Chapter 22

UPPER LIMB AMPUTATION AND PROSTHETICS EPIDEMIOLOGY, EVIDENCE, AND OUTCOMES

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INTRODUCTION

The hand has been described as the most individual and personal part of the human being.[1] However, in the civilian sector, research, funding, and access to specialized care for upper limb amputees have been overshadowed by the substantial increase in lower limb amputation because of dysvascular disease.[2–5] The prosthetic and rehabilitation needs of injured service members from Operation Enduring Freedom and Operation Iraqi Freedom have brought upper limb amputation to the forefront of current debate and attention. As of July 2008, over 800 individuals have sustained major limb amputations as a result of military operations in Iraq and Afghanistan, 20% of which were upper limb amputations. At the same time, an unprecedented number of upper limb amputees are returning to active duty military service.[6] This has led to a resurgence of research to improve the lives of individuals with upper limb loss both in the civilian and military communities.

Relying on the prevalence of upper limb amputation in the general US population to plan rehabilitation for all upper limb amputees is problematic for three reasons. First, most amputation epidemiological research in the general population has been funded by diabetes research dollars, and thus focuses on dysvascular-disease–related (and primarily lower limb) amputations. Second, results vary depending whether amputees, amputations, or amputation-related hospitalizations are counted.[7] Finally, most disability survey data are more than 10 years old. "Prevalence" is determined by the number of people living with amputations and looks at how many people are affected, and most estimates of amputation prevalence are derived from the 1996 National Health Interview Survey–Disability (NHIS-D).[8] "Incidence" refers to the number of new cases, usually per year, per population at risk. Sources of incidence data include community hospital and hospital emergency room discharge data and employment-related data. When interpreting incidence data, it is important to consider whether amputations or amputees are being counted and to identify the population at risk. For example, incidence rates of lower limb amputation for a population of individuals with dysvascular disease will be different than incidence rates for the US population. Frequently, statistical techniques are used to standardize the incidence rates to the US population by age, sex, and geographical region.[9]

Prevalence

According to analyses of the NHIS-D, there are 1.2 to 1.9 million people in the United States living with limb loss (data excludes finger tip and toe amputations), or about one in every 200 people. The 1.2 million figure was derived from analyses of 1996 NHIS-D data,[10] and the 1.9 million figure is a 2005 estimate based on 1996 NHIS-D data and US population growth.[8,11] One limitation of 1996 NHIS-D data is that only amputees are counted; the numbers of amputations were not considered. Also, upper and lower limb amputees were not distinguished from one another. Thus, the prevalence of upper limb amputation cannot be found in NHIS-D data. A third limitation of 1996 NHIS-D limb loss data is that fingers and toes are excluded from the count; though loss of a finger or toe may not be as disabling as loss of a limb, amputation of a finger can be more expensive than amputation of a limb (paid for by workers compensation funds).[12]

Incidence

According to a report published online by the Limb Loss Research and Statistics Program, a collaboration between the Johns Hopkins Bloomberg School of Public Health and the Amputation Coalition of America, 185,000 Americans undergo amputation each year.[13] Using community hospital discharge data from the Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, Dillingham et al identified 1,199,111 hospital discharges that involved amputation or congenital limb deficiency from 1988 through 1996, averaging 133,235 amputations per year, and a 1996 annual rate of 52 amputations per 100,000 US population.[14] Unlike the NHIS-D data, the data from the Healthcare Cost and Utilization Project, Nationwide Inpatient Sample are categorized by upper limb amputation versus lower limb amputation. Dillingham et al[14] identified 166,464 community hospital discharges related to upper limb amputations over the 9-year period (14% of all discharges). During this time, there was an average of 18,496 upper limb discharges per year.[14,15] The 1996 incidence rate for discharges related to upper limb amputation was 5 per 100,000 US population, as opposed to a rate of 47 per 100,000 US population discharges related to lower limb amputations. These numbers include hospital discharges and not amputations; however, more than one amputation can occur during one hospitalization, and an amputee can be hospitalized more than once during a 9-year period. Of the upper limb amputation rate, 3.8 in 100,000 were trauma related, 1.3 in 100,000 were dysvascular related, and less than 1 in 100,000 were cancer related.

