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Functional Outcomes of Persons Undergoing Dysvascular Lower Extremity Amputations:

Effect of a Post-Acute Rehabilitation Setting

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Abstract

Objective—To examine the effect of post-acute rehabilitation setting on functional outcomes among patients undergoing major lower extremity dysvascular amputations.

Design—A population-based, prospective cohort study conducted in Maryland and Wisconsin. Data collected from medical records and patient interviews conducted during acute hospitalization following amputation and at six-month following the acute care discharge were analyzed using multivariate models and instrumental variable techniques.

Results—A total of 297 patients were analyzed based on post-acute care rehabilitation setting: acute inpatient rehabilitation (IRF), skilled nursing facility (SNF) or home. The majority (43.4%) received care in IRF, 32% in SNF, and 24.6% at home. On SF-36 subscales, significantly improved outcomes were observed for patients receiving post-acute care at an IRF relative to those cared for at a SNF in physical function (PF), role physical (RF) and physical component score (PCS). Patients receiving post-acute care in IRFs also experienced better RF and PCS outcomes compared to those discharged directly home. In addition, patients receiving post-acute care at an IRF were significantly more likely to score in the top quartile for general health in IRF compared to SNF or home, and less likely to score in the lowest quartile for PF, RF and PCS in IRF compared to SNF. Lower ADL impairment was observed in IRF compared to SNF.

Conclusions—Among this large and diverse cohort of patients undergoing major dysvascular lower limb amputations, receipt of interdisciplinary rehabilitation services at an IRF yielded improved functional outcomes six months after amputation relative to care received at SNFs or home.

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Keywords

Rehabilitation; Amputation; Peripheral Vascular Diseases; Outcome Assessment

Currently, the incidence of limb loss secondary to dysvascular etiology accounts for the majority (82%) of amputations in the United States¹ and the incidence of such amputations is expected to rise with climbing rates of co-morbid diseases such as peripheral vascular disease and diabetes.² The prevalence of dysvascular lower extremity amputations (i.e. non-trauma and non-congenital related amputations) as of 2005 is estimated to be 846,000 people, with the number of such amputees projected to nearly triple to over 2.27 million people by the year 2050.³ High rates of mortality and morbidity, impaired function and reduced quality of life are common outcomes of major amputations.^{4–7} The positive effects of comprehensive inpatient rehabilitation on patients' survival, clinical stability, general health, and re-amputation rate has been established in several studies.^{7–12} Despite growing evidence of its effectiveness, the proportion of patients who receive inpatient rehabilitation following a major dysvascular lower extremity amputation remains low, with less than one third of those patients being discharged to an inpatient rehabilitation facility.^{13,14} To a large extent, papers examining the effects of post-acute care setting on outcomes have not focused on physical function or physical independence as outcomes,^{6,15–18} despite evidence that improved physical functioning is correlated with increased survival.¹⁹ In addition, with one notable exception, studies to date have been most often retrospective, relying primarily on claims data, administrative data, and chart review.^{7–12,15,17–18} Most recently, a prospective study showed that Veteran dysvascular amputees treated in a VA inpatient rehabilitation facility experienced better long-term mobility than those who did not receive inpatient rehabilitation care.²⁰

The purpose of this study was to examine, prospectively, the effectiveness of rehabilitation received at alternative post-acute care settings at improving functional outcomes among patients undergoing major lower extremity amputation secondary to dysvascular disease. Specifically, we analyzed physical functioning and impairment in ADLs six months post-amputation among patients who received post-acute care in three main settings: (1) inpatient rehabilitation facilities (IRF), (2) skilled nursing facilities (SNF), or (3) home. Recognizing that patients are not randomly assigned to these various settings, the study was designed to account for factors that influence both receipt of care at alternative post-acute settings as well as outcomes.

METHODS

Study Population

Persons undergoing a major dysvascular lower limb amputation, defined as amputations at the foot (trans-metatarsal or above), transtibial or transfemoral levels, as well as bilateral amputations (excluding toes), were identified during their surgical acute care stay. Eighteen participating hospitals in Baltimore, Maryland and Milwaukee, Wisconsin served as the referral base for this study. Upon identification, all potentially eligible subjects were approached by a trained interviewer who described the study and obtained consent. Patients who were aged 21 or younger, those undergoing amputations secondary to non-dysvascular etiology (i.e. trauma-related, congenital disease), those who were cognitively unable to provide informed consent (as determined by a score of 6 or lower in the administration of the *Short Portable Mental Status Questionnaire*) or non-English speaking, and those who had any previous history of stroke or paraplegia were excluded from the study. In addition, patients who died during their acute hospital stay were withdrawn from the study. The study was approved by all appropriate Institutional Review Boards.

