COMORBIDITY HAS NO IMPACT ON UNPLANNED DISCHARGE OR FUNCTIONAL GAINS IN PERSONS WITH DYSVASCULAR AMPUTATION

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Objective: To examine how factors associated with infection, organ failure, poor wound healing, or indices of chronic vascular disease are associated with unplanned transfers and functional gains in a population of dysvascular amputees during inpatient rehabilitation.

Design: Cross-sectional.

Setting: Inpatient rehabilitation unit at an academic medical centre.

Patients: A total of 118 patients with new, dysvascular, lower-extremity, amputation participating in inpatient rehabilitation.

Methods: Logistic regression and indices of change (minimal detectable change; MDC90), standardized response mean and effect size were used to examine the risks of unplanned transfer and functional change.

Main outcome measurements: Rate of unplanned transfers from rehabilitation, and Functional Independence Measure (FIM).

Results: Out of the total of 118 patients 19 had unplanned transfers due to medical complications. Age, creatinine, haemoglobin, white blood cell count, haemodialysis, wound vacuum device use, intravenous antibiotic use, or previous amputations were not independently associated with unplanned transfers, motor FIM change or efficiency. The MDC90 for motor FIM was 17.84, with 21.2% of patients exceeding this value; standardized response mean and effect size were large (1.03 and 1.39, respectively).

Conclusion: This study suggests that the presence of comorbidities in a population of dysvascular amputees participating in inpatient rehabilitation did not increase the risk of unplanned transfers or affect FIM gains.

Key words: amputation; inpatient rehabilitation; comorbidity; interrupted stay; healthcare quality; lower extremity amputee.

Accepted Mar 25, 2019: Epub ahead of print Apr 9, 2019

J Rehabil Med 2019; 51: 369–375

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In the USA, patients are currently being admitted to inpatient rehabilitation more quickly following major surgery, and lengths of stay in acute care are decreasing. This is due to many factors, including increased scrutiny of inpatient rehabilitation facilities by payers and an increase in prospective payment structures for many surgical services that discharge patients to inpatient rehabilitation (1–3). As the medical complexity of patients admitted to inpatient rehabilitation increases, the incidence of unplanned transfers from inpatient rehabilitation units to acute medical services due to medical complications has also increased (4). Unplanned transfers negatively affect patients’ rehabilitation trajectories and increase healthcare costs, making appropriate selection and medical management of patients admitted to inpatient rehabilitation increasingly important (5). Screening patients to identify those at high risk of medical emergencies is essential to avoid unplanned transfers from inpatient rehabilitation.

Among common diagnoses seen in inpatient rehabilitation patients, dysvascular lower extremity amputee patients represent a population that is particularly vulnerable to medical complications due to the significant chronic comorbidities that often contributed to the amputation, such as diabetes. As a result, patients with lower extremity amputation are at particularly high risk of unplanned transfers from inpatient rehabilitation units compared with other diagnoses commonly admitted to inpatient rehabilitation (4, 6). Patients with dysvascular lower extremity amputation also have a higher rate of re-hospitalization, more so than other common inpatient rehabilitation diagnoses, such as spinal cord injury (SCI) (6), traumatic brain injury (TBI) (7), and stroke (8), which suggests that the co-
The primary objective of this study was to examine whether certain indicators of medical comorbidities, available at the time of admission to inpatient rehabilitation, were associated with an increased risk of unplanned transfers from inpatient rehabilitation among patients with amputation due to vascular disease. Specifically, the study focused on factors associated with infection, poor wound healing, organ failure, and/or previous amputations that were commonly available at the time of admission to inpatient rehabilitation. No previous study has evaluated indicators of infection risk, such as the presence of wound vacuums, ESRD, or diagnoses that confound vascular disease, such as diabetes, as they relate to the risk of unplanned transfers from inpatient rehabilitation in dysvascular amputee patients. The secondary objective was to examine whether the aforementioned factors were associated with decreased functional gains during inpatient rehabilitation. A greater understanding of these risk factors can help identify patients at greater risk of severe medical complication, which could allow for the reduction in unplanned discharges by identifying specific comorbidities that might require more proactive management, or situations that may warrant a delay in admission to rehabilitation in order for medical stability to be firmly established prior to transfer.