Emergency room visits, tracked by the National Electronic Injury Surveillance System All Injury Program, are another source of incidence data. According to analysis of 2001–2002 National Electronic Injury Surveillance System data, approximately 30,000 people with non-work–related amputations were treated in emergency rooms each year, an annual rate of 10 per 100,000 US population.[16] Most (91%) were treated for finger amputation. Work-related amputation data is tracked both at the national and state levels.[16] The Bureau of Labor Statistics reported a 1999 work-related amputation rate of 15 per 100,000 population (the results did not differentiate upper from lower limb amputations).[17] For example, in Kentucky between 1994 and 2003, 96% of the Kentucky worker's compensation amputation claims were for upper limb amputation.[12]

UPPER LIMB RESEARCH: OUTCOMES

When designing any effective research program, it is imperative to reach some consensus on the best way to measure outcomes in various domains, such as functional performance, independence, quality of life, and cost. Research focused on upper limb amputation presents its own unique challenges. Recently, the Limb Loss Research and Statistics Program performed a survey to understand how both upper limb and lower limb amputation impact the outcomes of daily living and quality of life. Although the sample included 109 upper limb amputees (11% of the sample), results did not distinguish between upper and lower limb amputees. The results indicated 30% of the sample experienced difficulty with bathing and 7% required help with activities of daily living. It is possible that an upper limb amputee could have more difficulty with activities of daily living than a lower limb amputee because of the fine motor component of activities of daily living. Additionally, 81% of the sample used assistive technology (AT) other than prosthetic devices; for example, canes, walkers, and wheelchairs. AT needs of upper limb amputees remain unknown, though understanding an amputee's need for AT is an important consideration for reimbursement policy and best practice guidelines (ie, what type of equipment should be made available to amputees to maximize function when they are not able to use their prostheses). For example, 41% of lower limb amputees have dermatologic conditions associated with the amputation, regardless of prosthetic use.[18–20] Frequently, lower limb amputees are unable to use their prostheses during dermatologic episodes and must rely on mobility-related AT. No studies were found that addressed dermatologic conditions and AT needs for upper limb amputees.

An amputee's access to care is another important ideological factor to consider. The Limb Loss Research and Statistics Program study found 10% of amputees surveyed did not receive medical care when needed, and 20% did not receive rehabilitation when needed.[13] An earlier study (1979–1993) of acute inpatient data found the mean acute length of hospital stay was nearly double for lower limb versus upper limb amputees.[21] This is likely because most lower limb amputations are for dysvascular disease, a condition that may have associated comorbidities that may also require inpatient care. Another finding of the Dillingham et al[21] study was that only 3% to 4% of upper limb amputees were discharged from acute care to rehabilitation, as opposed to 20% to 23% of lower limb amputees. It remains unknown if upper limb amputees fail to undergo inpatient rehabilitation because they do not use prostheses.[21]

Cost of care is another important consideration when designing a research program. In a 2004 study of both upper limb and lower limb amputees, Pezzin et al found the mean out-of-pocket expense for trauma-related amputation was $890, versus $485 for dysvascular-disease–related amputations.[22] Other important cost-related factors to consider include the costs of amputation in the United States (including the cost of hospitalization and the cost of a prosthetic device) and whether or not the cost is considered over the continuum of care. When considered across the entire continuum of care, the cost of a prosthetic device may appear more reasonable to third-party payers.

