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Research Article

A Novel Treatment Algorithem for Infected Diabetic Foot Ulcers-One Step Procedure

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Abstract

Background: Foot and ankle infections are the most common reason for hospital admissions and have the most devastating and costly complications in patients with diabetes mellitus worldwide. Foot ulceration can lead to a limb or even life-threatening infection. It is estimated that 85% of all amputations in diabetic patients are related to an ulcer and 59% of amputation are performed due to infection. When treating diabetic foot ulcers, achieving eradication of the infection and saving the limb can be difficult. In order to avoid amputation, which often is associated with functional impairment, the goal of treatment should be to be as preserving as possible. We would like to present our new treatment algorithm for infected diabetic foot ulcers in the first ray. This new algorithm avoids amputation and preserve ambulation. A thorough debridement of the ulcer, primary stabilization by fusing the infected joint and closing the skin over the ulcer and the fused joint. We would like to present our experience with this new treatment algorithm.

Methods: The study includes 34 patients (36 feet) with IPJ or 1st MTPJ septic arthritis or osteomyelitis due to diabetic ulcers between 2018- 2021 treated in a tertiary referral hospital. All patients had preoperative radiographs, 17 patients had a preoperative MRI scan and were evaluated pre or postoperatively by angiography. A thorough debridement was performed until macroscopically judged clear of infection. Histology and microbiology samples were collected during surgery. The fusion of the infected joint was made under fluoroscopy control. Wound closure was performed with minimal soft tissue tension. All the patients were followed up for an average period of 12 months after surgery.

Results: By one year after surgery healing of the ulcer was achieved in 86% (31/36) of the cases. Overall average time to heal was 6.9 weeks (range 1-20 weeks). One year postoperatively radiological fusion was achieved in 26/36 (72%) cases. Clinically, by one year after surgery, 28 of 36 cases (77%) were stable on physical examination.

Conclusion: One step debridement and arthrodesis of IPJ or 1st MTPJ in diabetic foot patients with an ulcer and infection proved to be a successful way of treatment. A thorough debridement of the infected tissue and stabilizing the joint in the same procedure dramatically reduce the number of 1st toe or 1st ray amputation, improve patient's satisfaction and help maintain a good walking pattern and mobilization.

Keywords: Septic arthritis; Diabetic foot; Ulcers; First ray; Osteomyelitis; Arthrodesis; Amputation; Polyneuropathy; Primary Wound Closure (PWC); Joint fusion

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INTRODUCTION

Foot and ankle infections are the leading cause of hospitalizations and result in the most severe and expensive complications for individuals with diabetes mellitus in the United States and England [1,2]. It is estimated that more than 5% of all patients with diabetes will have at least one episode of foot ulcer during their life [2]. Yearly incidence is

estimated to be around 2% and reported recurrence rate range between 30% and 40% in the first year [3-6]. There is also a risk of 40% to sustain a new ulcer after wound healing [7]. The site of the ulceration is indicative of its cause. Plantar ulceration is due to weight-bearing pressure whereas ulcers on the dorsum and borders of the foot are usually caused by the pressure of shoes [8]. According to the International Working Group on the Diabetic Foot (IWGDF) key risk factors for formation of foot ulcers include presence of peripheral neuropathy, peripheral vascular disease, foot deformity (including hammer toes, mallet toes, claw-toes, hallux valgus, prominent metatarsal heads), elevated HbA1c and a history of prior foot surgery or ulceration [4,9,10]. Boyko et al., showed that 17% of diabetic patients with one of these risk factors will develop an ulcer over a period of three years [11]. Foot ulceration can lead to a limb or even life-threatening infection. It is estimated that 85% of all amputations in diabetic patients are related to an ulcer and 59% of amputation are performed due to infection [2].

Preventing formation of ulcers is therefore the primary objective goal when treating diabetic patients. Great effort should be made on patient's education about foot hygiene, proper footwear, specific insoles and regular visual checks by the patient himself and/or healthcare professionals in intervals indicated by the individual risk score (IWGDF) [9].

