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Post-operative healing in the diabetic foot is impacted by discharge destination

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STRUCTURED ABSTRACT

Aim: To evaluate the impact of discharge destination on diabetes related limb salvage surgery outcomes post hospitalization.
Methods: A single-centered, observational, descriptive study of 175 subjects with diabetes who underwent a limb salvage surgery of a minor foot amputation or a wide incision and debridement, for an acutely infected diabetic foot ulcer. Comparisons were made between subjects discharged home versus a skilled nursing facility for twelve months post-operatively. Univariate, multivariate, and time-to-event analyses were performed.
Results: The skilled nursing facility discharge group (n=40) had worse outcomes with longer healing time (p=0.022), more re-hospitalizations requiring a podiatry consult (p=0.009), increase of subsequent ipsilateral major lower extremity amputation (p=0.028), and a higher mortality rate (p=0.012) within the twelve-month post-operative period. There was no significant difference between the cohorts in surgically cleared osteomyelitis (p=0.8434). The Charlson Comorbidity Index between those discharge home compared to a short term nursing facility were similar (p=0.3819; home $\bar{x}$=5.33 ± 2.84 v SNF $\bar{x}$=5.75 ± 2.06).
Conclusions: The planned discharge destination after limb salvage surgery among people with an acutely infected diabetic foot ulcer should be an added risk factor for healing outcomes. Patients discharged to skilled nursing facilities experience additional morbidity and mortality compared to patients discharged home post hospitalization.

Keywords:

Diabetic foot
Ulcer
Infection
Limb salvage
Minor foot amputation
Discharge planning

1. Introduction

Approximately 25% of patients with diabetes mellitus (DM) experience a diabetic foot ulcer (DFU) in their lifetime.[1, 2] Healing is often complicated by re-ulceration, with reports suggesting greater than 50% within three years. [3-5]Consequently, DFUs increase the risk of a major lower extremity amputation (LEA). Literature estimates 85% of all major LEA are preceded by a DFU.[6] The mortality rate of patients with DM who require a major LEA is greater than 70% within five years and a median survival is approximately two years.[7-9] Due to the high prevalence[1, 2], reoccurrence[5, 9], patient psychosocial burden[10, 11], and financial expenditure associated with DFU [9], many efforts have been taken to better understand and improve outcomes for this multifaceted health problem.

Any procedure that spares part of the foot including toe, ray, or midfoot, is considered a minor LEA. Surgeons utilize minor LEAs when medical management will not successfully clear an infection. Minor LEAs may reduce the rates of major LEAs in patients with infected DFUs.[12] Patients who required a minor LEA demonstrate increased mobility and ability to return to their baseline activity needs compared to patients who required a major LEA.[13, 14]

A review of the literature yields conflicting conclusions regarding outcomes based on hospital discharge destination. In a study evaluating the discharge destinations of over 17 million hospital admissions of Medicare beneficiaries, patients who were discharged home had a 5.6% higher re-admission rate compared to patients discharged to a skilled nursing facility (SNF), and no mortality differences between the discharge destinations.[15] Other studies that examined discharge destination after either vascular surgery, total knee arthroplasty, transcatheter aortic valve replacement, or emergent general surgery, found patients discharged to a SNF, as opposed to their home, experienced worse outcomes including higher readmission rates, morbidity, or mortality.[16-19]

To our knowledge, no publications have evaluated the differences in outcomes of patients discharged home versus a SNF after a minor LEA for a complicated DFU. The primary aim of this study was to examine if the discharge destination could be a risk factor for prolonged healing times after a minor LEA for a complicated DFU. The secondary aim of this study was to examine the influence of patient variables on post-hospitalization discharge destination.

2. Material and Methods

2.1. Study design and population

This was an observational, descriptive study. All 175 subjects were inpatients at a tertiary medical center who underwent a limb salvage surgery of either minor LEA or wide forefoot incision or debridement for an infected DFU from October 2015 to May 2019. All subjects were admitted on an

urgent basis through the emergency department. Patients were excluded if they were managed in the outpatient setting or if they required a primary major LEA.