As technology becomes more sophisticated and prostheses become more expensive, the decision as to who is eligible for which technology becomes more complicated. The US military provides service members with upper limb amputations with a myoelectric prosthesis, a body-powered prosthesis, and a cosmetic prosthesis. This level of care is rare in the civilian community, where third-party payers typically fund only one prosthesis unless there is evidence that additional devices will increase function. The Limb Loss Research and Statistics Program study found most amputees wore their prostheses all day if satisfaction with the fit was high, and associated the highest level of satisfaction with ease of use. These results, however, include satisfaction with both upper limb and lower limb prostheses, so they do not accurately describe patient happiness with upper limb prosthetics, alone. One of the main problems in research investigating satisfaction with and use of prosthetic devices is inconsistency in the definitions of "use" and "satisfaction." Use has been measured with both continuous scales (ie, counting days per week and hours per day the prosthesis is worn) and categorical scales (ie, whether the prosthesis is worn regularly, a lot of the time, all the time, occasionally, not at all, or never).[13, 22–25] The Limb Loss Research and Statistics Program study found 95% of participants used their prostheses regularly; however, only 21% of the participants were upper limb amputees. Studies of upper limb amputees performed in England found 72% of participants used their prostheses "regularly."[23] A study performed in Australia found 18% of participants used their prostheses "all the time," and 13% used their prostheses "a lot of the time."[26] Additionally, Davidson measured the extent to which upper limb amputees used the grasp feature of their prostheses; 7% used the grasp feature "all the time" and 29% "never" used the grasp feature. A limitation of the satisfaction and use studies is that measurement has not been standardized. Additionally, the type of prosthesis used was not typically mentioned. In order to determine what factors account for variability in use of devices, future studies need to use consistent, standardized scales to evaluate "use" per type of device. For example, a study performed in Ireland by Graham et al found 56% of upper limb amputee participants used their prostheses functionally, and 34% used their prostheses cosmetically (however, participants could only select one of the two use responses).[24] Future studies should consider that participants may have more than one prosthesis, each used for a different purpose. In addition, studies should also account for other comorbidities that may affect outcomes. The Graham study was the only study found to include posttraumatic stress disorder (PTSD) as a factor related to use; 69% of the participants reported having PTSD. Most studies of upper limb amputation, including the Graham study, provide only descriptive analyses. Future studies could use PTSD as a variable in a regression model to more robustly determine the relationship between PTSD and use of a prosthesis.

A study published in 1989 used descriptive statistics to find an association between successful use of a prosthetic device and having a high school diploma, being employed or rapidly returning to work, accepting the amputation, perceiving that the prosthesis was expensive, and exhibiting less than two comorbidities.[27] Factors cited as unrelated to successful use of a prosthesis included age, hand dominance, rehabilitation, training in use of the prosthesis, and use of a temporary prosthesis. Forty participants with upper limb amputations were classified as successful users if they used a prosthesis every day, partially successful if they used a prosthesis for certain tasks, and unsuccessful if they did not use a prosthesis or did not use it functionally (ie, wore it only for cosmetic purposes). Forty-six percent of the successful users (n=12), 70% of the partially successful users (n=7), and 57% of the unsuccessful users (n=3) had received rehabilitation.[27] Whether or not a participant had access to rehabilitation was not considered. One problem with this study is that descriptive statistics were used to explain multivariate relationships. However, this study could be helpful if it was repeated using a regression model design and current technology.

Time and error have been employed to measure successful prosthetic use with a motor learning approach. For example, in a 1993 study by Edelstein and Berger, children with traumatic upper limb amputation randomized to either a body-powered or myoelectric prosthesis were able to perform some tasks faster with a myoelectric prosthesis (donning socks, cutting paper, applying bandage) and other tasks faster with a body-powered prosthesis (playing cards, using form board) following a 3-month training period.[28]

Satisfaction with prostheses has also been inconsistently defined. In Australia, Davidson used a survey to measure the following: satisfaction with the ability to perform specific activities (ie, unsatisfied, just satisfied, or very satisfied), overall satisfaction with the prosthesis (ie, very satisfied, quite satisfied, okay, quite unsatisfied, or very unsatisfied), and satisfaction with the characteristics of the prosthesis (ie, not acceptable, fair, good, very good, or excellent).[26]

In 2004 Pezzin et al[22] used multivariate regression to examine use and satisfaction of prosthetic devices. Seventy-six percent of respondents were satisfied with the overall performance of their prostheses; however, data were not presented separately for upper limb and lower limb amputees. Other outcomes investigated by Pezzin et al included the relationship between satisfaction and use with time interval between amputation and receipt of prosthesis, level of amputation, geographic location, gender, race, ethnicity, insurance coverage, comorbidity, and age.[22]

