watts, and treadmill ($v_{4mmol-L}$, v_{max}) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	p_{max} W	$v_{4mmol-L}$ km/h	v_{max} km/h
Group 1 (N=25/21) WC<94 cm	167.8 (±40.9)	239.5 (±52.5)	11.1 (±1.3)	13.6 (±1.4)
Group 2 (N=27/9) WC=94-102 cm	160.4 (±33.3)	214.3 (±46.2)	9.4 (±1.5)	11.5 (±0.9)
Group 3 (N=23/1) WC>102 cm	160.2 (±28.8)	204.3 (±39.7)	8.0	10.0
P	.599	.018	.012	.002

physical fitness was established between those affected and those not (data not shown).

Hypertension

Of the 122 subjects, 38 had high blood pressure. A significant difference was established at maximum performance in the treadmill and the bicycle stress tests. Subjects without high blood pressure were significantly fitter than those with high blood pressure. At the 4 mmol lactate threshold, this could be observed as a trend (Table 7).

Orthopaedic Disorders

A total of 98.2% of the senior officers (n=54) and 84.8% of the generals (n=56) specified that they had orthopaedic disorders.

No significant difference was established at the 4 mmol lactate threshold or at maximum performance in the bicycle cardiac stress test (Table 8).

Table 4. Overview of performance, grouped by nutrition information, at the 4 mmol lactate threshold in the bicycle ($p_{4mmol-L}$) in watts, and treadmill ($v_{4mmol-L}$) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	$v_{4mmol-L}$ km/h
Group 1 (N=37/8) isocaloric (balanced)	164.32 (±28.7)	10.05 (±1.8)
Group 2 (N=7/5) hypercaloric (balanced)	188.29 (±44.0)	9.9 (±1.2)
Group 3 (N=3/1) hypercaloric (imbalanced)	168.00 (±51.4)	8.8
Group 4 (N=29/17) hypocaloric	158.72 (±39.6)	10.67 (±1.5)
P	.215	.441

Table 5. Overview of the performance of subjects by smoking status at the 4 mmol lactate threshold in the bicycle ($p_{4mmol-L}$) in watts and the treadmill ($v_{4mmol-L}$) cardiac stress tests in km/h, and at maximum performance in the bicycle (p_{max}) in watts.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	$v_{4mmol-L}$ km/h	p_{max} W
Smokers (N=11/6)	166.91 (±41.6)	10.32 (±1.7)	209.73 (±48.2)
Nonsmokers (N=75/30)	164.27 (±36.0)	10.59 (±1.6)	224.68 (±63.4)
P	.856	.51	.403

Table 6. Overview of the performance of subjects who exercised outside of working hours (exercisers) and those who did not (nonexercisers) at the 4 mmol lactate threshold and at maximum performance in the bicycle ($p_{4mmol-L}$, p_{max}) in watts, and treadmill ($v_{4mmol-L}$, v_{max}) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	p_{max} W	$v_{4mmol-L}$ km/h	v_{max} km/h
Nonexercisers (N=17/2)	138.76 (±23.1)	178.12 (±33.1)	8.00 (±1.0)	11.05 (±0.4)
Exercisers (N=65/32)	172.51 (±37.0)	236.98 (±46.7)	10.63 (±1.5)	13.06 (±1.6)
P	<.001	<.001	.028	.066

Performance levels differed significantly in the treadmill cardiac stress test. Subjects with orthopaedic disorders were significantly faster than those without (Table 8).

Mental Disorders

Only 2 subjects specified that they currently had a mental disorder. Physical fitness was only determined by means of a bicycle cardiac stress test. The $p_{4mmol-L}$ revealed no significant difference, but subjects with a mental disorder clearly tended to be less fit than subjects who had no mental disorder: 2 subjects with disorder, $p_{4mmol-L}$ 120±22.6 W; 84 subjects with no disorder, $p_{4mmol-L}$ 165.7±36.2 W; *P*=.057. At maximum performance, the effect rated previously as just a tendency proved to be a significant difference despite the small number of subjects: with disorder, p_{max} 139±43.8 W; no disorder: p_{max} 224.76±48.9 W; *P*=.039. Both subjects mentioned pain in the knee. No internal disorders were detected. The subjects' respective BMIs were 22 kg/m^2 and 26 kg/m^2.