Once medically stable, patients were discharged to their home or to a SNF. The discharge destination was strategically selected for the patient based on discussions with the patient, patient's caregiver support system, primary medical team, physical therapy team, case manager, and surgical team. Social and medical factors influenced the discharge destination for each patient. Variables that influenced the discharge destination included patient safety measures with focus on weight bearing recommendations of the operative foot, administration of post-operative medications such as parenteral antibiotics, and need for skilled wound care. Electronic medical records (EMR) were reviewed for the first twelve months following surgery.

2.2 Study-Outcome

Each subject's EMR was interrogated following surgery for twelve consecutive months post-operatively. Patient demographics, laboratory values, wound characteristics and imaging, were collected upon admission. Time-to-heal the surgical site (in months), re-hospitalizations for diabetic foot infections, additional limb salvage foot surgeries, major LEA, mortality and follow up were recorded. The Charlson Comorbidity Index (CCI) was calculated for each subject to assess the individual's burden of disease. The complete healing date was noted in the surgeons' clinical notes. The days between the surgical date and the complete healing date were counted. Intervals were also calculated from the date of surgery and either loss of follow-up, failure to heal by twelve-months post-operation, major LEA, or death.

2.3 Statistical Analysis

Categorical variables were analyzed with Fischer's exact test between the home discharge group and the SNF discharge group with a *p*-value <0.05 indicative of a significant difference between the groups. ANOVA compared the continuous variables examined between the two groups. Lastly, a Kaplan-Meier curve assessed the time for complete healing between the two cohorts. Censored data consisted of loss to follow-up, unhealed surgical site after twelve months, major LEA, and death prior to complete healing of ulcer and surgical amputation site, and was included in the analysis for generalizability.

3. Results

3.1 Demographic and comorbidity comparisons

There were 175 patients who met the inclusion criteria. After the limb salvage surgery, 135 (77.1%) patients were discharged home and 40 (22.9%) patients were discharged to a SNF. **Figure 1** depicts the study population and the outcomes. Cohorts were similar in age and comorbid status using the validated CCI ($p > 0.05$). There were more subjects with a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) diagnosis in the SNF cohort ($p < 0.05$). DSM-V diagnosis are not utilized in CCI scoring.

Table 1 displays the findings for all demographic values. The mean age of all subject was 57.03 years (±12.75 years), comprised of 76% males, with a median CCI score of 5.42 (IQR 5). More subjects in the SNF group had a DSM-V diagnosis ($p < 0.05$).

3.2 Laboratory and imaging comparisons

All laboratory values were collected at time of admission. Laboratory values that reached statistical significance are displayed in Table 1. Subjects discharged to a SNF had higher erythrocyte sedimentation rates (ESR) ($F < 0.05$), mean corpuscular hemoglobin concentration (MCHC) ($F < 0.001$), red blood cell distribution width (RDW) ($F < 0.0001$), lymphocyte percentage ($F < 0.05$), absolute lymphocytes ($F < 0.05$), and calcium ($F < 0.01$).

There were no statistically significant differences between groups in terms pre-surgical radiograph, magnetic resonance imaging (MRI), and non-invasive peripheral vascular study results.

3.3 Comparisons of initial diabetic foot ulcer characteristics and surgical findings

According to infection staging by the Infectious Disease Society of America (IDSA) [20], the SNF discharge cohort had more severe infected DFU as compared to those discharged home (2.65 v 2.38; $p < 0.05$). No DFU clinical characteristic (i.e. associated erythema, purulent drainage, positive probe to bone) reached statistical significance ($p > 0.05$).

No difference was noted in terms of achievement of surgically clear microbiology margins, with 71.9% (n=97) of the discharged home and 70.0% (n=28) of the SNF discharged group ($p>0.05$).

3.4 Longitudinal healing outcome comparisons

Table 2 displays healing outcome variables within the twelve-month post-operative period. The SNF discharge group required longer hospitalization for admitting diagnosis (Significant $F <0.0001$). The SNF group showed higher rates of re-admission with a foot related issue ($p < 0.01$). In addition, more patients in the SNF group required a major LEA ($p < 0.05$) or underwent additional forefoot limb salvage surgery within the first 6 months post-operatively ($p < 0.05$). Lastly, the SNF group had a higher mortality rate compared to the home discharge group ($p < 0.05$).

