Bedside versus operating room debridement of osteomyelitis of a phalanx of a given toe

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Key words

- Diabetic foot ulcers
- Bedside debridement
- Operating room debridement
- Osteomyelitis

Article points

1. Osteomyelitis occurs frequently in the forefoot
2. Bedside debridement of bone is safe and effective to manage toe osteomyelitis
3. Patient smoking history was associated with DFU recurrence in multivariate analysis in patients with toe osteomyelitis.

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Introduction: Digital osteomyelitis can be surgically treated at bedside or in the operating room. The rate of recurrent diabetic foot ulcers between bedside versus operating room debridement is unknown. A study of 70 consecutive patients with diabetes who underwent either operating room (OR) debridement or bedside debridement for suspected distal phalangeal digital osteomyelitis between January 2018 and December 2019 at a single academic centre in the US was performed. Baseline demographics and medical history were recorded. The primary outcome was DFU recurrence, re-operation or death at 3-, 6- and 12 months. Secondary outcomes included rates of re-admission, length of stay(days) and disease severity. Univariate and multivariate analysis were performed. Results: Seventy patients met inclusion criteria; 45 underwent bedside and 25 OR debridement. The bedside cohort was older (M = 64.0 vs. 58.0, *P*=.028), had a normal BMI (17.8% versus 0%, *P*<.001), and had chronic kidney disease more frequently (84.4% versus 24.0%, *P*<.001). The bedside cohort was significantly less likely to develop a diabetic foot ulcers at 3 months (15.6% vs. 40.0%, *P*=.040), 6 months (8.9% vs. 32.0%, *P*=.021) and within 12 months of intervention (24.4 vs. 80.0%, *P*<.001). The bedside cohort had shorter median (IQR) LOS (4 [2–5] vs. 5 [3.5–6]) and were less likely to have re-operation at 6 months (0% vs. 12.0%, *P*=.042), whereas the OR cohort had lower mean disease severity scores (2.3 [0.5] vs. 2.6 [0.6]). There was no difference in re-operation, readmission rate, or death within 1 year between cohorts. Multivariate analysis demonstrated smoking to be predictive of outcome. Conclusions: Bedside debridement of digital osteomyelitis was independently associated with lower rates of recurrent diabetic foot ulcers. In addition, lengths of stay were shorter with bedside debridement, in spite of these patients having higher severity of infection.

Osteomyelitis (OM) is an inflammatory bone disease with microbial invasion, which leads to destruction of bone tissue (Beck-Broichsitter et al, 2015). Although OM may be polymicrobial, it is mostly commonly caused by opportunistic Gram-positive *staphylococci* and nearly always preceded by a diabetic foot ulcer (DFU)(Kavanagh et al, 2018). Due to the increase in incidence of methicillin-resistant *Staphylococcus aureus* OM, among other multidrug resistant organisms, it is more difficult for healthcare providers to treat this problem without surgical intervention (Ashong et al, 2017; Schmidt et al, 2020). Many patients with OM in the foot require surgical debridement to effectively eradicate an infection.

Surgical versus medical management to treat diabetic foot OM continues to be a topic of debate. Although many physicians continue to consider bone infection a primarily surgical disease

(Henke et al, 2005), studies have shown surgical treatment of OM can lead to recurrent ulcerations and episodes of recalcitrant OM (Greteman and Dale, 1990; Quebedeaux et al, 1996). For instance, in multiple studies evaluating outcomes after partial first ray amputation, including hallux disarticulations, to manage a neuropathic hallux ulcer, over two-thirds of patients developed new ulcerations and required additional amputations following initial surgical management (Greteman and Dale, 1990; Quebedeaux et al, 1996).

OM is predominately prevalent in patients with other comorbidities, such as diabetes mellitus (DM) and peripheral vascular disease among others (Kavanagh et al, 2018), and this significantly impacts medical decision making around the safety of proceeding with OR intervention. As a result, this has necessitated the performance of aggressive bedside debridement to manage digital OM in conjunction with antibiotic therapy. Commonly, systemic antibiotic therapy is provided for these individuals and is a common management strategy for OM of the phalanx. However, the effectiveness is not well elucidated. Available studies do not specifically disaggregate data based on the type of surgical procedure performed and suffer from small sample sizes.