Effects of Training Advice

The subjects returned for a follow-up examination, for which the same procedure was used as for the initial examination. As an example, for reevaluating and presenting the effect, this study only compares the subjects' main parameters (BMI, waist circumference, $p_{4mmol-L}$, p_{max}, $v_{4mmol-L}$, v_{max}, and heart rate at the individual anaerobic threshold) with the values established during the initial examination. A total of 37 participants took part in a second seminar approximately one year after the first one. The BMI of the subjects who presented for the second examination had decreased from 27.3±3.3 kg/m^2 to 26.9±3.4 kg/m^2 (*P*=.116), which was insignificant. Waist circumference had decreased from 98.2±9.3 cm to 97.3±10.5 cm, which was also insignificant (*P*=.575). On average, the performance test did not reveal any change in comparison with the previous values either. However, a lower heart rate (HR) was established at the individual anaerobic threshold (HR_{T0}: 140.5±17.0/min, HR_{T1}: 135.9±17.1/min; *P*=.053).

Comment

Risk factors for cardiovascular diseases and the development of such diseases in executives were found to be less common in our sample than in the normal population.[13-15] The conventional limiting factors for fitness (age, BMI, waist circumference) were evident.[6] What is more, patients who had had an orthopaedic condition were fitter than those who had none.

Table 7. Overview of the performance of subjects with high blood pressure and those with healthy blood pressure at the 4 mmol lactate threshold and at maximum performance in the bicycle ($p_{4mmol-L}$, p_{max}) in watts, and treadmill ($v_{4mmol-L}$, v_{max}) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	p_{max} W	$v_{4mmol-L}$ km/h	v_{max} km/h
High blood pressure (N=30/8)	158.0 (±35.0)	205.97 (±52.3)	9.8 (±1.2)	11.95 (±1.1)
Healthy blood pressure (N=56/28)	168.0 (±37.2)	231.77 (±47.1)	10.7 (±1.7)	13.33 (±1.7)
P	.223	.02	.118	.037

Table 8. Overview of performance of subjects with and those without orthopaedic disorders at the 4 mmol lactate threshold and at maximum performance in the bicycle ($p_{4mmol-L}$, p_{max}) in watts, and treadmill ($v_{4mmol-L}$, v_{max}) cardiac stress tests in km/h.

Subjects (N=bicycle/treadmill)	$p_{4mmol-L}$ W	p_{max} W	$v_{4mmol-L}$ km/h	v_{max} km/h
Orthopaedic disorders (N=81/30)	164.4 (±37.1)	222.1 (±49.7)	10.9 (±1.5)	13.3 (±1.6)
No orthopaedic disorders (N=5/8)	167.8 (±29.4)	233.0 (±63.2)	9.0 (±1.2)	11.5 (±1.0)
P	.644	.657	.012	.012

However, at this point it is important to understand that these conditions included sports injuries, and of course sports were identified as a performance-enhancing factor. The fact that there were many cases of sports injuries and injuries resulting from excessive strain as well as back pain is a significant basis for intervention as part of occupational health promotion. The fitness level of people with high blood pressure who were rated in our examination as not very fit, could, under controlled conditions, also be improved.[16] Although no significant improvement was achieved in the body measurements and fitness of the subjects who returned for a second examination, the tendency was positive, and there was no deterioration in physical condition after receiving training advice. This comment, however, is limited to a large degree by the fact that less than a third of the initial subjects turned up for the second seminar. In part this was due to early retirement of military executives. Another important limiting factor that must be mentioned at this point is that although clear differences in fitness levels were sometimes detected, it was at times almost impossible to prove the statistical significance of these differences because of the small number of cases in some of the groups. Nevertheless, the difference can still be of clinical relevance. This becomes particularly clear when looking at alterations in the patients' mental state. It is a well-known fact that physical fitness reduces susceptibility to psychological stress.[17] Our study showed that subjects who were under psychological stress were not as physically fit as the other subjects. However, in 2 of the subjects who specified that they had psychological problems, this assertion can only be assessed to a limited extent, even if it is consistent with what is stated in the relevant literature.