A Kaplan-Meier curve with censored data (Figure 2) compared time to heal between the home discharge group and the SNF discharge group. The cohort discharged to a SNF experienced less complete healing than the home discharge cohort ($p < 0.05$). The average days to heal for patients discharged home versus SNF was 81.9 days and 140.4 days respectively. Approximately, 50% of the patients discharged home healed within 1 month post-operatively, while the SNF group experienced that threshold at approximately 3 months post-operatively.

4. Discussion

Subjects that were discharged to a SNF following a limb salvage surgery of minor LEA or wide incision and debridement were more likely to experience post-operative complications. These complications including a longer initial hospitalization, increased need for re-hospitalized with the need for an additional podiatry evaluation, convert to an ipsilateral major LEA, increased time to heal the limb salvage operative site, and an increased mortality rate.

Patients discharged to a SNF had a significantly longer hospitalization for the limb salvage surgery ($p < 0.001$). This longer hospitalization may be related to the planning of services required for SNF discharge. A previous study examined the concepts of Medically Fit for Discharge (MFFD) vs. Therapy Fit for Discharge (TFFD). [21] The average post-operative stay was 18 days, despite patients on

average being MFFD and TFFD on days eight and eleven after amputation, respectively.[21] This study also found that patients electively admitted for major LEA, compared to an emergent admission resulting in a major LEA, had shorter hospitalizations. The study theoretically explained this length of stay difference with the ability to plan and coordinate services for the elective admissions group prior to the admission and general health differences of the elective versus emergent admissions groups. [33] However this study did not include patients with a minor LEA and unfortunately our subjects required emergent admissions for their DFU infections.

The CCI is a method to compare subjects as a whole patient, as opposed to any one comorbidity. The patient age, along with 16 differently weighted comorbidities, are used to calculate the estimated 10-year survival.[22, 23] The CCI focuses on comorbidities that have previously shown to effect and predict mortality risk in patients. The CCI has gained popularity and validity with comprising part of the LACE index (Length of stay, Acuity of admission, Charlson Comorbidity Index, and Emergency department use) which is a validated, predictive scoring model that identifies patients at high risk of costly re-hospitalization.[24] The fact that there was no significant difference of CCI scores between the cohorts in our study, yet subjects who discharged to a SNF did significantly worse in post-operative outcomes, highlights the complexity of treating diabetic foot infections and osteomyelitis.

Our current data analysis revealed patients were more likely to be discharged to a SNF if they had a DSM-V diagnosis ($p < 0.05$). Mental health comorbidities are not utilized for calculating CCI scores and may explain some of the differences in our outcomes. Mental health comorbidities have a negative impact on overall diabetes outcomes. A previous study found that patients with DM and depression were at a 33% higher risk of a major LEA, but no significant difference for risk of a minor foot amputation.[11] We did not find a difference in the need for conversion to major LEA occurrence in patients with a DSM-V condition compared to those without ($p > 0.05$).

There was a significant difference of ESR values between our cohorts ($p<0.05$; Home $\bar{x}$ = 64.71mm/h; SNF $\bar{x}$ = 81.03mm/h). However, both cohorts had an average ESR greater than 60mm/h which has been the benchmark when combined with a CRP level greater than 7.9mg/dL as predictors of underlying osteomyelitis.[25] The statistical significant difference of ESR averages may not be clinically significant since at this time no literature supports the presumption that elevation of the ESR is proportional to severity of diabetic foot osteomyelitis.[25]

It would be expected that the SNF cohort would have more assistance in care, compared to patients discharged to their home, and the result of additional support would allow patients to reduce complications and be a protective factor. Our data demonstrates this was not the case and home discharge resulted in improved outcomes for our patient population. Specifically, during the 12-month post-operative period the SNF group had higher re-admission rates ($p < 0.01$), slower time to- and lower rates of complete healing ($p < 0.05$), were more likely to convert to a major LEA ($p < 0.05$), and had a higher mortality rate ($p < 0.05$). Our findings parallel previous work demonstrating patients discharged to a SNF following vascular surgery had higher readmission and mortality rates.[19] Thus, discharge destination planning is complicated, multifactorial, has improvement potential, and significantly impacts post-operative diabetic limb salvage surgery outcomes.