Sources of Data

Data for this study were drawn from a prospective, multi-center, longitudinal survey of persons undergoing major lower limb dysvascular amputations at the participating hospitals in two geographically and racially diverse metropolitan areas: Baltimore, Maryland and Milwaukee, Wisconsin. A survey instrument was developed to obtain comprehensive clinical and functional data from patients with regard to their baseline, acute post-surgical, and post-acute rehabilitation status. Details of the survey can be found in Dillingham, et al.²¹ Information was obtained from three main sources: 1) clinical data abstracted from acute care medical charts; 2) a baseline face-to-face patient interview that collected pre-amputation information about the patient's health and functional status during the four weeks preceding the amputation (administered during the acute (surgical) hospitalization); and 3) a follow-up telephone interview at six months post-acute care discharge. The chart review utilized a structured abstraction instrument to obtain specific information about the patient's past medical and amputation histories as well as hospital course, including ICU stay, length of stay, and hospital complications. The initial, in-hospital interview relied on existing, validated measures of physical functioning and disability (most notably, the Medical Outcomes Study Short Form measure (MOS-SF36)^{22–25} and basic activities of daily living (ADL) scales,²⁶ further defined below, to establish baseline measures of health and functional status for the (retrospectively assessed) reference period of one month pre-amputation. At the six month follow-up telephone interview, information was obtained on those same physical functioning measures (SF-36 and its components and ADL scale), as well as development of secondary medical conditions (e.g., pain), health service use, and health-related quality of life. All interviews were conducted by trained interviewers and took place between 2001 and 2006.

Key Variable Definitions

Outcomes—Measures of physical health are based on the MOS Short Form (SF-36) instrument, a collection of 8 sub-scales and two summary components, capturing physical and mental health.^{22–25} In addition to being one of the most widely used, cross-setting measures of patient reported outcomes, the SF-36 has excellent psychometric properties and has demonstrated sensitivity to assess treatment effectiveness across a variety of patient populations. We focus on the four sub-scales of the SF-36 designed to capture physical health: physical functioning (PF, ascertaining the extent to which a person's physical health limits him/her in moderate activities); role limitations due to physical problems (RF, ascertaining the extent to which physical health has hindered a person's ability to perform his/her work or other activities); vitality (VT, self-report measures of energy and fatigue), and general health perceptions (GH) as well as the overall physical composite score (PCS). In order to assess whether alternative post-acute rehabilitation settings were more or less effective in protecting patients from falling in the most severely impaired group or in increasing their likelihood of achieving the highest levels of function, we also examined the probability of patients being in the highest and lowest quartiles of these categories. Physical functioning was further examined with regard to disability, as measured by limitations with basic activities of daily living (ADLs), using a well-validated scale developed by Katz that is amenable for administration via telephone and applicable to patients regardless of post-acute care setting.²⁶ Persons were subsequently coded as having (i) any disability defined as any ADLs (versus no ADLs) as well as (ii) severe disability defined as three or more ADL impairments (relative to 2 or less, including no ADLs), based on self-reported difficulty with six basic self-care activities (dressing, bathing, transferring, toileting, eating, getting around the house).

Post-Acute Rehabilitation Setting—Initial discharge setting and post-acute utilization data were obtained through a combination of hospitals' administrative records and self-

reported data on medical service use that were collected as part of the patient interview. Post-acute care settings were classified into three mutually exclusive categories: comprehensive inpatient rehabilitation facility (IRF), skilled nursing facility (SNF), and discharge home (with or without home health care). As a first step, patients were classified as receiving post-acute care in inpatient rehabilitation if they (i) were discharged directly to or (ii) spent at least one night in a free-standing rehabilitation hospital or a rehabilitation unit within a hospital over the six month study period. Likewise, patients who were directly discharged to or had spent at least one night during the six-month following their amputation at either a designated subacute rehabilitation facility or a nursing home were classified as receiving post-acute care at a skilled nursing facility. For patients initially discharged to IRF who were subsequently admitted to a SNF, the relevant setting was determined based on the place in which the patient spent the majority of his/her institutional post-acute care during the six month study period. Patients were assigned to the home category if they were discharged home from the acute setting and were never admitted to either an inpatient rehabilitation or skilled nursing facility.