Once an ulceration has occurred the optimal treatment depends on a multidisciplinary approach that addresses the underlying disorders.

The classic objectives in treating diabetic foot ulcers are offioading the ulcer, a thorough debridement of the infected and nonvital tissue followed by proper antibiotic treatment [2,12,13]. Closure of the skin over the ulcer or the creation of a stable joint or wound are not typically included in the classical treatment protocols. However insufficient soft tissue coverage and constant micro motion of the soft tissue layers around the ulcer prevent epithelialization and thus wound healing.

In the classic orthopedic literature, in the presence of active infection, internal fixation was contraindicated, as bacterial biofilm formation on implants incapacitates the response of the immune system and antibiotic penetration. The use of external fixators on the small bones of the foot is technically demanding and rarely used [14].

Bhatia et al., studied the treatment of infected nonunion of the tibia. The study explored antibiotic coated nails as a single stage treatment modality for infected nonunion. The study showed high rate of healing after the one stage procedure [15]. Calvert et al., performed a retrospective study on 15 patients treated for spondylodiscitis with implantation of metal cages. The results suggest that the stabilization allowed to maintain alignment while not perpetuating infection [16]. This concept presented by Bhatia et al., and Calvert et al., encouraged us to deploy the same philosophy when treating infected plantar ulcers of the first ray [15,16].

According to our knowledge there is no orthopedic or wound literature papers studying the use of internal fixation when treating diabetic forefoot plantar ulcers.

We would like to share our treatment protocol for first ray ulcers:

- A thorough debridement of macroscopically infected and nonviable soft-tissue and bone.
- Stabilizing the infected joint and correction of the deformities by joint fusion in the acute setting.
- Facilitation of primary soft-tissue closure through the correction of the deformity including shortening within the joint.
- Targeted antibiotic therapy based on deep wound swabs and cultures taken during the operation.

We believe that following this treatment protocol will show higher rates of ulcer healing, fewer recurrences, lower amputation rates and less functional impairment for the patient. This paper is to share our experience and results with this protocol.

MATERIALS AND METHODS

Hospital database was searched for patients' files with 1st ray ulcers treated by primary fusion between 2018 and 2021. 34 patients (36 feet) were identified. No patients were lost to follow-up. Demographic data and patient characteristics are summarized in Table 1. In 67% of feet (24/36) infection was located at the 1st MTP-joint while in 33% (12/36) the ulcer was at the IP-joint.

	Male=24 (70%)

Patients (n=34)	Female=10 (30%)
Average age	70.3 (Range: 16-85)
Diabetes melitus type 2	N=30 (88%)
Insulin dependent	N=24 (70%)
Peripheral artery disease	N=11 (32%)
Infection location	
1st MTPJ	24/36 (67%)
IPJ	12/36 (33%)
Pre operative MRI	17/36 (47%)
Wagner stage	
1	5/36 (14%)
2	4/36 (11%)
3	27/36 (75%)
PEDIS score	
<6	13/36 (36%)
>7	23/36 (63%)
Fusion method	
Screw	16/36 (44%)
KW'S	13/36 (36%)
Plate	4/36 (11%)
Combination (screw+kw)	3/36 (8%)

Table 1: Patient's demographics on 1st ray ulcers treated by primary fusion between 2018 and 2021.

All patients had preoperative radiographs. Seventeen patients (47%) underwent MRI scan preoperatively to define the extent of the bony and soft-tissue infection. All ulcers were classified according to the Wagner system and the PEDIS score (Table 1).

All patients had been assessed by lower limb arterial Doppler prior to surgery. If needed, a vascular intervention was done prior to the orthopedic surgery. The primary end point of the study was defined as complete healing of the ulcer. Secondary end points were radiological joint fusion, (defined as continuation of at least 3 cortices on dorsoplantar, oblique and lateral x-ray views) and a clinically stable joint. We assessed time to ulcer healing, time to fusion, revision surgeries, recurrent ulcers and the amputation rate.