METHODS

Study design

Using a cross-sectional, retrospective design, data were collected from electronic medical records of patients who received inpatient rehabilitation in an academic tertiary rehabilitation centre. Ethics approval for a waiver of informed consent was obtained before initiation of the study from the University of Michigan, Medical School Institutional Review Board. Data were collected from consecutive patients over the age of 18 years who were admitted to the acute inpatient rehabilitation unit from January 2011 to April 2015 following new transfemoral or transtibial amputation(s) due to sequelae of chronic vascular disease. Patients with previous amputations were included in the sample if they were undergoing a new, contralateral amputation. Patients were excluded from the sample if they had missing or incomplete data, were admitted for partial foot or toe amputations, or if their rehabilitation stay followed hospitalization for a reason other than amputation. In total, 49 patients were excluded, primarily because their admission to inpatient rehabilitation was not due to a new amputation. Only 3 patients were excluded due to having had foot or toe amputations, compared with above/below knee amputations (Fig. 1).

Study variables

The primary outcome of this study was the incidence of transfer from inpatient rehabilitation to an acute care medical service due to a medical complication. The secondary outcome was func-
were 4 cases of studentized residuals with values greater than 3.00 standard deviations (SD), which were kept in the analysis. Because of interest in the potential functional benefits of a full course of inpatient rehabilitation, patients with unplanned transfers were excluded from the analysis of functional gains. In addition to examining the relationship of medical variables and functional gains, 3 indices of change for total and motor FIM scores (i.e. gain scores) were evaluated: minimal detectable change (MDC); Cohen’s effect size; and the standardized response mean (SRM). The MDC is a statistical measure of change, defined as the minimum amount of change that exceeds measurement error. In other words, the smallest change that is due to “true” change and not variation in measurement (14). The intraclass coefficients (ICC) for total and motor FIM gain scores, within each group, were used to calculate the standard error of measurement (SEM) and MDC at the 90% confidence level (MDC90) using the following formula: 1.64*SEM*. The percentage of patients whose total and motor FIM gain scores exceeded the MDC90 using the $\chi^2$ test of homogeneity were also examined. Cohen’s effect size quantifies the size of the difference between baseline and follow up (i.e. admission and discharge) and estimates the magnitude of treatment effect; in this case, inpatient rehabilitation. Within-group effect size as admission to discharge difference divided by the admission score SD was also calculated. Similar to effect size, SRM attempts to quantify the effect of the treatment, or inpatient rehabilitation. It is preferred to paired t-test because it removes the dependence on sample sizes (19). The model contained 12 independent variables: white blood cell count (WBC, value), use of IV antibiotics (no/yes), creatinine (value), haemodialysis status at admission (no/yes), wound vac presence at admission (no/yes), history of diabetes treated with insulin and/or medication (no/yes), haemoglobin (value), history of a previous amputation (no/yes), length of stay on the rehabilitation unit (days), gender (male/female), time between amputation and admission to the acute inpatient rehabilitation unit (days), and motor FIM at admission (value). These variables were selected due to their correlation with chronic disease, risk of infection, and/or risk of poor wound healing. The same predictive model was used for all regression testing with the exception of length of stay for motor FIM efficiency, as this is used in the calculation of the outcome. Model variables were entered in a step-wise fashion, beginning with factors expected to have the most explanatory power, to observe the degree of change in the amount of variance in the outcome each step contributed. All analyses were conducted in IBM SPSS version 23, Armonk, NY, USA.

**RESULTS**

Patient characteristics

The sample was primarily male (82, 70.1%), Caucasian (84, 75.7%), with a mean age of 60.8 years (standard deviation (SD) 12.9). The patients had a mean of 10.9 days (SD 10.5) between amputation and admission to acute rehabilitation with a mean length of stay of 14.1 days (SD 7.1). Descriptives of study variables are given in Table I. In general, the sample reflected the medical complexity of the dysvascular amputee population. The mean creatinine value of the sample was above the upper limit of normal (SD 1.3 mg/dl), and the mean haemoglobin was below the lower limit of normal (SD

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**Fig. 1.** Inclusion and exclusion criteria.
12.6 g/dl); 22% were being treated with IV antibiotics at the time of admission to the inpatient rehabilitation unit. Ten percent of the sample had incisions requiring wound vac, and 11% were on haemodialysis at the time of admission to the inpatient rehabilitation unit.