Amputation Level—Amputation was classified into four mutually exclusive categories according to the level of the amputation: foot (transmetatarsal or above), unilateral transtibial (below knee), unilateral transfemoral (through or above knee), or bilateral amputations (excluding toe amputations). Patients classified as bilateral amputees had a pre-existing (most often, transtibial) amputation and underwent a second contralateral amputation at the foot or above level during the index study period amputation surgery. Although eligible, there were no hemipelvectomy or hip disarticulation surgical patients in our follow-up study population. Whenever a patient had undergone an amputation prior the index surgery, the final level of limb loss was used for classification of amputation level.

A number of additional variables, capturing variations in patients' health, socio-demographic, and economic, were derived from patient interviews and medical chart data, and included as covariates in all analyses. These included baseline, pre-amputation measures of patients' health and functional status (measured, as described above, by the SF-36 physical component summary score (PCS) and mental component summary score (MCS), the presence and number of pre-existing medical conditions (coded using the algorithm developed by Deyo²⁷), the presence of perioperative complications (sepsis or cardio-respiratory events), the patient's length of stay during the acute surgical hospitalization, the patients' socio-economic characteristics including age (in years), gender, race (coded as African American versus other racial groups), marital status (married, divorced/separated, relative to other statuses), insurance coverage (Medicare, Medicaid, or other public programs vs. private insurance), income level (four groups, including a missing category), baseline measures of social support (if the patient lived alone or with others), and the geographic region where the patient received acute care services.

Statistical Analysis

Descriptive statistics were used to characterize the sample according to socio-demographic profile, amputation level and health status using means, distributions and tabular data. In addition to general descriptive information, the characteristics of the groups receiving post-acute care at each alternative setting (IRF, SNF or home) were contrasted and compared using univariate (t and χ^2) test statistics.

Our primary empirical goal in the multivariate analyses was to estimate the relationship between post-acute care setting and physical functioning at six months post-amputation, controlling for baseline functioning and other confounders. One important econometric issue complicated the estimation process, namely, the potentially biasing effects of non-random

“assignment” (discharge to or extent of utilization of) alternative post-acute care settings. To the extent that discharge to a specific post-acute care setting (e.g. IRF) is correlated with the outcome through unobservable variables, then estimates of the post-acute care settings coefficients will be biased. Such a correlation may be due, for example, to unobserved or unmeasured health status, which might affect simultaneously discharge to a post-acute care setting and physical outcomes conditional on post-acute care use. A necessary prelude to carrying out our multivariate analyses of the effects of post-acute care setting on outcomes, therefore, was obtaining selection-corrected estimates of post-acute care setting use. We applied the leading statistical method for addressing such source of endogeneity bias, the two-stage instrumental variable (IV) technique, when conducting our analysis.²⁸ Specifically, the two stage IV approach entailed estimating first the probability that an amputation patient would receive rehabilitation at each of the possible post-acute care settings. Coefficient parameters from this first stage were then used to form individual-level predictions of the probability of receiving care at each setting for the entire sample. These predicted values (rather than the actual post-acute care indicators) were used as additional regressors in the physical functioning outcome equations (stage two) yielding estimates of the effect of post acute care setting on outcomes that are free of endogeneity/selection bias.^{29–30} A multinomial Probit model was employed to estimate factors associated with utilization of each of the three post-acute care settings while standard Ordinary Least Squares (for continuous SF-36 scores) and binary Probit (e.g., probability of scoring in top or bottom quartile of each scale) specifications were used to estimate physical functioning outcomes.