Our efforts are not without limitations. First, the study is one of observational design and the objective decision-making process surrounding discharge disposition, including the specific reasons for determination of discharge disposition were not fully captured. Second, the data evaluated is based on relatively non-modifiable variables, such as patient age and certain comorbidities. Third, due to the nature of the large tertiary care facility where we recruited our subjects, 11.4% of our patients were lost to follow up. However, the 11.4% loss to follow up rate should have a minimal effect on our measured variables between the two groups and could be explained by our hospital acting as regional medical center for the entire state.

5. Conclusions

Discharge to a SNF after a limb salvage surgery for an infected DFU had worse outcomes in terms of healing, re-hospitalization, need for a major LEA, and mortality, compared to patients who were discharged home, despite similar proximal bone surgical clear microbiological margin rates. This was previously unrecognized as a stand-alone risk factors which could partially predict outcomes in this patient cohort. It is also important that future research endeavors should examine modifiable factors that contribute to post-operative outcomes for an infected DFU. Modifiable risk factors which may improve outcomes include direct communication between the surgical team and SNF providers, ensuring SNF providers are trained for limb salvage post-operative patients with diabetes, tracking SNF staff to patient ratios, and surgical team awareness that a discharge to a SNF can indicate the post-operative course is likely to be more complicated compared to a patient who is deemed to safely discharge home.

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	Home Group Mean (SD) or *n (%)*	SNF Group Mean (SD) or *n (%)*	*p Value*
Charlson Comorbidity Index total score	5.33 (2.84)	5.75 (2.06)	0.38
History of myocardial infarction	*24 (17.8%)*	*10 (25.0%)*	*0.36*
Congestive heart failure	*26 (19.3%)*	*12 (30.0%)*	*0.18*
Peripheral vascular disease	*46 (34.1%)*	*20 (50.0%)*	*0.09*
History of cerebrovascular accident or transient ischemic attack	*13 (9.6%)*	*5 (12.5%)*	
Dementia	*0 (0.0%)*	*0 (0.0%)*	*1.00*
Pulmonary disease	*11 (8.1%)*	*6 (15.0%)*	*0.38*
Connective tissue disease	*7 (5.2%)*	*2 (5.0%)*	*1.00*
Peptic ulcer disease	*2 (1.5%)*	*1 (2.5%)*	*0.54*
Liver disease	*14 (10.4%)*	*0 (0.0%)*	***0.042***
Diabetes mellitus	*135(100.0%)*	*40 (100.0%)*	*1.00*
Hemi/paraplegia	*4 (3.0%)*	*0 (0.0%)*	*0.58*
Severe renal disease	*15 (11.1%)*	*7 (17.5%)*	*0.29*
Malignant solid tumor	*22 (16.3%)*	*4 (10.0%)*	*0.45*
Leukemia	*0 (0.0%)*	*0 (0.0%)*	*1.00*
Lymphoma	*1 (0.7%)*	*5 (12.5%)*	***0.003***
AIDS	*0 (0.0%)*	*0 (0.0%)*	*1.00*
Body mass index (kg/m2)	33.29 (7.12)	32.78 (6.22)	0.68
Sex (% male)	*106 (78.5%)*	*27 (67.5%)*	*0.28*
Employed at time of surgery	*30 (22.2%)*	*7 (17.5%)*	*0.66*
Tobacco use	*35 (25.9%)*	*15 (37.5%)*	*0.17*
Ambulating prior to surgery	*132 (91.0%)*	*40 (100.0%)*	*1.00*
Prior established podiatric care	*94 (69.6%)*	*29 (72.5%)*	*0.85*
DSM-V diagnosis	*17 (12.6%)*	*11 (27.5%)*	***0.047***
Depression	*16 (11.9%)*	*10 (25.0%)*	*0.07*
Diabetic peripheral neuropathy	*125 (92.6%)*	*37 (92.5%)*	*1.00*
History of previous pedal amputation	*49 (36.3%)*	*14 (35.0%)*	*1.00*
ESR	64.71 (33.62)	81.03 (33.02)	**0.013**
MCHC	33.10 (1.49)	32.34 (1.09)	**<0.001**
RDW	13.82 (1.79)	15.66 (4.74)	**<0.001**
Abs. lymphocytes	1.79 (1.14)	1.40 (0.69)	**0.045**
Calcium	9.06 (0.53)	8.85 (0.59)	**0.039**
IDSA classification	2.38 (0.71)	2.65 (0.79)	**0.041**

Table 1- Demographic, comorbidity, and laboratory value comparison between the two discharge destinations.