Importantly, the difference in outcomes of these patients who have debridement of the bone infection in the OR versus bedside is not known, despite this being commonly performed in hospitals and at wound care centres alike. Thus, the purpose of this investigation is to evaluate the effectiveness of bedside debridement versus OR debridement of (distal) phalangeal OM to establish a baseline understanding of the outcomes and characteristics of patients who may benefit from this procedure.

Methods

Patient selection

The authors performed an observational study of 70 consecutive patients with type 1 or type 2 DM who underwent either operating room (OR) debridement or bedside debridement for suspected digital OM of the distal phalanx between January 2018 and December 2019 at a single academic centre in the US. A patient database was constructed to collect data upon admission on these patients. This study was approved by the University of Michigan Institutional Review Board.

OM was diagnosed based on available clinical suspicion, inflammatory markers, and radiographic evidence by a board-certified podiatrist at the time of admission (Lazzarini et al, 2002; Lázaro-Martínez et al, 2014). Clinical suspicion of phalangeal OM was elevated with increasing depth of an index DFU in combination with a positive probe to bone and the presence of local signs of infection, such as erythema, malodour, drainage and temperature. Inflammatory markers monitored included erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) and white blood cell (WBC) counts.

Radiographic evidence of OM included cortical destruction, periosteal reaction, or frank osteolysis followed by advanced imaging, such as magnetic resonance imaging (MRI) for select patients. MRI images were demonstrative of osteomyelitis when T1- and T2- (and short tau inversion recovery; STIR) were congruous for marrow enhancement in similar anatomic location as contiguous DFU (Johnson et al, 2009). Data from five board certified podiatrists were included in the study. Patients were excluded if they did not have 1-year follow-up.

Study variables

Demographics and comorbidities of patients with digital OM who underwent either OR or bedside debridement of infected tissue were abstracted from the electronic medical record, then compared against each other. Baseline patient demographics including age, sex, body mass index (BMI), amputation history, ambulatory status, smoking history, Infectious Disease Society of America (IDSA) diabetic foot infection severity classification and medical comorbidities were assessed.

Lower-extremity arterial perfusion and, therefore, peripheral arterial disease (PAD) status, was assessed by ankle-branchial index (ABI) and toe-brachial index (TBI), including absolute pressures (in mmHg) on the affected limb. Patients with ABI >1.3 were demonstrative of arterial non-compressibility, 0.9–1.3 demonstrated no evidence of PAD, >0.7–<0.9 were demonstrative of mild PAD, >0.4–<0.7 indicated moderate PAD, while <0.4 equated to severe PAD (Conte et al, 2015).

Similarly, the authors used absolute toe pressures >40 mmHg as a cutoff to demonstrate sufficient pedal perfusion to undergo intervention when ABI demonstrated non-compressibility (Brownrigg et al, 2016).

Patients were followed longitudinally for 1 year following intervention and primary outcomes of DFU recurrence and re-operation at 3-, 6-, and 12 months were obtained. For the purposes of this study, DFU recurrence was defined as healing of the surgical site followed by DFU on the operative foot within the provided follow-up period. Re-operation refers to an individual who required another surgical procedure at the index DFU site within a specified period of time. Secondary analysis included rate of re-admission, length of stay (LOS; in days) and severity of disease, according to criteria by the Infectious Diseases Society of America (Lipsky et al, 2012).

Statistical analysis

Univariate and multivariate analyses of the primary outcome were performed. All *P*-values are two-sided and findings were considered statistically significant at $P<0.05$. Chi-squared and Fisher's Exact tests were used for categorical variables. A student t-test was used to evaluate for differences between means, and a Mann Whitney U-test was used to evaluate for differences between medians. A multivariate regression analysis was performed to evaluate the association between the cohorts and our primary outcomes, accounting for baseline demographics, laboratory values and medical history.

Results

Patient demographics, medical and social history

In total, 70 patients met inclusion criteria, consisting of 45 patients who underwent bedside debridement and 25 patients that underwent OR debridement. The median age of the population was 62 (IQR 55–71), consisting of 50 males, and 20 females. Patients that underwent bedside debridement were older (M=64.0 vs. 58.0, *P*=.028), had a normal BMI (17.8% versus 0%, *P*<.001) and had a prior history of chronic kidney disease (CKD) (84.4% versus 24.0%, *P*<.001), compared with patients that underwent OR debridement. The remaining baseline demographics and medical history were comparable between the groups, as shown in *Table 1*.

Table 1: Patient demographics including relevant past medical and social history.