Surgical technique

All patients were treated by 2 fellowship trained foot and ankle surgeons in the same institution. In the index procedure under general or regional anesthesia, a thorough surgical debridement was done until macroscopically all infected and necrotic tissues have been removed. Multiple deep biopsies and swabs for bacteriological cultures were gathered and only then empiric antibiotic treatment was started. The surgical approach for fusion was planned trying to respect angiosomes and anticipating tension-free skin closure at the end of the procedure. Joint preparation for fusion was performed under direct vision. The joint was reduced anatomically and temporarily fixed with Kirschner Wires (K-wire) [17-20]. After

fluoroscopic check the mode of fixation (K-wires, screws, plates or combination) was chosen based on bone stock and possibility of soft-tissue coverage (Table 1) (Figures 1-4)

Postoperative treatment

The antibiotic regimen was adjusted based on the bacteriogram. The average duration of antibiotic treatment was six (range, 4 to 10) weeks. Mobilization of the patient started when wound healing was considered safe. For mobilization hard sole protective shoe or a short boot were used depending on the stability of fixation and patient compliance and comfort. Percutaneous K-wires were removed at six to eight weeks postoperatively in the clinic. Patients were followed clinically and radiographically at least for 12 months after surgery [17].

Statistical analysis

We reported descriptive statistics for all the different measures, variables and outcomes using mean, range and percentage.

RESULTS

31/36 feet (86%) had a closed ulcer by one year follow up after index surgery. Overall average time to heal was 6.9 (range, 1 to 20) weeks. In the group of ulcers under the IPJ (n=12/36, 33%) ulcers were closed after an average of 4 (rang, 1 to 6) weeks. Ulcers under the 1st MTPJ (n=24/36, 67%) were closed after an average of 8 (range, 2 to 20) weeks (Figure 5) [21].

Radiographic fusion was defined as the continuation of at least 3 cortices on standard foot X rays. (AP, lateral, oblique views). By three months after index surgery radiographic fusion was reached in 10/36 (27%) cases. By six months postoperatively radiographic fusion was seen in 20/36 cases (55%) and by 12 months the rate increased to 26/36 (72%) (Table 2) (Figure 1). Clinically, by one year after surgery, 28 of 36 cases (77%) were stable on physical examination.

Closed ulcer by 12 months after surgery	**(86%) 31/36**
Fusion rates radiographically 12 months after surgery	
Total	26/36 (72%)
Screw	12/16 (76%)
KW'S	7/13 (53%)
Plate	4/4 (100%)
Combination (screw+kw)	3/3 (100%)
Fusion rates clinically 12 months after surgery	28/36 (77%)
Amputations	
Total	5/36 (14%)
MTPJ	4/5 (80%)
Below knee amputation	1/5 (20%)
Revisions	4/36 (11%)
Accurate bactriogram	34/36 (94%)
Polymicrobial	27/36 (75%)
MSSA	14/36 (38%)
Pseudomonas	7/36 (20%)
Enterobacter Cloaca	6/36 (16%)

Table 2: Results

In five cases (14%) an amputation within one year of follow up had to be done. 4 patients had a first ray amputation, and only 1 patient due to ongoing infection required a below knee amputation. In 40% cases (2/5) there was a need to amputate within the first week.

In 4 of 36 cases (11%) a second debridement without hardware removal was necessary within the first month after surgery

due to persistent infection. In all of the cases the patient's ulcers healed without further intervention (Table 2). 3 of the 5 failures leading to amputation were in cases with attempted interphalangeal fusion (IP). None of these fusions achieved bony consolidation and only one was judged clinically stable.

Six of 36 patients (17%) died during the follow up period all from unrelated causes. The data about their clinical and radiographic outcome was included in this study.

