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Impact of Time to Receipt of Prosthesis on Total Healthcare Costs 12 Months Postamputation

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Objective: The objective was to assess the impact of a prosthesis and the timing of prosthesis receipt on total direct healthcare costs in the 12-mo postamputation period.

Design: Data on patients with lower limb amputation (n = 510) were obtained from a commercial claims database for retrospective cohort analysis. Generalized linear multivariate modeling was used to determine differences in cost between groups according to timing of prosthesis receipt compared with a control group with no prosthesis.

Results: Receipt of a prosthesis between 0 and 3 mos post lower limb amputation yielded a reduced total cost by approximately 0.23 in log scale within 12 mos after amputation when compared with the no-prosthesis group. Despite the included costs of a prosthesis, individuals who received a prosthesis either at 4–6 mos postamputation or 7–9 mos postamputation incurred costs similar to the no-prosthesis group.

Conclusion: Earlier receipt of a prosthesis is associated with reduced spending in the 12 mos postamputation of approximately \$25,000 compared with not receiving a prosthesis. The results of this study suggest that not providing or delaying the provision of a prosthesis increases costs by about 25%.

Key Words: Amputee, Costs, Prosthetic Rehabilitation, Timing of Prosthesis

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O ver the past 30 yrs, healthcare costs have increased in the United States as adults live and work longer with an increase in comorbidities.^{1,2} Many discussions have occurred around the best way to address the increasing healthcare expenses with emphasis on those with chronic conditions or disability.^{2,3} It is important to consider care structure, delivery of care, and costs of health services as healthcare procedures are advancing.^{3–5} Based on current research of people aging, most want to remain independent and in their own home, which often requires use of rehabilitation health services.^{4,6}

To maintain health and mobility, rehabilitation services are a critical part of health care. Rehabilitation health service is a broad category in health care, targeting a wide population (children, adults, and older people) with a range of conditions impacting function and participation, including diverse interventions (eg, rehabilitation medicine, physical therapy, occupational therapy, prosthetics, orthotics, and assistive devices) and

What Is Known

 Healthcare costs have increased, and the economic burden associated with care for those with chronic health conditions remains high. Postamputation rehabilitation is critical for patient health and return to activities of daily living. Evidence on timing of prosthesis receipt may inform clinical practice to guide practitioners and influence patient health while being cost-effective.

What Is New

The clinical benefits of prosthetic rehabilitation services can actually serve to reduce other nonprosthetic costs while timing of prosthesis receipt is critical. Earlier receipt of a prosthesis within 12 mos postamputation reduces total direct healthcare costs.

outcomes.³ Clinical and policy decisions about appropriate and optimal rehabilitation interventions require evidence on resource allocation, costs, and effectiveness.³ Prosthetic rehabilitation is no exception. With increasing pressure from payers to provide health services more efficiently and effectively, evidence to demonstrate and describe the effect of prosthetic rehabilitation is crucial.^{7,8}

Lower limb amputation (LLA) is a major event that affects an individual's life both physically and mentally. However, a lower limb prosthesis can restore functional mobility and independence, which may reduce costs in other areas owing to overall improved physical and mental health.^{9–11} Furthermore, a shorter time from amputation to prosthesis delivery may result in a more active and sustained recovery.⁷

The first 12 mos postamputation is critical as an individual requires rehabilitation to return to previous activities of daily living, to maintain independence, and to return to work. Among adults who are not fit with a prosthesis within 6 to 12 mos postsurgery, mortality is a common endpoint to measure post-LLA and mortality risk remains high (odds ratio, 2.60; 95% confidence interval, 1.16–6.25) beyond the initial 30 days.¹² This includes concern of deconditioning, which leads to poorer cardiovascular health, limb health, and lack