### Table I. Descriptives of study variables

| Study variable                                                                 | n = 118                   |
|--------------------------------------------------------------------------------|---------------------------|
| Days since amputation at admission to acute rehabilitation, mean (SD) [range] | 15.3 (34.8) [2 to 288]    |
| Days in acute rehabilitation, mean (SD) [range]                                | 14 (7.1) [2 to 41]        |
| Creatinine at admission, mean (SD) [range]                                    | 1.61 (1.7) [0 to 8]       |
| Haemoglobin at admission, mean (SD) [range]                                   | 8.89 (1.4) [7 to 14]      |
| White blood cell count at admission, mean (SD) [range]                        | 9.12 (3.0) [4 to 19]      |
| On haemodialysis at admission, n (%)                                          | 8 (11.3)                  |
| On wound vac at admission, n (%)                                              | 7 (9.9)                   |
| Taking intravenous antibiotics at admission, n (%)                            | 16 (22.5)                 |
| Previous amputations, n (%)                                                    | 7 (9.9)                   |
| Motor FIM admission and discharge, mean (SD) [range]                          | 39.8 (10.8) [12 to 61] and 50.8 (14.1) [21 to 76] |
| Motor FIM gain (admission – discharge motor FIM score, mean (SD) [range]     | 10.87 (10.3) [–25 to 35]  |
| FIM efficiency (admission – discharge motor FIM score, mean (SD) [range]     | 0.84 (2.8) [–25 to 5]     |

SD: standard deviation; FIM: Functional Independence Measure.

### Table II. Primary reasons for unplanned discharge from rehabilitation unit

| Reason                                              | Number of patients |
|-----------------------------------------------------|--------------------|
| Infection, unrelated to amputation                  | 5                  |
| Acute kidney injury                                 | 4                  |
| Hypoxia/respiratory failure                         | 3                  |
| Myocardial infarction                               | 2                  |
| Amputation wound dehiscence                         | 1                  |
| Amputation wound infection                          | 1                  |
| Other wound complication                            | 1                  |
| Altered mental status                               | 1                  |
| Gastrointestinal bleeding                           | 1                  |
| **Total**                                           | **19**             |

### Table III. Logistic regression predicting likelihood of unplanned transfer from inpatient rehabilitation

|                  | B      | SE     | Wald  | df | Sig. | Exp(B) | 95% confidence interval |
|------------------|--------|--------|-------|----|------|--------|-------------------------|
|                  |        |        |       |    |      |        | Lower | Upper                   |
| White blood cells| -0.18  | 0.13   | 1.91  | 1  | 0.17 | 0.84   | 0.65 | 1.08                    |
| Intravenous antibiotics<sup>a</sup>                 | -1.18  | 1.12   | 1.10  | 1  | 0.29 | 0.31   | 0.03 | 2.77                    |
| Creatinine      | 0.27   | 0.31   | 0.77  | 1  | 0.38 | 1.32   | 0.71 | 2.42                    |
| On haemodialysis at admission<sup>b</sup>            | 0.49   | 1.53   | 0.10  | 1  | 0.75 | 1.63   | 0.08 | 32.88                   |
| Wound vac at admission<sup>c</sup>                   | -0.20  | 1.10   | 0.03  | 1  | 0.86 | 0.82   | 0.10 | 7.09                    |
| Diabetes<sup>d</sup>                                | -0.48  | 0.74   | 0.43  | 1  | 0.51 | 0.62   | 0.15 | 2.63                    |
| Haemoglobin     | 0.18   | 0.29   | 0.42  | 1  | 0.52 | 1.20   | 0.69 | 2.10                    |
| Previous amputation<sup>e</sup>                     | -0.36  | 1.01   | 0.12  | 1  | 0.73 | 0.70   | 0.10 | 5.12                    |
| Length of stay                                        | 0.10   | 0.06   | 3.30  | 1  | 0.07 | 1.11   | 0.99 | 1.24                    |
| Gender<sup>f</sup>                                   | 2.24   | 0.81   | 7.71  | 1  | 0.01 | 9.40   | 1.93 | 45.74                   |
| Age                                                       | 0.00   | 0.03   | 0.00  | 1  | 0.96 | 1.00   | 0.95 | 1.05                    |
| Days since amputation                                   | -0.07  | 0.05   | 1.57  | 1  | 0.21 | 0.94   | 0.84 | 1.04                    |
| Admission motor FIM                                    | -0.05  | 0.04   | 1.26  | 1  | 0.26 | 0.95   | 0.88 | 1.04                    |
| Constant                                                | -2.05  | 4.11   | 0.25  | 1  | 0.62 | 0.56   | 0.25 | 0.98                    |

<sup>a</sup> referent=yes; <sup>b</sup> referent=male. SE: standard error; df: degree of freedom.

and did not have an unplanned transfer from inpatient rehabilitation. The model explained between 15.7% (Cox and Snell R square) and 29.6% (Nagelkerke R-squared) of the variance in unplanned transfers and correctly classified 88.3% of cases. As shown in Table III, only gender made a unique and statistically significant contribution to the model.