Studies by Pezzin et al[22] and Pinzur et al[29] have shown a positive relationship between early fitting of a prosthesis and satisfaction and use. Early fitting is problematic for many service member amputees injured in Operations Enduring Freedom and Iraqi Freedom because of the extent of upper limb damage. Multiple surgeries may be necessary before a temporary prosthesis can be fitted. The Otto Bock MyoBoy (Otto Bock HealthCare, Minneapolis, Minn) computer-based technology enables upper limb amputees to train to use myoelectric prosthetic devices while waiting to be fitted for prostheses. This allows early muscle strengthening and retraining. A second reported benefit of myoelectric prosthetic use is reduced phantom limb pain.[30]

In a 1988 study by Melendez and LeBlanc,[31] upper limb amputees who did not use prostheses attributed their choice to lack of education and information on prosthetic devices.[31] Providing consistent delivery of prosthetic information and resources to both rural and urban populations remains a challenge.

Research on the effect of upper limb amputation on the outcomes of employment, driving, and participation in society is sparse. In a study of upper limb amputees in England, Datta et al found that 73% of upper limb amputees became employed or reemployed following their amputations, although 67% had to change jobs.[23] The study descriptively characterized the sample according to amputation level and type of prosthetic device used. Similarly, Pinzur et al found 72% of upper limb amputees in the United States were employed following amputation.[29] Future studies could use multivariate methods to associate amputation site and type of prosthetic device with employment-related factors. Predictors of return to work have been identified for lower limb amputees, but not for upper limb amputees.[32]

Jones and Davidson investigated the driving patterns and vehicle modifications of upper limb amputees in Australia.[25,26] The only US study of driving involved lower limb amputees. Boulias et al found 81% of lower limb amputee participants returned to driving an average of 4 months after their amputations. However, in the United States, the percentage of drivers with upper limb amputations who return to work, and the modifications they use, remains unknown. It is also unclear how these drivers are assessed for safety and how their need for modifications is determined.[33]

Participation in society is an important outcome of rehabilitation according to the World Health Organization's *International Classification of Functioning, Disability, and Health*.[34] The US Centers for Disease Control and Prevention and Bureau of Labor Statistics measure participation by counting days missed from work as a result of a work-related amputation. Methods developed by the World Health Organization, Centers for Disease Control and Prevention, and Bureau of Labor Statistics to measure participation could be applied to study the degree to which upper limb amputees are able to participate in society.

Evidence for effectiveness of training in the use of upper limb prosthetics is necessary for third-party reimbursement of rehabilitation, but cannot currently be found in the literature. Models of prosthetic training should also be investigated (eg, peer training, inpatient, outpatient, and telerehabilitation).[35]

UPPER LIMB RESEARCH: MEASURES

From a health-services perspective, outcome measures monitor the extent to which invested resources contribute to desired results.[36] From a clinical perspective, outcome measures predict the relationship between doses of therapy and patient responses.[37] From a rehabilitation perspective, outcomes to be measured are functional health status and patient satisfaction.[38] Thus, outcomes can be measured at the system and patient levels. A challenge to measuring upper limb amputee and prosthetic outcomes is the interaction between the technology and the patient—a relationship that complicates AT research. Finally, once desired outcomes and appropriate measures have been identified, robust analyses must also be conducted.

Informal measures typically include using checklists developed by clinicians for assessment, developing an intervention plan, and monitoring progress. There are several informal checklists available. Occupational therapist Diane Atkins developed informal measures for upper limb amputees using body-powered prostheses. Occupational therapists at Otto Bock have developed the Occupational Therapist Upper Extremity Functional Evaluation and the Upper Extremity Prosthetic Functional Activity Checklist, both available on the Otto Bock Web site.

Formal measures have resulted in published psychometric properties; that is, reliability and validity have been tested. Reliability measures the consistency or repeatability of the measurement with the intent of separating true score from error. Validity is the strength of the inference or the extent to which the construct was measured, minus the threats and biases that can undermine results and generalizations. One problem with upper limb amputation and prosthetic research is the inconsistency in operational definitions of prosthetic "use" and "satisfaction," resulting in the vast range (7%–88%) discussed earlier in this chapter.[39–43] Without a valid, reliable, and preferably standard measure of use, the relationship between use and functional status cannot be established. Without a valid, reliable and preferably standard measure of satisfaction, the quality of care provided to amputees cannot be established. In this context, a standard measure is one that may be considered the goal and used in a variety of environments so study results can be compared. For example, there are many measures of quality of life. For many, the Short Form-36 Health Survey remains the subjective standard that is conducive to comparison of health status across populations.[44,45] The Short Form-36 Health Survey has been used in at least one study of lower limb amputees.[44]