Event within 12 month follow up period	Home Group Mean (SD) or *n (%)*	SNF Group Mean (SD) or *n (%)*	Significance F or *P Value*
Length of hospitalization at time of surgery	6.46 days (3.60)	10.78 days (10.16)	<0.001
Re-hospitalized with a pedal issue	*42 (31.1%)*	*22 (55.0%)*	*0.009*
Ipsilateral Below or above knee amputation	*2 (1.5%)*	*4 (10%)*	*0.028*
Mortality	*6 /110(5.5%)*	*7 /34(20.6%)*	*0.012*
New diabetic foot ulcer at 3 months follow up	*43/130 (33.1%)*	*12/37* (32.4%)	1.00
New diabetic foot ulcer at 6 month follow up	*43/107 (40.2%)*	*14/29 (48.3%)*	0.53
New diabetic foot ulcer at 12 month follow up	*47/104 (45.2%)*	*16/26 (61.5%)*	*0.19*
Any additional limb salvage surgery needed by 6 month follow up	*24/107 (22.4%)*	*11/29 (37.9%)*	*0.045*
Any additional limb salvage surgery needed over the 12 month follow up	*36/135 (26.7%)*	*16/40 (40%)*	0.12

Table 2—Comparison of 12-month outcomes between the home discharge group and the SNF discharge group

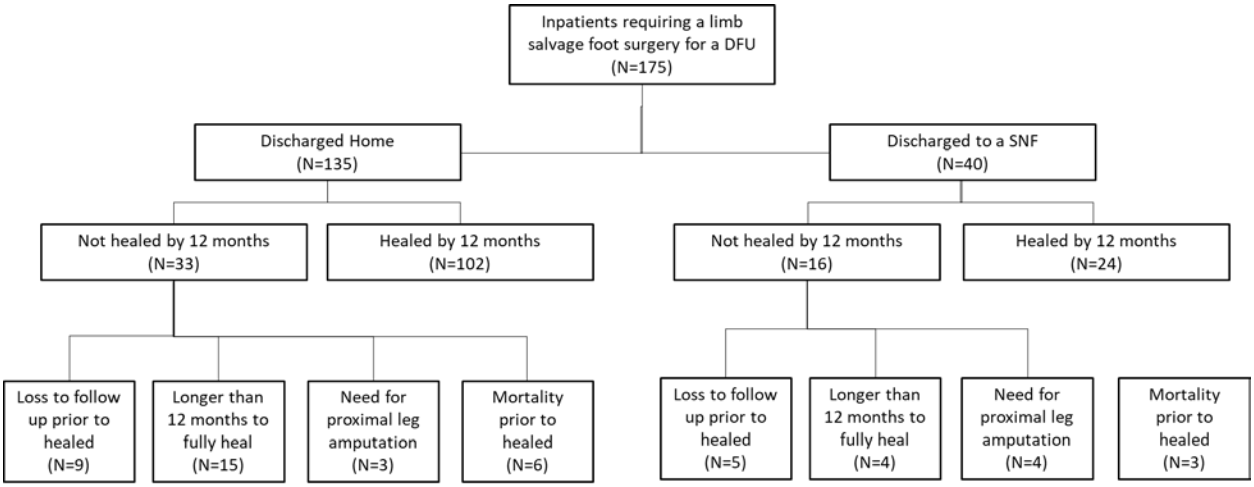

Fig. 1—Study population and outcomes.