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of work or socialization, all of which are attributed to increased healthcare costs^{13–16} that may be associated with the lack of a prosthesis. Limited data would suggest that if a patient does not receive a custom prosthesis within 12 to 18 mos, it is possible for the individual to decline to a health state so poor that they are considered unlikely to benefit from a prosthesis.^{8,17} About 30% to 60% of adults exclusively use a wheelchair after LLA, which significantly reduces quality of life, independence, and cardiovascular health.¹⁸ However, adults who receive early rehabilitation after a transtibial amputation have improved mobility compared with matched individuals with no rehabilitation services and up to 80% lower hazard of death if they are a prosthesis user.^{17,19}

It has been recommended that, on average, a patient receives a custom lower limb prosthesis between 8 and 20 wks after surgery depending on individual acuity and healing process.²⁰ Any delay in prosthesis receipt can lead to difficulty with fitting a prosthesis as there is an associated decrease in limb health (e.g., contracture development or adhesions). Earlier receipt of a prosthesis improves mobility, independence with activities of daily living, and ambulation, all of which promote good physical health while reducing risk of contractures and mortality.²¹ Early receipt of a prosthesis potentially reduces negative health effects and potentially may reduce overall resource utilization and direct costs. Therefore, there is clinical benefit to removing barriers to a patient's ability to be fitted with a prosthesis earlier in the process.

The purpose of this analysis was to develop a greater understanding of the impact of receiving a lower limb prosthesis, as well as the timing of such an event, on the total direct healthcare costs. The resulting evidence could assist the interdisciplinary team in decision making relative to time since amputation surgery or other demographic factors during the recovery period. A better understanding of timing in terms of economics of health care may also help with improved policy and practice for more cost-effective care. Previous work would suggest that clinical benefits are associated with early prosthesis intervention.^{12,21,22} Based on this previous work, the current study hypothesized that earlier prosthesis provision would provide economic benefits through reduced total direct healthcare costs among a cohort of commercially insured adults.

METHODS

Study Design and Data Source

This retrospective cohort study used data from the International Business Machines Corporation Watson/Truven Health Analytics MarketScan Database (Watson) from January 2014 through December 2016. The Watson database is a large United States private sector health claims database containing deidentified records representing approximately 25% of all commercial claims aggregated into one database with patient-level enrollment history, medical, and pharmacy commercial claims nationwide. The database is populated by approximately 350 payers. Specifically, this dataset includes individual level information on all durable medical equipment, orthoses and prostheses, inpatient services, and outpatient services. The subset that was extracted was limited to only claims on patients who received orthoses and prostheses. Claims data within the database represent adjudicated claims (i.e., actual charges and dollars spent). The data initially were collected by a third party, not part of this study, for administrative billing purposes for healthcare services. Then the data were deidentified by International Business Machines Corporation before release of the data for secondary analysis. Therefore, it was not possible to collect informed consent from subjects as individuals are unable to be identified. Moreover, as the data are maintained in a deidentified nature and complies with the Health Insurance Portability and Accountability Act, the subsequent analysis is not considered human subject research and therefore does not require approval from an institutional review board. This study conforms to all STROBE guidelines and reports the required information accordingly (see Supplemental Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/B12).

The final subset that was extracted was limited to only claims on unique patients that maintained continuous enrollment in the same health plan from January 1, 2014, through December 31, 2016. The sample was restricted to adults 18 to 64 yrs of age. Next, inclusion was based on initial amputation procedure codes (first procedure claim = index date); only individuals with initial surgical amputation procedures that occurred within the given time while requiring a 3-mo presurgery window to establish baseline preamputation costs and proxy acuity and 12-mo postsurgery window for dependent variable calculation were included. To ensure that initial amputation was captured, the inclusion criteria required no previous or subsequent amputation within the study period. Preamputation and postamputation time window lengths were chosen to maximize the number of individuals with coverage during the months available for analysis. The final sample includes all eligible patients with data to cover the preamputation and postamputation windows; if individuals did not meet these criteria, they were not in the final analytic sample for retrospective analysis.