Instrumental variables provide a powerful means to account for unobservable heterogeneity when addressing potential self-selection biases but only insofar as valid “instruments” (exclusion variables) are available.²⁹ Specifically, the IV method requires that, in addition to all variables included in the second-stage, outcome regressions, additional variables be included in stage one that are predictive of a patient’s post-acute care setting choice but that do not affect physical functioning or disability, *conditional* on having received post acute care at a given setting. Our choice of IVs was guided by factors often considered by discharge planners when making recommendations for post-acute care placement and included insurance coverage (Medicare, Medicaid or other public program, private insurance), social support (pre-amputation living arrangements, number of persons in the household), and architecture/accessibility of the patient’s home (single floor, wheelchair accessible). We tested the validity/quality of our instruments using over-identification tests based on the partial R^2 and F-statistics on the excluded variables in the first stage regression.³¹ The adequacy of the instruments was also tested with respect to the extent to which they could be legitimately excluded from the second stage (physical functioning, disability) estimations, conditional on post-acute care setting.

Finally, in order to provide a sense of the magnitude of the (adjusted) differences in outcomes across settings, we used the coefficient estimates from our outcome equations to estimate the magnitude of the *independent* effect of post-acute care setting on physical functioning. Specifically, we calculated the adjusted outcome score (continuous variables, e.g., RF score) and adjusted probabilities (binary outcomes, e.g., 3+ ADLs) assuming all patients were treated, alternatively, at each of the three post-acute care settings, while holding all other factors constant at their original levels. All analyses were conducted using SAS 9 and STATA 11.0 statistical software.

RESULTS

Seven-hundred and eighteen patients were approached for participation and 625 patients (or 87.1%) agreed to take part in the study. Of those, 277 were found to be ineligible during the

screening interview due primarily to a pre-existent stroke (regardless of severity, $n=238$) or temporary or permanent cognitive impairment affecting ability to provide informed consent ($n=20$).²¹ Of the 348 eligible consented patients, 297 patients participated in the 6-month follow-up interview and comprise the study sample for the purpose of these analyses.

Following their acute surgical hospitalization, 178 patients were discharged directly to an IRF. Of those, 49 experienced a relatively short IRF stay (mean=13, SD=9 nights) followed by a much longer SNF stay (mean=54, SD=65 nights). For the purpose of this analysis, these patients were assigned to the SNF category as the setting where the vast majority of their post-acute care was received, resulting in 129 patients (43.4%) receiving most of their post-acute care in an acute inpatient rehabilitation facility, 95 patients (32%) at a skilled nursing facility and 73 patients (24.6%) at home. The groups varied significantly with respect to age, but not with respect to gender or race. The mean age of those using skilled nursing facility was significantly higher (67.4 years old) than those in inpatient rehabilitation or at home (62.0 and 60.1 years old, respectively). Nearly 40% of all patients undergoing major dysvascular amputations were poor, reporting household incomes at or below \$20,000 per year. Those patients with the lowest income (<\$20,000) were more likely to receive post-acute care in a skilled nursing facility compared to home (44.2% vs. 28.8%, respectively) and those of middle income (between \$20,000 and \$49,000) were more likely to receive post-acute care in an inpatient rehabilitation facility relative to a skilled nursing facility (34.1% vs. 21.1%, respectively). Consistent with their age, the majority (71%) of patients were Medicare beneficiaries, an insurance status that afforded a higher likelihood of receiving post-acute care at an inpatient rehabilitation or skilled nursing facility relative to persons with private medical insurance.

With respect to health characteristics, the post-acute care groups varied significantly based on amputation level and perioperative complications, but no significant variation was observed with regard to the presence of previous amputation or the number of comorbidities. Transtibial (below knee) amputations accounted for the highest percentage of amputees in this population (45.8%), followed by bilateral lower extremity amputations (26.6%); the least number of patients received transfemoral (above knee) amputations (13.8%) and foot amputations (13.8%). Significant variation existed among the level of amputation with regard to rehabilitation setting. Patients who received transtibial (below knee) amputations were more likely to receive post-acute care in an inpatient rehabilitation facility (55.0%) or skilled nursing facility (49.5%) compared to home (24.7%). Surprisingly, those with bilateral amputations were more likely to receive post-acute care in a home setting (38.4%) compared to a skilled nursing facility (18.9%). Additionally, peri-operative complications varied significantly, with those patients treated post-acutely in an inpatient rehabilitation facility having fewer complications (4.7%) compared to those treated in a skilled nursing facility (12.6%).