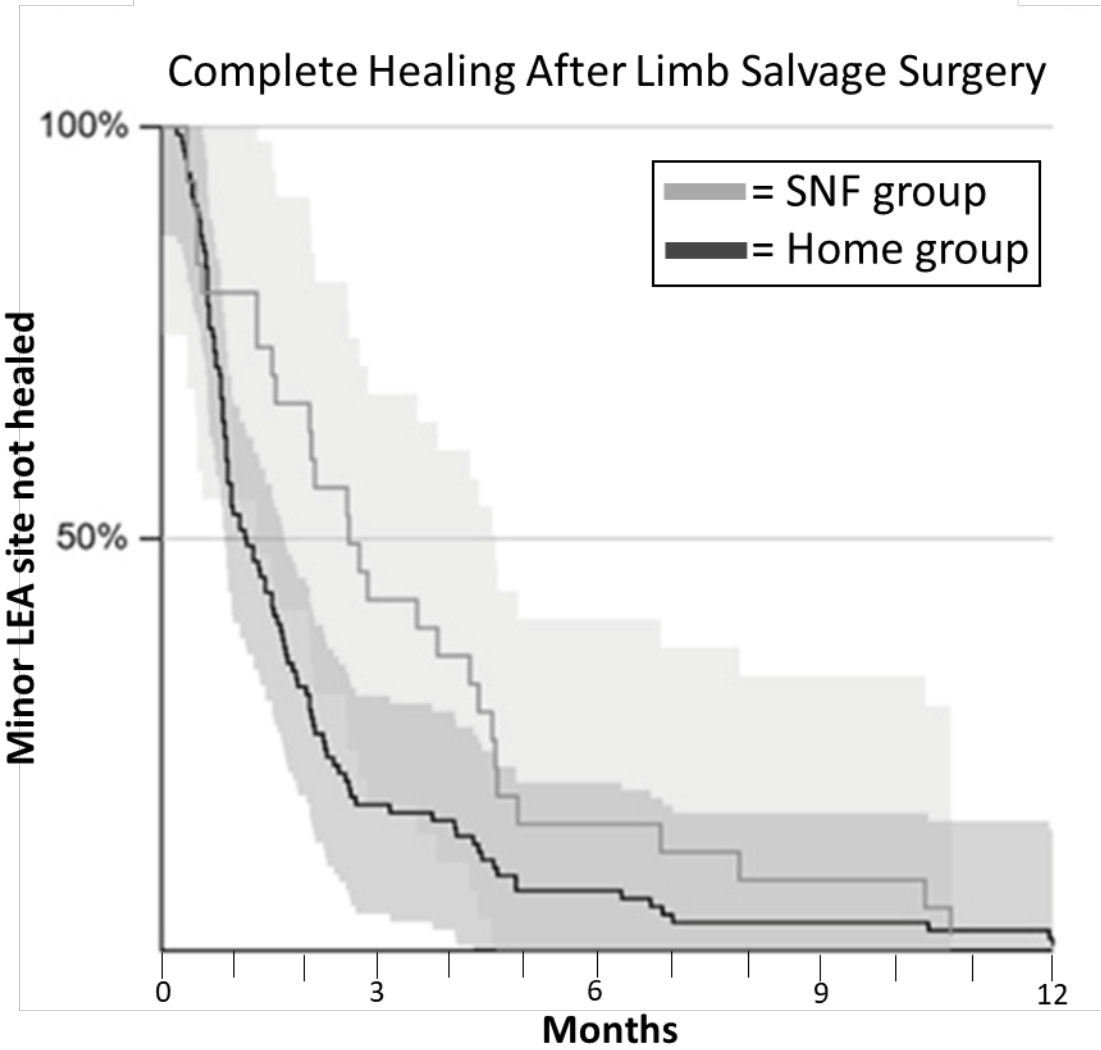

Figure 2—Kaplan-Meier curve compared time to complete healing after limb salvage surgery between subjects discharged home vs. to a SNF.

Key Points

A minor lower extremity amputation(LEA) is often a patient's last option of limb salvage before requiring a below- or above knee amputation. Improving outcomes after minor lower extremity amputations is critical for improving limb salvage rates. Better understanding what complicates the post-operative course after a minor LEA can help us improve our care in the post-operative period. We identified a discharge to a SNF after a minor LEA is a risk factor for increased risk of prolonged post-operative healing, need for additional limb salvage surgery, progressing to a major LEA, re-hospitalization with a foot issue, and mortality. Yet our cohorts did not differ in their Charlson Comorbidity Index or rate of surgically cleared osteomyelitis. Surgeons and other care providers should know if their patient is discharged to a SNF following a minor LEA for diabetic limb salvage this is a risk factor of poorer outcomes and care providers should not used the previously presumed "safety net" of a SNF as a false protective factor.