	Bedside Debridement (*n*=45)	OR Debridement (*n*=25)	*P*-value
Age, mean (SD)	64.0 (3.4)	58.0 (6.2)	0.028
Female sex, No. (%)	16 (35.6)	4 (16.0)	0.08
BMI, No. (%)			
Underweight	4 (8.9)	0 (0)	0.29
Normal	8 (17.8)	0 (0)	0.043
Overweight	7 (15.6)	8 (32.0)	0.11
Obese	26 (57.8)	17 (68.0)	0.40
Amputation history, No. (%)	14 (31.8)	10 (40.0)	0.49
Ambulatory status, No. (%)	43 (95.6)	25 (100.0)	0.53
Current or former smoker, No. (%)	13 (28.9)	7 (28.0)	0.93
Diabetes duration in years, median (IQR)	9 (5–13.5)	9 (6–12)	0.67
Medical history, No. (%)			
HTN	15 (33.3)	11 (44.0)	0.37
CKD	38 (84.4)	6 (24.0)	<.001
CAD	21 (46.7)	9 (36.0)	0.39
OM	37 (82.2)	22 (88.0)	0.52
Cancer	4 (8.9)	1 (4.0)	0.64
Depression	8 (17.8)	3 (12.0)	0.52

Patient clinical characteristics

ESR was collected in 23 of the 25 patients (92%) that underwent OR debridement compared to 43 of 45 (96%) patients that underwent bedside debridement. Similarly, CRP was collected in 22 of 25 (88%) patients that underwent OR debridement compared to 44 of 45 (98%) that underwent bedside debridement. In the OR cohort, 24 of the 25 patients (96%) had radiographs and 12 (50%) demonstrated OM. This was comparable to the bedside cohort where 42 of 45 (93.3%) had radiographs and 23 (54.8%) demonstrated OM (*P*>.05). Additionally, in the OR cohort, 15 of the 25 (60%) had an MRI with 14/15 (93.3%) demonstrating OM and was similar to the bedside cohort where 30/45 (66.6%) had an MRI with 24/30 (80%) demonstrating OM (*P*>.05).

Lower-extremity perfusion assessment occurred prior to intervention. The number of patients who underwent non-invasive vascular assessment was dissimilar between groups with 30/45 (66.6%) in the bedside cohort and 9/24 (37.5%) in OR cohorts undergoing ABI/TBIs (*P*<.05). In patients who underwent non-invasive testing, rates of non-compressibility were 8/30 (26.6%) and 2/9 (22.2%) and were similar between bedside and OR cohorts (*P*>.05). Everyone in each cohort with non-compressible arteries demonstrated absolute toe pressures >40 mmHg. Rates of PAD and its severity (mild-, moderate- and severe) were also similar among groups (all *P*-values >.05).

Longitudinal outcomes

Patients who underwent bedside debridement were significantly less likely to have developed DFU at 3-months (15.6% vs. 40.0%, *P*=.040), 6 months (8.9% vs. 32.0%, *P*=.021), and by 12 months of intervention (24.4 vs. 80.0%, *P*<.001). Bedside debridement patients had shorter median (IQR) LOS (4 [2–5] vs. 5 [3.5–6]) and were less likely to have undergone re-operation at 6-months (0% vs. 12.0%, *P*=.042). Whereas the OR debridement patients had lower mean (SD) IDSA severity (2.3 [0.5] vs. 2.6 [0.6]). There was no difference in re-operation rate within 12 months, readmission rates, or deaths within 1 year of the intervention (*Table 2*).

Multivariable regression analysis

A multivariable logistic regression analysis was performed to evaluate the association between the surgical debridement approach and DFU accounting for baseline demographics, laboratory values and medical history. Multivariate testing revealed smoking to be a strong predictor of outcome in our population (*P*<.001). Several laboratory factors, including absolute eosinophil count (*P*<.001), absolute early granulocyte count (*P*<.001), sodium concentration (*P*=.053) and chloride concentration (*P*=.024) were also associated with DFU recurrence. Other factors that are traditionally associated with healing were not significantly associated with DFU recurrence.

Table 2: Patient outcomes.