Measures and Analysis

All adjudicated paver costs for inpatient and outpatient procedures were summed across the 12-mo postamputation period for each individual. Prescription drug expenses were not included. Cost within the database was limited to the total amount paid by insurance and did not include charges, patient out-of-pocket costs, travel, or other indirect costs such as lost work. The dependent variable, total cost, was right skewed and subsequently log transformed for analysis. Individuals were classified into mutually exclusive groups for comparison into 3-mo blocks based on length of time from surgery to device receipt within the 12 mos postamputation (group A: 0-3 mos; group B: 4-6 mos; group C: 7-9 mos; group D: 10-12 mos; and a final group that did not receive a prosthesis: group X). Receipt of prosthesis, a binary variable, was determined based on presence of a lower limb prosthesis base code billed after LLA (Appendix A, Supplemental Digital Content 2, http://links. lww.com/PHM/B13). All types of prostheses were included as captured by base code and dichotomized, yet specific type or kind of prosthesis was not extracted. Additional control variables entered into the model included age, sex, amputation level, diabetes/vascular status, and 3-mo presurgery baseline healthcare costs. Presurgery costs were treated as a continuous variable and thus similarly log-transformed. Diabetes/vascular disease

Demographic Characteristics	Group X	Group A	Group B	Group C	Group D	Total	Р
Total population	67 (13.1)	174 (34.1)	186 (36.5)	58 (11.4)	25 (4.9)	443 (100)	_
Amputation level							
Transtibial or below knee	33 (6.5)	141 (27.6)	150 (29.4)	46 (9.0)	15 (2.9)	352 (75.4)	< 0.0001 ^a
Transfemoral or above knee	34 (6.6)	33 (6.5)	36 (7.1)	12 (2.4)	10 (2.0)	125 (24.6)	
Sex							
Male	40 (7.7)	142 (27.8)	121 (23.7)	41 (8.1)	14 (2.7)	355 (70.0)	0.06
Female	27 (5.2)	32 (6.2)	65 (12.7)	17 (3.2)	14 (2.7)	155 (30.0)	
Diabetes/vascular status						× ,	
Yes	37 (7.3)	123 (24.1)	120 (23.5)	33 (6.5)	14 (2.7)	327 (64.1)	0.11
No	30 (5.9)	51 (10.0)	66 (12.9)	25 (4.9)	11 (0.2)	183 (33.9)	
Age, years	52.1 ± 0.69	52.4 ± 0.69	52.4 ± 0.68	53.2 ± 1.20	50.7 ± 2.45	52.16 ± 0.42	0.06
Postindex total cost, log scale	9.03 ± 0.19	8.59 ± 0.14	8.79 ± 0.11	9.06 ± 0.18	9.05 ± 0.37	8.8 ± 0.19	0.8

TABLE 1. Baseline characteristics of patients stra	atified by time from amputation	to receipt of prosthesis within 12 mos or no p	prosthesis
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Group X: no prosthesis; group A: 0-3 mos postamputation prosthesis receipt; group B: 4-6 mos postamputation; group C: 7-9 mos postamputation; group D: 10-12 mos postamputation. Data are presented as *n* (%), except for continuous variables, which are presented as mean \pm SE.

^a Significant at 0.05.

status was determined by the presence of associated diagnosis codes in claims any time after enrollees' first admission with assumption the disease persisted throughout the study period (Appendix A, Supplemental Digital Content 2, http://links. lww.com/PHM/B13).

Summary and descriptive statistics were calculated among the sample population across individual characteristics (Table 1). Chi-square tests of independence or Wilcoxon-Mann-Whitney U tests were used to compare groups. All statistical analyses assumed two-tailed test of significance and alpha was set a priori at 0.05. Next, bivariate linear regression with lognormal distribution was used to model the relationship between independent variables and total cost. Each independent variable was also analyzed in a bivariate model to measure the unadjusted association. Lastly, generalized linear multivariate modeling was used to calculate estimates with a priori alpha values set at 0.05.