In 34 of 36 feet (94%) pathogens could be identified. The bacteriogram shows a poly-microbial growth in 75% of cases. Most commonly Methicillin Sensitive *Staphylococcus aureus* (MSSA) were isolated (14/36 (38%), followed by, *Pseudomonas aeruginosa* (7/36 (20%)) and *Enterobacter faecalis* (6/36 (16%)). No polyresistant bacteria were identified (Table 2).

DISCUSSION

Primary prevention of foot ulcers in diabetic patients is crucial. However, with growing age of the population and increasing rates of patients suffering from diabetes we are facing a rapid growth in the numbers of patients suffering from diabetic foot ulcers. Currently, the amputation rate is as high as 50% and recurrence rates are still elevated [2]. Örenholm et al., found that 42% of the patients in their study developed a new foot ulcer and 15% developed a recurrent ulcer at the same site and at the same foot [7].

In this study we described a new treatment algorithm based on one stage- debridment and fusing the involved joint in one setting for diabetic foot ulcers. We assumed that achieving a stable fusion of the infected joint after debridement will lead to faster ulcer healing and lower rates of recurrence. Our results show 86% success rate in ulcer healing by 12 months after surgery.

In this study the amputation rate was 14% (5/36 patients), which seems favorable compared to the 50% amputation rate described by Aragón-Sánchez et al., when treating forefoot ulcers with osteomyelitis [22]. In 80% of the amputated patients, it was a first ray amputation and not above or below knee amputations. These patients have better outcomes and can ambulate better compared to patients who have bellow or above knee amputations.

3 of the 5 failures leading to amputation were in cases with attempted interphalangeal fusions (IP). None of these fusions achieved bony consolidation and only one was judged clinically stable. We believe that this supports the importance of stability for wound healing and reflects the difficulty in achieving fusion in the small IPJ compromised by infection.

Ulcer recurrence is estimated to be around 30%-40% in the first year after ulcer healing [3-6]. In this study we had 11% (4/36 feet) rate of wound revisions due to recurrences. In all cases hardware was retained and all of these ulcers healed without further intervention. We believe that the aggressive ulcer debridement followed by stabilizing the joint provide a favorable environment for the diabetic ulcer to heal.

In this study we describe a treatment algorithm that include hardware implantation into an infected environment. Doing so is considered in some orthopedic fields an absolute contraindication. With the success rate that is described in this study we question this dogma. One year after surgery the fusion rates were 77% clinically and 72% radiographically. While such fusion rates would not be accepted for the general population undergoing joint fusions due to osteoarthritis, in this patient's population the success is defined by ulcer healing without recurrence and preserving the limb. This is achieved in this population even with a stable pseudarthrosis. Due to polyneuropathy in this patient's population pain is usually not a concern. Even if stable fusion is not reached ulcers may heel as shown by the comparison between rates of ulcer healing (86%) and clinical fusion (77%). Preparation for fusion includes bone shortening and deformity correction thus reducing the soft tissue tension and allowing primary wound closure. Together with targeted antibiotic therapy this might explain the high numbers of ulcer healing even if the joint was not completely fused.

The high accuracy of the bacteriograms in the study (94%) was reached by insisting that swabs are taken only from deep tissue during surgery and by avoiding prior antibiotic treatment. The profile of the bacteriograms is consistent with those reported in the literature by Bader et al., and by Lipsky et al., and is different from places where antibiotics is administrated freely before surgery, creating a multi resistant drug bacterias [12,23].

LIMITATIONS

A small group of predispose is used for selection bias. The retrospective design and short follow-up time can also limit the study conclusions accuracy because the recurrence rate might be higher then reported in this study. Fixation methods were per surgeon's choice taking into consideration the soft tissue envelop and the bone stock after debridement. Doing a

subgroup analysis comparing fixation techniques could not be done due to the small study group.

CONCLUSION

This study shows that internal fixation in an infected bone and joint is reasonably safe when treating infected diabetic ulcers in the 1st ray. This novel approach for treating ulcerations of the forefoot with underlying small bones osteomyelitis has shown to be both safe and effective.

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