	Bedside debridement (*n*=45)	OR debridement (*n*=25)	*P*-value
Diabetic foot ulcer recurrence, No. (%)			
3 months	7 (15.6)	10 (40.0)	0.040
6 months	4 (8.9)	8 (32.0)	0.021
12 months	0 (0)	2 (8.0)	0.124
All	11 (24.4	20 (80.0)	<0.001
Reamputation, No. (%)			
3 months	3 (6.7)	1 (4.0)	1.000
6 months	0 (0)	3 (12.0)	0.042
12 months	1 (2.2)	1 (4.0)	1.000
All	4 (8.9)	5 (20.0)	0.265
Readmission, No. (%)	4 (8.9)	3 (12.0)	0.694
Length of stay, median (IQR)	4 (2–5)	5 (3.5–6)	0.047
IDSA score, mean, (SD)	2.6 (0.6)	2.3 (0.5)	0.039
Death within 1-year, No. (%)	0 (0)	1 (4.0)	0.357

Discussion

The aim of this paper was to compare the rates of DFU recurrence after bedside or OR debridement for digital OM. The authors found that bedside debridement resulted in significantly less DFU at 3-, 6-, and within 12 months of follow-up compared to OR debridement. In a study of 185 sequential cases of patients with diabetes-related OM of the foot undergoing surgical treatment (Conte et al, 2015), recurrent infections occurred in 18% of patients and was comparable with our study's findings in the bedside debridement cohort (24.0%) but significantly less than the OR debridement group (80.0%). Other studies have reported recurrence rates as high as 40–60%, although these studies were not exclusive to those with OM (Murdoch et al, 1997; Nehler et al, 1999). In the literature, the available studies did not stratify the surgical approach based on bedside or OR debridement, limiting comparison with our research question.

There was no significant difference in re-operation at 1 year between the cohorts. The rate of re-operation in both groups was comparable to the rates found in prior studies (Murdoch et al, 1997; Lipsky et al, 2012). Bedside debridement patients were older, had a normal BMI and presented with a history of CKD, and had shorter lengths of stay. The OR debridement cohort presented with lower IDSA scores upon admission. Although non-invasive vascular testing frequency was different amongst groups ($P<.05$), this is attributable to standardise clinical care and physician assessment of vascular status via presence of palpable and doppler-able pedal pulses per institution guidelines (Mills et al, 2019). Rates of PAD, including severity of PAD, were not different among groups ($P>.05$).

There was no difference in mortality at 1 year between the groups. Smoking was the only variable that was predictive of DFU recurrence in our multivariate analysis, which perhaps can be indirectly explained by the hindrance of wound healing by smoking. Other factors associated with poor would healing (e.g., malnutrition, presence of peripheral vascular disease and obesity, etc.), were not associated with DFU recurrence.

The clinical implications of these findings are highly relevant. Patients with diabetic foot infection and/or osteomyelitis, even when provided care by a multidisciplinary team and follow agreed upon treatment strategies (Richard et al, 2011; Mills et al, 2019), suffer prolonged hospitalisations without necessarily improved outcomes. The authors' analysis demonstrates patients can have a non-inferior outcome in terms of wound healing, re-operation and mortality, when provided a more rapid treatment option versus standard OR debridement. Thus, when a provider performs a 'bedside' resection of infected bone, it may shorten hospital stay, shift care acuity to an outpatient model, and would likely significantly reduce cost burden to any healthcare system.

This study has several limitations. First, our study has a limited sample size (n=70). Although we had enough patients in each cohort to conduct the statistical analysis as planned, a larger sample size would allow us to capture smaller effect sizes. Second, our study is of retrospective design; there was no randomisation or allocation. Despite this, the data were collected prospectively in a longitudinal dataset. Thus, we were able to evaluate consecutive cases within the dataset to reduce potential sampling bias.

Finally, OM was diagnosed at the discretion of the podiatrist without pre-specified criteria other than commonly attained patient characteristics gathered through an institutional multidisciplinary algorithm on diabetic foot infection (Mills et al, 2019). This algorithm informed the medical decision-making process and represents the real-world circumstances often encountered by providers. As was demonstrated in patient characteristics, the rate of imaging (advanced), inflammatory markers and clinical picture was not significantly different ($P>.05$) other than severity of initial presentation at hospital admission per IDSA classification.

In conclusion, these results demonstrate and strongly supports the practice of performing bedside debridement as an alternative to OR intervention when admitted patients present with distal phalangeal digital OM. Future studies should be aimed at prospectively analysing the decision-making process of providers who choose to perform bedside debridement when faced with digital OM and possibly evaluate utilising random allocation given the non-inferior outcomes demonstrated in this study. ■

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