Generalized linear multivariate modeling with log link function was used to compare total healthcare cost based on timing of prosthesis receipt while adjusting for individual characteristics. All analyses and data management were conducted using SAS 9.4 (Cary, NC).

RESULTS

Study Population and Baseline Characteristics

There were 1100 individuals aged 18–64 yrs with continuous enrollment through the 3-yr window. After applying inclusion/exclusion criteria, 510 individuals with a first major LLA were available for analysis (Table 1). Among the sample of continually insured adults, 87% received a prosthesis within 12 mos, whereas 13% did not receive a prosthesis. Patients who received a prosthesis were more likely to have a transtibial amputation (352 is the total of transtibial patients who received a prosthesis), whereas it seems a similar proportion of transtibial and transfemoral patients did not receive a prosthesis. Among the 125 individuals with a transfemoral amputation, 34 did not receive a prosthesis within 12 mos. Overall, 70% were men and the mean (SD) age was 52 (9.4) yrs. Within the sample, the proportion with diabetes or vascular disease was 327 (64%) individuals.

Influence of Time in Multivariate Model

The generalized linear regression model of cost included age, sex, diabetes/vascular status, and baseline cost (presurgery) as covariates with length of time (Table 2). In this model, age, sex, and diabetes/vascular status turned out to be nonsignificant. Higher presurgery costs at baseline affected the total costs significantly by an increase of 0.125 (P < 0.0001) in log scale. The lowest total cost, while holding all other factors constant,

TABLE 2. Multivariate linear regression results comparing total direct cost post-index on timing of prosthesis receipt while adjusting for covariates

	Estimate		
Variables	(% Change)	Standard Error	Р
Age	-0.0049 (-0.5%)	0.004	0.1997
Sex (female vs. male)	-0.058 (-5.8%)	0.079	0.4639
Diabetes/vascular status (no vs. yes)	-0.059 (-5.9%)	0.075	0.4339
Presurgery cost ^a	0.125 (12.5%)	0.019	< 0.0001
Group A (vs. group X) ^{<i>a</i>}	-0.236 (-23.6%)	0.188	0.044
Group B (vs. group X)	-0.021 (-2.1%)	0.115	0.86
Group C (vs. group X)	-0.051 (-5.1%)	0.144	0.72
Group D (vs. group X) ^{a}	0.458 (45.8%)	0.089	0.015

Timing is stratified by groups. Group A results demonstrate a significant influence on total direct cost associated with a decrease as seen with the negative estimate as opposed to group D with an increase on total cost as seen with the positive estimate all compared with no prosthesis. The percentage change represents the magnitude by ratio that the variable influences the outcome (total costs). ^{*a*} Significant influence at 0.05.

occurred when an individual received a prosthesis in group A (between 0 and 3 mos). Receipt of a prosthesis in group A post-LLA decreased total cost by 0.24 (P = 0.044) in log scale when compared with not receiving a prosthesis within 12 mos (Fig. 1). Note that costs for group A patients included the cost of a prosthesis, whereas those for group X patients did not.

DISCUSSION

In a large representative population of commercially insured adults with LLA, earlier receipt of a prosthesis was associated with approximately 25% lower total direct healthcare costs compared with those who did not receive a prosthesis within 12 mos of LLA surgery. Inverse log transform of group means reflected an average of approximately \$99,409 in healthcare costs in the 12 mos postamputation for individuals in the earliest group compared with \$125,459 when no prosthesis was delivered within 12 mos. This demonstrates a potential cost saving with the intervention of a prosthesis earlier post-LLA. The finding that presurgical costs, which represent patient health spending, increase total postamputation costs by 12.5% supports that health acuity before surgery impacts overall total cost. However, it does not change the findings related to earlier prosthesis receipt on total healthcare expenditures. In other words, earlier receipt of a prosthesis is associated with reduced total healthcare expenditures while controlling for the level of spending per patient before surgery.