Overall, the number of patients from whom data were obtained was nearly equal based on geographic data collection site. However, the post-acute care discharge distribution varied significantly by geographic area. In Baltimore, MD the percentage of patients who received inpatient rehabilitation care (36.4%) was significantly lower than the percentage who received post-acute care in either a skilled nursing facility or home (65.3% and 58.9% respectively). In contrast, among patients in Milwaukee, WI there was a significantly higher percentage that received inpatient rehabilitation (63.6%) compared to the skilled nursing facility group or home group (34.6% and 41.1%, respectively).

Using SF-36 scores to examine baseline, pre-amputation health status among rehabilitation sites for post-acute care, the patients in each group notably had no significant differences in their pre-amputation health status with regard to physical function, role limitations due to

physical health, vitality, general health, or physical component score. The only exception to this was that scores in general health were significantly higher for those patients receiving care in an inpatient rehabilitation facility (41.6) compared to a skilled nursing facility (39.1).

The top panel of Table 2 displays multivariate adjusted outcomes at the six month follow-up for physical function, role physical, vitality general health and overall Physical Component of the SF-36 scale. For four of the five sub-scales, receipt of care at an inpatient rehabilitation facility resulted in significant differences in physical function relative to care received at a skilled nursing facility. The adjusted physical function score for patients treated at an IRF was 3 points (or 12.7%) higher than that of patients treated in an SNF. With respect to role physical and general health, there was a 4.7 point and 2.6 point difference between settings, corresponding to a 13.9 % and 6.8% higher values, respectively, in reported scores at the 6-month follow-up. Overall, the physical component subscore suggests a 3.3 point difference, or 10.6% higher score among patients treated at an IRF relative to those receiving most of their post-acute care at an SNF. Persons treated at an IRF also scored 4 points (or 11.8%) higher in the role physical and 2.3 points (or 7.4%) higher in the overall physical component summary score than those discharged directly home. There were no significant differences between any of the groups for vitality.

The two middle panels of Table 2 show predicted (adjusted) probabilities of scoring in the highest and lowest quartile, respectively, of the SF-36 affording a comparison of the ability of different settings to move patients across the within-sample distribution of outcomes. Patients receiving most of their post-acute care in an inpatient rehabilitation facility were about twice as likely to achieve the best within-sample scores in general health than those treated at home or at a SNF (132% and 92.7% higher, $p < 0.05$, respectively). Similarly, the likelihood of being in the top quartile in physical component score was 62.1% higher (30.2% compared to 18.6%) for inpatient rehabilitation compared to skilled nursing facility (0.05 $p < 0.10$). In addition, receipt of post-acute care at an inpatient rehabilitation resulted in significantly lower likelihood of a patient scoring in the lowest quartile in physical function, role physical, and physical component scores ($p < 0.05$) relative to SNF and lower likelihood of scoring in the lowest quartile with regard to role limitations due to physical health compared to those at home (0.05 $p < 0.10$).

Finally, the bottom panel of Table 2 shows setting effects on the probability of any and severe ADL disability. Patients receiving post-acute care at an IRF were less 31% less likely to report any ADL disability and 55.6% less likely to report severe (3+) ADL disability than dysvascular amputees receiving post-acute care at SNFs (both at $p < 0.05$). There were no significant differences in disability probabilities between those cared for at inpatient rehabilitation facilities or discharged directly home.

DISCUSSION

Results of this multicenter prospective study of a diverse group of dysvascular amputees who received post-acute care at different settings in two different geographic areas indicate that patients who received post-acute care in an inpatient rehabilitation setting generally experience better outcomes 6-months post amputation than those who were treated at a skilled nursing facility or discharged directly home, even after adjusting for case mix and setting selection effects. The effects were consistent along the range of outcomes assessed, which included physical functioning, general health and ADL disability. Specifically, persons receiving most of their post-acute care in inpatient rehabilitation facility during the 6-month period following a major amputation experienced better physical function, were better able to perform physical roles, reported better general health and scored higher in the overall physical component than those receiving most of their institutional post-acute care at

a skilled nursing facility. In addition, persons receiving care at an inpatient rehabilitation facility reported a greater ability to perform physical roles than those discharged directly home, a compelling finding as patients sent home are often thought to have better function and sufficient support systems to succeed in a home rehabilitation environment. Although the adjusted scores for patients treated at an IRF remained relatively low (ranging from 27.2 to 47.2), most of the point differences between IRF and other settings were of a magnitude considered clinically and socially relevant (difference equivalent to a 0.25SD unit for most SF-36 subscales).²²