In summary, we believe that it is necessary as part of occupational health promotion to intervene in patients with a risk profile. Executives suffering from hypertonia, high BMI and waist circumference as well as executives with low physical activity level should be addressed by health promotion programs. These patients should perform regular weight and endurance training. In order to achieve optimum effects and avoid injuries as a result of excessive strain, this training should initially take place under guidance. Military executives have the potential to be a multiplier for health promotion in the military units where they are responsible for the well-being of their subordinate personnel.

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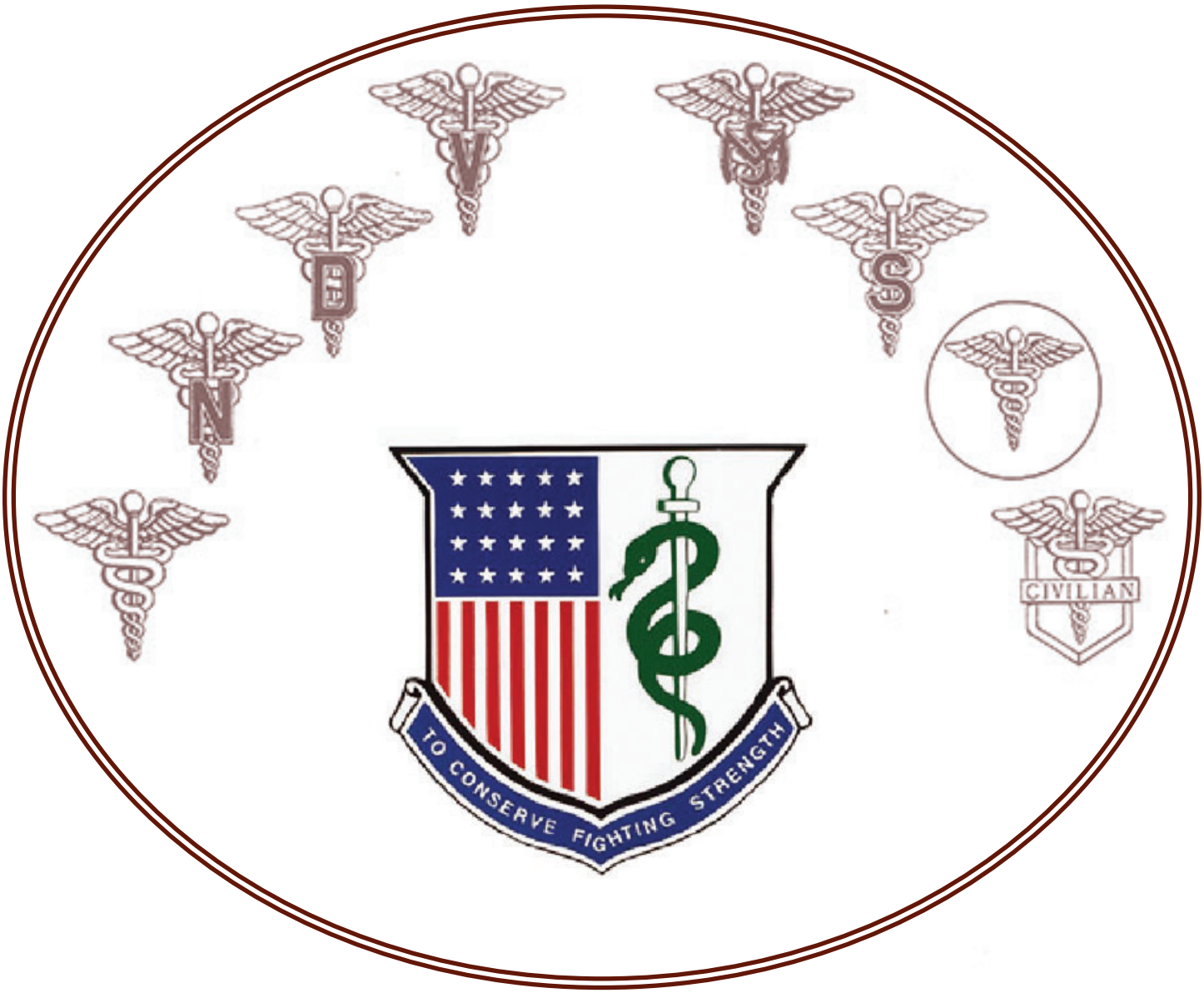

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