The primary finding of financial benefits coinciding with earlier delivery of a prosthesis is in alignment with previous evidence regarding the clinical benefits of early fitting of a prosthesis.^{17,21,23} Proposed clinical practice guidelines have suggested that intervention with a prosthesis early in the rehabilitation process is critical to individual physical health and improved quality care and promotes cost-effective patient management.²⁴ There is a likelihood of different healing rates among patients post-LLA. Yet, without appropriate prosthetic care, individuals have an increased risk of clinical complications, which may coincide with increases in healthcare utilization, such as acute hospitalizations and increased spending.⁸ The study sample contained a proportion of individuals with diabetes or vascular disease that was greater than the percentage of individuals noted in previous work²⁵ yet falls within the reported LLA among persons with diabetes in a more recent systematic review, which ranged from 27% to 65%.²⁶

The potential value added by the receipt of a prosthesis is also highlighted with findings when comparing the individuals with no prosthesis to those who received their prosthesis from 4–6 mos to 7–9 mos postamputation. Although the average total healthcare costs in the 12 mos postamputation were similar for individuals receiving their prosthesis 4-6 mos (~\$123,000) or 7-9 mos (~\$119,000) compared with no-prosthesis (~\$125,000), it should be noted that the cost of a prosthesis was included in the healthcare costs for those who received a prosthesis. Thus, in light of recent work noting the positive relationship between prosthetic mobility and quality of life,²⁷ there is considerable value in providing a prosthesis before 10 mos postamputation to afford patients the opportunity for improved quality of life. The notable increase in costs for individuals receiving a prosthesis after 10 mos postamputation should elicit individual level considerations for prosthetic rehabilitation.

Several studies have discussed the clinical benefits and advantages of prosthesis use, such as reduced falls, improved use and satisfaction of a prosthesis, and overall higher quality of life.^{20,28,29} This study excludes sources of other outcomes, such as mobility level or K-level. However, administrative data offer the opportunity to study utilization patterns and longitudinal health outcomes, such as date and timing of prosthesis receipt. It has also been documented that delayed fitting of a prosthesis or delayed rehabilitation can increase risk of complications such as reamputation and result in lower functional status.^{21,23} By measuring time to receipt of a prosthesis in groups anchored to LLA surgery, it was possible to objectively estimate the difference in cost associated with each group as time passed from LLA up to 12 mos, which demonstrated a financial benefit of a prosthesis from a payer perspective. A limited amount of analyses have evaluated costs and utilization for prostheses. A recent study by Dobson et al. (2016) estimated the cost and utilization anchored around receipt of prosthetic services as opposed to amputation surgery. Yet, the results of the Medicare analysis demonstrated that over a 12-mo period,



Cost Result of Time to Prosthesis

FIGURE 1. Group comparisons of total healthcare costs revealed earlier receipt of a prosthesis coincided with reduced total healthcare costs. Individuals receiving a prosthesis 4–9 mos postamputation had similar costs to those who never received a prosthesis despite inclusion of the costs of a prosthesis in their healthcare costs, which is not part of the expenses incurred by individuals grouped in the no-prosthesis group. Group estimated marginal means shown with associated standard error. Inverse log-transformation values for means presented above bar for qualitative comparison. Group A: 0–3 mos postamputation prosthesis receipt; group B: 4–6 mos postamputation; group C: 7–9 mos postamputation; group D: 10–12 mos postamputation; group X: no prosthesis.

those who received a prosthesis had reduced total Medicare payments by a reduction in hospitalizations, physician visits, and facility-based care and a lower rate of emergency room admissions compared with controls who did not receive prosthetic services.⁸ Overall, this study includes a generally younger population with access to commercial insurance. Although the findings demonstrate the potential value of early receipt of a prosthesis with associated decrease in healthcare costs, age is a risk factor with increased comorbidities.^{11,29} Furthermore, in the United States, as adults reach the age of 65 yrs, they qualify for Medicare insurance.