Findings from within-sample quartile analyses, designed to contrast the effect of alternative care settings in affecting a patient's ranking within their peer distribution, suggested that patients who were treated in an inpatient rehabilitation setting were more likely to score at the highest level of general health and overall physical functioning than amputees discharged home or receiving most of their post-acute care at an SNF, and less likely to score at the lowest levels of physical function when compared to their counterparts who received post-acute care at a skilled nursing facility. In addition, inpatient rehabilitation resulted in amputees achieving the highest within-sample levels of general health compared to both home and SNF, a finding that indicates that inpatient rehabilitation enhances one's likelihood of achieving the maximum functioning possible for patients with similar circumstances. Finally, patients treated at inpatient rehabilitation facilities had less ADL disability than those treated in SNFs at six months after amputation.

Our results confirm findings from retrospective analyses showing a positive association between inpatient rehabilitation and several health-related outcomes for a dysvascular amputee population.^{7-12,21} Dillingham, et al demonstrated that receiving inpatient rehabilitation care following dysvascular amputation was associated with reduced mortality, lower rates of re-amputation, greater medical stability and improved prosthesis acquisition using Medicare claims data.⁸ A study of outcomes for traumatic amputees by Pezzin, et al showed that long term physical function was associated with length of stay in inpatient rehabilitation.⁷ Stineman, et al examined outcomes of dysvascular amputee patients in the VA setting using administrative databases and showed a greater likelihood of one year survival and home discharge of patients receiving immediate post-acute inpatient rehabilitation.¹⁰ A number of studies have also examined physical function and independence following receipt of inpatient rehabilitation care.^{6,9, 16,17,19, 20} Studies have shown that quality of life and return to work in the amputee population is strongly influenced by mobility (including prosthesis acquisition and prosthesis use), physical function and general activity level.^{15-16,33-34} Additionally, improved physical independence has been shown to be correlated with survival¹⁹, further highlighting the importance of optimization of functional outcomes during the rehabilitation process for amputee patients.

More importantly, our study contributes to the emerging literature on comparative effectiveness of post-acute care settings for the rehabilitation of dysvascular amputees. In a recent study, Czerniecki et al²⁰ examined long-term mobility outcomes among a cohort of Veterans with dysvascular amputations, showing a similar positive effect of post-acute care received at an inpatient rehabilitation setting (relative to not receiving care in an IRF) within the context of a unique health care system --the Veterans Affairs.

There are a number of reasons why outcomes might be superior among those receiving care at an inpatient habilitation facility, even after correction for selection effects. The amount and variety of therapy services received in an inpatient rehabilitation facility are generally greater than those received in a skilled nursing facility or in a home setting.³² Czerniecki et al,²⁰ however, report that the number of therapy sessions did not fully explain variations in mobility outcomes in their sample, and concluded that inpatient rehabilitation environment

likely provides a dimension to improved mobility that goes beyond increased number and intensity of therapy sessions. In addition, patients admitted to an inpatient rehabilitation unit typically receive daily care from a physiatrist and from rehabilitation nursing, coordinated discharge planning via individual meetings and weekly team meetings, and focused goal setting.³² Patients participate in early postoperative mobility, transfer and self-care training, and extensive patient and family education that facilitates a successful transition to independent or assisted community living is provided. The initial goals of an inpatient rehabilitation stay for a person with an amputation is to become independent from a wheelchair or at a crutch or walker level of ambulation. As importantly, patients and their family members are instructed in optimal wound care, and complex chronic medical conditions, such as diabetes and hypertension, are stabilized on an inpatient rehabilitation unit. In addition, the improvements in psychological adjustment frequently seen through working with a rehabilitation psychologist while on an inpatient unit may also have a positive impact on functional outcomes. Patients are closely monitored for postoperative complications. In contrast, rehabilitation services received at a subacute or skilled nursing facility are frequently less intense with less medical oversight.³² Discharge directly to a home setting usually implies either outpatient therapy if the person has transportation and is not homebound, or home therapies are instituted to achieve rehabilitation goals. The added value of an integrated, coordinated team approach and more intense rehabilitation received on an inpatient rehabilitation unit, as well as the close medical monitoring, disposition planning, and patient and family education may have influenced the improved functional outcomes observed in this and other studies.