### Predictors of functional gains

Controlling variables of days since amputation, age, admission motor FIM, and days in inpatient rehabilitation (for discharge motor FIM only) were entered in Step 1, explaining 0.9% of the variance in FIM efficiency, F (3, 93 = 0.29, p = 0.83. After entry of infection factors (WBC, presence of IV antibiotics) in Step 2, the total variance explained was only 6.7%, F (5, 91) = 1.31, p = 0.26. After entry of poor wound healing factors (creatinine, on haemodialysis, and on wound vac) in Step 3, the total variance explained gained only a nominal amount, with 7.0%, F (8, 88) = 0.82, p = 0.56. After entry of organ failure factors (diabetes, haemoglobin value) in Step 4, there was no gain in variance explanation with 7.0%, F (10, 86) = 0.65, p = 0.77. In the final model adding previous amputation, shown in Table III, only 7.2% of the variance was
unplanned transfers found in previous studies of amputation rehabilitation unit. This is consistent with the rate of amputation required an unplanned transfer from the inpatient rehabilitation due to a lower extremity amputation. This is the first study to evaluate factors potentially associated with unplanned transfers from inpatient rehabilitation. The effect size was large (1.03), as was the SRM value (1.39), using Cohen’s criteria (19).

At the time of discharge, 24 (21.2%) patients exceeded a FIM motor gain of 17.84, or the threshold of change not due to measurement error. This suggested a significant association with the outcome. In the final model, shown in Table IV, 14.3% of the variance was explained, F (11, 96) = 1.08, p = 0.38.

### DISCUSSION

This is the first study to evaluate factors potentially associated with unplanned transfers from inpatient rehabilitation. In this study, 16.2% of dysvascular patients participating in inpatient rehabilitation due to a lower extremity amputation required an unplanned transfer from the rehabilitation unit. This is consistent with the rate of unplanned transfers found in previous studies of amputee patients, which ranged from 6.6% to 22.8% (6, 20). Model testing indicated that renal function, use of IV antibiotics, previous contralateral amputation, presence of a wound vac, and age were not associated with an increased risk of an unplanned transfer from inpatient rehabilitation. Together, these factors explained a relatively modest amount of the variance, suggesting that other factors may better predict unplanned transfers. The only factor significantly associated with unplanned transfers was gender, with an increased incidence of unplanned transfers in women compared with men, which is also consistent with the findings of a previous study by Meikle et al. (6) Other factors, such as a shorter span of time between amputation and inpatient rehabilitation admission, and other markers of peripheral vascular disease were also not statistically significantly associated with the incidence of unplanned transfers in our study. Although older age also did not appear to increase the risk of transfer in our study, other studies have found evidence that older patients have a higher rate of transfer from acute rehabilitation to acute care across all rehabilitation diagnoses (12).

The analysis of our results also found that none of the factors examined were significantly associated with functional outcomes in terms of FIM efficiency in this limited sample. No definitive conclusions can be drawn from these results due to the limited scope and sample size of this study; however, our findings would be consistent with the idea that comorbidities associated with dysvascular amputations do not increase the risk of unplanned transfers from inpatient rehabilitation, nor do they limit functional gains during rehabilitation. This may be influenced by the increased level of medical supervision during inpatient rehabilitation, which allows for the prevention of many major medical complications, and is consistent with previous research showing the overall benefits of inpatient rehabilitation over subacute rehabilitation in this population (17, 21). Finally, only approximately one-fifth of patients exceeded a FIM motor gain of 17.84, or the threshold of change not due to measurement error. This suggested modest actual gains in motor function for the sample.