Another estimation on total cost of care for adults with LLA was conducted by Jindeel and Narahara based on a cohort in California that included patients who experienced LLA at an academic tertiary county hospital. They included patients with and without insurance, yet the study contained only descriptive information and did not present timing of prosthesis receipt within the cost estimate.³⁰ Rehabilitation is a complex process with many factors involved, including variation in reasons that may contribute to the delay of a prosthesis, such as administrative delay. The evidence base on health economics of lower limb prosthetic rehabilitation is limited. The information deficits in this area have been discussed in recent articles, for example, in the RAND report on transfemoral economics and a literature review by Highsmith et al. on transtibial prosthesis economics.^{7,31} More detailed information on the timing of prosthesis receipt will continue to assist informing key stakeholders including physicians and payer sources on the benefits of early referral and delivery of a device anchored to a specific time, such as within 3 mos post-LLA.

STRENGTHS AND LIMITATIONS

The main strength of the current study was the ability to analyze a large nationwide dataset with 12 mos of follow-up post-LLA. Furthermore, this sample is representative of adults who have an LLA and who are continuously enrolled in a commercial health plan for at least 12 mos postamputation but does not represent all people with amputation in the United States. Receipt of prosthesis as well as diabetes/vascular status with the corresponding costs could be directly assessed from these claims data without relying on self-reported information. This is advantageous as, often, there is poor or inaccurate recall on self-reported information such as when an individual received his/her prosthesis or on status of health conditions, which could lead to bias in the analysis.

However, there are also limitations to be considered in the current study. First, the costs represented individuals who had commercial insurance and did not include individuals with Medicare or Medicaid or the uninsured. Second, classification according to type of diabetes was not possible because a large amount of diagnoses were coded as unspecified. Also, cause of amputation was inferred to be due to diabetes or vascular disease based on the presence of this diagnosis; therefore, it is possible that some individuals with the diagnosis had a traumatic amputation. However, the proportion of individuals with diabetes or vascular disease in the cohort in this study was similar to reported incidence rates among adults with LLA.^{25,26,32} Third, there are limits to the ability to understand the factors associated with the timing of prosthesis receipt owing to the

nature of claims data, such as clinical or administrative decisions that may influence timing of prosthesis receipt. Finally, not all direct medical costs were included that may represent additional healthcare resource use, such as expenditures related to prescription drugs, dentist related costs, or out-of-pocket spending. However, the inpatient, outpatient, and emergency department settings are reflected in the current analysis. It is noted that a 3-mo preamputation window could be longer to gather seasonal variations in healthcare use. Furthermore, given the magnitude of the group mean costs over a 12-mo period, it seems unlikely that the results would be heavily swayed by prescription drug costs. Nevertheless, future work should consider prescription drug and out-of-pocket expenses. It is also pertinent to note that private insurance plans may vary and not cover all services equally. However, as costs of treatment for chronic conditions and health care in the United States have continually increased over the past decades, several studies have reported the significance of access to rehabilitation services for restoration of mobility and independence postamputation.^{11,28,29}

CONCLUSION

In conclusion, although the economic burden associated with health care for those with chronic health conditions and the aging population remains high, the clinical benefits of prosthetic rehabilitation services can actually serve to potentially reduce other nonprosthetic costs. The current findings suggest that age, sex, and diabetes/vascular status alone are not drivers of total healthcare costs in the 12 mos postamputation. As such, efforts to mitigate total healthcare costs likely will not do well when driven by such factors. Alternatively, earlier delivery of a prosthesis is associated with reduced overall direct healthcare costs. Not only are there physical, social, and mental benefits to receiving a prosthesis, the current study notes there are also economic benefits.^{8,21,29} The physical, social, and mental benefits may be responsible for the economic benefits, but future work is needed to explore this notion. Presurgical costs and health acuity result in increased healthcare costs, but there are benefits of earlier prosthesis receipt in reducing an individual's overall healthcare costs.

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