Three valid and reliable formal measures used in upper limb amputee and prosthetic research are the Disabilities of the Arm Shoulder Hand (DASH) questionnaire, the Orthotics and Prosthetics User Survey-Upper Extremity (OPUS-UE) scale, and the Trinity Amputation and Prosthetic Experience Scales (TAPES).[36,46–49] The DASH is a 30-item questionnaire developed by the Canadian Institute for Work & Health and the American Academy of Orthopaedic Surgeons. It measures the physical and social impact of upper limb disorders. Scoring is done on a 5-point Likert scale, with a lower score indicating less disability. Davidson used the DASH to determine disability of patients with upper limb amputations and to compare those to other upper limb injuries.[41] According to her findings, patients with brachial plexus injuries, Complex Regional Pain Syndrome, and bilateral upper limb amputations demonstrated significantly higher levels of disability compared to patients with unilateral upper limb amputations. Additionally, partial hand amputees reported a higher level of disability than major unilateral upper limb amputees.[41]

The OPUS-UE is a Rasch scale that measures activity limitations (23 items), quality of life (23 items), and patient satisfaction with services and devices (20 items). A lower score indicates higher function. The OPUS-UE is commonly used in lower limb amputation research; no studies were found that used the upper limb version.

The 54-item TAPES is designed to examine the psychosocial processes involved in adjusting to a prosthesis. There are four sections: (1) psychosocial (general adjustment, social adjustment, and adjustment to limitation subscales), (2) activity restriction (functional, social, and athletic restriction subscales), (3) satisfaction with the prosthesis (functional, aesthetic, and weight characteristics), and (4) exploration of phantom limb pain, residual limb pain, and other medical conditions not related to the amputation. The only known study using the TAPES with upper limb amputees was a study of the psychometric properties of the TAPES.[50]

ANALYSIS OF OUTCOMES

The majority of studies cited previously in this chapter used a survey design with descriptive statistical analyses that yield measures of central tendency. More recent studies use more robust study designs, such as logistic regression, that adjust for confounding factors such as marital status, employment status, educational level, and location of amputation.[43,50] These studies control for factors that vary from one amputee or one prosthetic device to another. In addition, these studies can identify interactions between the amputee and the device, amputee factors that are present only when certain device factors are present, and vice versa. From these studies, the conditions under which a device will benefit an amputee can be predicted.

Deathe et al studied formal versus informal outcome measures used in Canada.[51] Doffing and donning a prosthesis was informally assessed by 90% of respondents, dressing by 78%, bath transfers by 81%, and car transfers by 56%. Informal home visit assessments were performed by 29% of respondents. Formal assessments were categorized according to whether they were used in the academic or clinic environments. The Functional Independence Measure (the most widely accepted functional measure in the research community; an 18-item, 7-level ordinal scale intended to be sensitive to change in an individual over the course of a comprehensive inpatient medical rehabilitation program), the Prosthetic Profile of the Amputee (a clinical follow-up questionnaire that measures both actual prosthetic use and factors potentially related to prosthetic use by individuals with lower limb amputation), and the walking speed, walking distance, repetitive chair rise, and timed up-and-go tests were performed in both environments.[52,53] The Barthel Index, a 10-item measure commonly used in rehabilitation medicine, measures functional outcome, including factors like mobility and self-care, and was only used in the clinic.[54] The Minimal Data Set (which evaluates the functional capabilities of residents in Medicare- and Medicaid-certified residential facilities), the Short Form-36 Health Survey (which produces a physical and mental component summary score), and goal attainment scaling (in which clinician and patient set individualized goals on a five-point scale) were only used in research.[45,55–58]

SUMMARY

Epidemiology and evidence-based research studies in upper limb amputation are few and outdated. There are potential upper limb amputation and prosthesis outcome measures that have yet to be used in research. Studies that pilot these measures, from surgery to community reintegration, are needed.

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