This study has several limitations that should be considered when interpreting the results. First, the sample was drawn from a single inpatient rehabilitation facility in a single health system and therefore the generalizability of these results is limited. Studies of amputee patients in different health systems and across different demographics are needed to show whether these outcomes are consistent for the amputee population at large, though the non-novel aspects of

### Table IV. Hierarchical multiple regression (final model) predicting motor Functional Independence Measure (FIM) gain

| Unstandardized coefficients | B         | Std. error | t       | Sig. | 95% confidence interval |
|-----------------------------|-----------|------------|---------|------|-------------------------|
|                             |           |            |         |      | Lower bound | Upper bound |
| Constant                    | 19.25     | 11.38      | 1.69    | 0.09 | –3.35       | 41.85       |
| Days since amputation       | 0.08      | 0.10       | 0.79    | 0.43 | –0.12       | 0.29        |
| Age                         | –0.01     | 0.08       | –0.99   | 0.34 | –0.17       | 0.15        |
| Admission Motor FIM         | –0.05     | 0.12       | –0.43   | 0.67 | –0.29       | 0.18        |
| Days on inpatient rehabilitation | 0.06     | 0.17       | 0.34    | 0.73 | –0.28       | 0.40        |
| White blood cells           | 0.23      | 0.37       | 0.64    | 0.53 | –0.50       | 0.96        |
| Intravenous antibiotics     | –4.07     | 2.55       | –1.59   | 0.11 | –9.14       | 1.00        |
| Creatinine                  | –1.85     | 1.05       | –1.76   | 0.08 | –3.94       | 0.24        |
| On haemodialysis at admission | 0.90     | 4.88       | 0.19    | 0.85 | –8.78       | 10.58       |
| Wound vac at admission      | 7.04      | 3.62       | 1.94    | 0.06 | –0.15       | 14.23       |
| Diabetes                    | –1.71     | 2.21       | –0.77   | 0.44 | –6.10       | 2.68        |
| Haemoglobin                 | –0.76     | 0.79       | –0.96   | 0.34 | –2.32       | 0.81        |
| Previous amputation         | 5.53      | 2.94       | 1.89    | 0.06 | –0.29       | 11.36       |

FIM: Functional Independence Measure; SE: standard error.
our results are consistent with previous studies (e.g. female gender as a risk factor for unplanned transfer).

Furthermore, our sample did exclude certain dysvascular amputee patients, which should be taken into account when interpreting the results. We did not include patients who initially went home after amputation or patients who were admitted months after amputation for the purpose of prosthetic training, because we felt they represented patients who were significantly more medically stable and less prone to complications than those admitted to inpatient rehabilitation immediately following amputation. Also, a small proportion of patients were transferred and re-admitted to inpatient rehabilitation several times. In these cases, only the patient’s first rehabilitation admission was analysed, as the goal of this study was to identify factors that could predict a patient’s likelihood of a major medical complication necessitating acute transfer, before the patient is identified as being at high risk of decompensation.

In addition, this study examined each risk factor for unplanned transfer or FIM gains independently and does not account for the aggregate effect of multiple comorbidities. Thus, the results do not account for the possibility that multiple comorbidities may have an additive effect, greater than the sum of each individual comorbidity. Another limitation is that the data for our regression models analysing motor FIM and FIM efficiency are limited to patients who completed rehabilitation, and did not include patients who developed medical complications necessitating transfer to an acute medical service. Furthermore, it is notable that clinical change indices suggested that only 20% of the sample exceeded motor FIM gains that were unlikely due to measurement error, although effect sizes were quite large. One explanation is that much of the benefit of inpatient rehabilitation for post-amputation patients is from complication avoidance and patient education, and that FIM, as a gross measure of function, may not fully capture the medical benefits of inpatient rehabilitation for patients with amputations. For example, many lower extremity amputees are discharged at a wheelchair level, which significantly lowers their motor FIM score potential. However, FIM has been used as the primary outcome measure in other research and is the current standard for evaluating inpatient rehabilitation performance of lower extremity amputees (14). For future studies, measures such as self-reported perception of functional independence, such as the SF-36 or Katz ADL disability tools, may be considered as additional ways to measure any benefits achieved in this patient population (16, 17).

Taken together, these results suggest that patients undergoing lower extremity amputation due to vascular disease benefit from inpatient rehabilitation despite the multiple comorbidities that are commonly associated with this population. This study supports the notion that dysvascular amputee patients should be considered for inpatient rehabilitation despite having high levels of medical complexity. This is especially true given the increased risk of harm or decompensation that may result from a lower level of care. Further research is needed to determine how comorbidities in dysvascular patients may affect the extent of functional gains in inpatient rehabilitation, and larger sample sizes would be needed to judge the reproducibility and generalizability of our findings across a wider range of patients.

Acknowledgements

Funding to partially support this study was received from the University of Michigan Health System-Ann Arbor Center for Independent Living advanced Rehabilitation Research Training Program, US Department of Education, National Institute of Disability and Rehabilitation Research (H133P090008).

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