There are several limitations that must also be recognized in this study. For ethical and operational reasons, this was not a randomized controlled trial. Issues of selection with respect to discharge disposition following amputation, therefore, were of concern in our observational study. Selection of patients deemed to most benefit from inpatient rehabilitation is a complex process requiring the clinical judgment of the consulting physiatrist and team. Careful consideration is given to medical needs, rehabilitation goals and tolerance, and home situation including family support. To address this concern, we employed instrumental variable techniques, the leading statistical approach for addressing “non-random assignment to treatment” in observational studies, as recognized by the recent PCORI Methodological Report.³⁵ This approach enabled us to control for observable (e.g., comorbidities, amputation level, social support network)²¹ and unobservable (e.g., frailty, rehabilitation potential) factors influencing both the referral decision regarding post-acute care setting and outcomes, thereby obtaining causal estimates of the relationship between post-acute care setting and outcomes. The ability to correct for likely selection bias, however, comes with a price: Despite the relatively large sample for a study of this nature, our power to detect differences was limited due to the demands of our instrumental variable modeling approach, which tends to increase standard errors around “instrumented” care setting estimates. For this reason, we discuss differences that were significant at conventional levels ($p < 0.05$) as well as those that were trending significance (p -values of less than 0.10). Another potential limitation is the use of general measures for assessing functional outcomes, the SF-36 and Katz’s ADL disability, rather than more traditional rehabilitation assessment tools, such as the Functional Independence Measure (FIM). As noted by Jette et al.,³⁶ however, no assessment tool is uniquely well-equipped to “meet the challenge of monitoring functional outcomes across settings where post-acute care is provided.” In addition to being a well-validated, widely utilized measure for a variety of conditions, with clear interpretation with regard to physical health,^{22–25} the SF-36 has the advantage of *not* having been developed for a specific inpatient setting and of being “the most precise for community dwelling patients,”³⁶ making it ideal for examining cross-setting, long-term outcomes for the sample of interest in this long-term outcome study. Lastly, our assessment of pre-amputation functioning is subject to recall bias, whereby

patients may have under or over-stated their perceived prior functional status at the time of the amputation. Although theoretically possible, recall bias is not likely a practical concern as there is no reason to anticipate that recall would differ systematically across patients discharged to alternative settings.

Despite these qualifications, there are several strengths of this investigation that merit mention. Prospective health-related outcomes research in the area of Physical Medicine and Rehabilitation is limited. To our knowledge, this is the first prospective, population-based study to contrast outcomes in an unselected sample of patients with dysvascular amputations across different post-acute care settings. Our findings underscore the value of providing increased access to inpatient rehabilitation facilities to persons undergoing major lower limb dysvascular amputations, which is currently relatively low (10% and 16% among dysvascular amputees in Maryland¹⁴ and Massachusetts¹³, for example). The study population was diverse with about 30% African Americans in all disposition categories. The outcome measures were patient-centered and derived directly from the subjects enabling consistent assessment of physical function at both baseline and follow-up periods.

The persistent and consistent differences in post-rehabilitation physical functioning across settings, despite a rigorous instrumental variable analysis, suggest that the observed better outcomes are attributable to care at an inpatient rehabilitation setting rather than patient selection. Set against a backdrop of national underutilization and increased regulations restricting access to inpatient rehabilitation services [37], our findings have important policy implications for improving the care and outcomes for the large and growing number of persons undergoing dysvascular amputations in the U.S.

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TABLE 1

Characteristics of the sample population

	Overall (N = 297)	By Discharge Destination		
		IRF (n = 129)	SNF (n = 95)	Home (n = 73)
Distribution		43.4%	32.0%	24.6%
Age, mean (SD), yrs	63.2 (13.3)	62.0 (12.0) ^b	67.4 (13.5) ^a	60.1 (14.0)
Men, %	59.3	61.2	54.7	61.6
Race: non-African American, %	72.7	76.0	72.6	67.1
Family income, %				
Missing	25.6	17.1 ^a	27.4	38.4
<\$20,000	38.7	40.3	44.2 ^a	28.8
\$20,000–\$49,999	26.9	34.1 ^b	21.1	21.9
>\$50,000	8.8	8.5	7.4	11.0
Insurance coverage				
Medicare	71.0	72.0 ^a	78.1 ^a	62.6
Medicaid	8.3	9.9 ^b	4.1	8.4 ^b
Other	20.7	18.2 ^a	17.8 ^a	28.4
Amputation level, %				
Foot (transmetatarsal or above)	13.8	6.2 ^{a,b}	13.7 ^a	27.3
Transfemoral (above-knee level)	13.8	13.2	17.9	9.6
Transtibial (below-knee level)	45.8	55.0 ^a	49.5 ^a	24.7
Bilateral	26.6	25.6	18.9 ^a	38.4
Any previous amputation, %	20.5	20.2	15.8	27.4
Comorbidities, mean (SD)	5.4 (2.1)	5.3 (2.0)	5.6 (2.1)	5.2 (2.2)
Perioperative complications, %	7.4	4.7 ^b	12.6	5.5
Location: Greater Baltimore, %	51.2	36.4 ^{a,b}	65.3	58.9
Preamputation health status, mean (SD)				
Physical function	29.9 (13.6)	28.7 (13.9)	30.4 (13.8)	31.3 (12.6)
Role physical	32.8 (13.4)	31.6 (12.8)	32.9 (14.4)	34.9 (12.9)
Vitality	45.2 (10.7)	44.9 (10.2)	44.7 (11.6)	46.5 (10.6)
General health	40.2 (9.7)	41.6 (9.5) ^b	39.1 (9.2)	39.1 (10.4)
Physical component summary score	32.2 (10.1)	31.8 (10.0)	31.8 (10.3)	33.4 (10.3)
Mental component summary score	46.1 (13.0)	45.5 (14.2)	46.5 (12.9)	46.5 (10.9)

^aSignificantly different from home at $P < 0.05$ level.^bSignificantly different from SNF at $P < 0.05$ level.

Selection-corrected, adjusted physical health and functioning by postacute care setting

TABLE 2

	Adjusted Outcome		Percentage Difference		Adjusted Outcome		Percentage Difference		Adjusted Outcome		Percentage Difference	
	Home	IRF	IRF vs. Home	SNF	Home	IRF	IRF vs. Home	SNF	Home	IRF	IRF vs. Home	SNF
Six-month follow-up scores												
PF	26.6	27.2	2.2	24.2								12.7 ^b
RF	34.2	38.2	11.8 ^b	33.5								13.9 ^b
VT	47.6	47.4	-0.4	46.8								1.3
GH	39.6	41.7	5.4	39.1								6.8 ^a
PCS	32.0	34.3	7.4 ^a	31.0								10.6 ^b
Probability of scoring in the top quartile of overall sample distribution at 6-mo follow-up												
PF	21.2	24.7	16.2	17.0								45.2
RF	19.7	26.9	36.6	20.1								34.1
VT	20.4	22.0	7.6	23.1								-4.9
GH	12.8	29.7	132.0 ^b	15.4								92.7 ^b
PCS	23.4	30.2	28.9	18.6								62.1 ^a
Probability of scoring in the bottom quartile of overall sample distribution at 6-mo follow-up												
PF	27.4	30.1	9.9	48.3								-37.8 ^b
RF	29.1	18.1	-37.9 ^a	36.8								-50.8 ^b
VT	24.7	27.6	12.0	34.3								-19.4
GH	22.7	26.4	16.3	34.4								-23.4
PCS	26.3	19.5	-25.9	32.6								-40.1 ^b
Disability level												
Severe: three or more ADLs	17.37	13.16	-24.24	29.66								-55.6 ^b
Any ADL impairment	44.75	43.13	-3.62	62.49								-31.0 ^b

Adjusted outcomes are based on regression analyses that control for amputation level, preamputation health functioning and disability, sociodemographic and economic characteristics of patients, as well as self-selection into alternative settings. Disability level is determined by the number of impaired basic ADLs.

^aDifferences that are statistically significant at 0.05 $P < 0.10$.

^bDifferences that are statistically significant at $P < 0.05$.