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Comparing Clinical Outcomes after Toe Amputation and Toe-Sparing Surgery in Patients with Diabetic Foot Ulcer

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Abstract

Background: Diabetic ulceration leads to amputation in up to 85% of cases. Managing a diabetic ulcer requires an expert team to prevent wound progression and apply proper supportive procedures, decreasing the risk of amputation. This study aimed to compare the clinical efficacy of toe-sparing surgery and toe amputation in patients with diabetic foot ulcers.

Methods: This cohort evaluated 54 consecutive patients with Diabetes Mellitus and chronic ulcers in the lower extremities. The patients were treated by bone resection with preserving toe and soft tissue or complete toe amputation. They were followed up for one year. We evaluated the relative risk for re-ulceration of the same toe, ulcers in other parts, increased levels of hemoglobin A1c (HbA1c), and infection between the two groups.

Results: The re-ulceration rate at the same toe was 12.9% in the toe amputation and 39.1% in the toe-sparing group ($P < 0.001$). The prevalence of other amputations in the toe amputation and toe-sparing surgery groups was 29.0% and 17.4%, respectively ($P < 0.001$). However, the infection rate was lower in the toe-sparing group ($P < 0.001$).

Conclusion: The re-ulceration rate was lower after toe amputation, and the infection rate was higher in the toe amputation group.

Keywords: Amputation, Diabetic foot, Toes, Foot ulcer, Limb salvage, Toe-sparing surgery

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Introduction

The lifetime risk of developing a foot ulcer in diabetic patients is reported to be up to 25%, with an annual incidence of about 10% in developing countries (1-3). Due to its progressive nature, in up to 85% of cases, there are diabetic ulcers prior to amputation. Nevertheless, by employing an appropriate team approach to wound care and applying proper supportive procedures, at least 40% of amputations can be successfully prevented (4).

Identifying the pathogenesis helps select the best therapeutic approach for diabetic ulcers. Multiple etiologic conditions, including peripheral neuropathy and ischemia due to peripheral vascular disorder, contribute to the development of this complication (5). The primary cause is often hyperglycemia-induced metabolic abnormalities that prompt oxidative stress pathways, affecting the nerves, increasing vasoconstriction, and ischemia (6, 7). Finally, tissue ischemia may cause damage to the innervations of the

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↑What is "already known" in this topic:
Diabetic ulceration and infection are devastating complications of diabetic patients. In addition to the classic treatment approach of amputation, there are other methods, such as limb-sparing surgery.

→What this article adds:
We studied the re-ulceration rate in diabetic patients with foot ulcers who underwent either toe-sparing surgery or toe amputation.

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intrinsic foot muscles, leading to bony prominence abnormalities, skin breakdown, and ulcers.

Moreover, the loss of sensation in the affected foot and the inability to sense the lower limb injury may lead to ulcers. Perfusion disorder is another reason for diabetic ulcers. Persistent hyperglycemic states can result in endothelial cell dysfunction and abnormalities of the vascular smooth muscle cell, leading to vasoconstriction, platelet aggregation, arterial lumen stenosis, and ischemia (8, 9).

In this regard, the cornerstone of treatment is redistributing the pressure from the ulcer site through several pressure-relieving methods (10). In the presence of necrotic tissue, debridement and antibiotic therapy are indicated. Also, select cases may be candidates for amputation since the peripheral arterial disorder is accelerated by infection and direct injury to nerves and vessels.

Overall, every therapeutic approach aims to preserve tissue vitality, limb function, and quality of life. In this regard, the current guidelines emphasize early recognition of disease progress and prevention of further problems.

Multidisciplinary management could reduce the amputation rate (11, 12). Limb salvage surgeries were introduced to preserve the limb and minimize the need for amputation (13, 14). An appropriate surgical approach can provide a good functional and biomechanical state, minimize the risk of tissue breakdown, prevent recurrent infection, save the affected limb, and improve survival and quality of life (15). However, the outcome of this method has remained uncertain compared to traditional major amputation due to a lack of conclusive reports.

This study aims to compare toe-sparing surgery with toe amputation in terms of the prevention of further complications such as ulcers and infections.

Methods

This cohort study evaluated 53 consecutive patients presenting to Rasoul Akram Hospital between April 2018 and April 2020. Patients received comprehensive explanations of the study and provided written informed consent.

The inclusion criteria were type I or II Diabetes Mellitus (DM) undergoing treatment and the presence of chronic ulcers in lower extremities, i.e., lasting more than four weeks. The exclusion criteria were prior surgery of the foot, vascular disorders, ischemic change, lack of palpable peripheral pulses, less than one year of follow-up, or a history of stroke, coronary heart diseases, hypertension, dyslipidemia, any form of smoking, or Charcot joint deformity.

The wounds without peripheral erythema or swelling were classified as dry wounds, and those with secretion, peripheral erythema, or swelling were considered moist wounds. The wounds were also categorized into groups with < 1 cm, 1-5 cm, and > 5 cm size in diameter.

Magnetic resonance imaging (MRI) was performed if patients had signs of toe osteomyelitis in the clinical examination. The clinical exams were performed by one physician. Macrovascular problems were ruled out, the toe pressure was measured by color flow Doppler sonography, and neuropathy was evaluated in all patients.

Patients with no contraindication for surgery were treated either by toe-sparing surgery, i.e., bone resection with preserving soft tissue and toe, or toe amputation, i.e., complete amputation of the toe. The treatment method was decided based on the characteristics of each patient. However, if the patient did not consent to undergo toe amputation, toe-sparing surgery was used.

The two groups were evaluated regarding re-ulceration of the same toe, ulcers in other parts, increased levels of hemoglobin A1c (HbA1c), and infection.

Surgical technique

Under spinal anesthesia, the fistula was removed, and the skin was dissected. In order to approach the lesion, the wound was extended laterally, and the entire affected subperiosteal bone was resected without damaging the soft tissue. The necrotic sections were resected completely, and the wound was irrigated with normal saline. Finally, the skin was sutured with a nylon thread. The appearance of the toes treated with this approach was preserved despite the resection of the bones. Intravenous (IV) ciprofloxacin and clindamycin were administered after the operation. Upon discharge, oral ciprofloxacin and clindamycin were prescribed for patients. Standard care for diabetic foot ulcers was conducted for all patients.

Follow-up

In the first follow-up visit, a dietician administered a diet, and medication was prescribed to manage infection, pain induced by neuropathy and ischemia, hyperglycemia, hyperlipidemia, or hypertension. Trained nurses explained the proper washing and dressing of the wound to the patients. The patients were regularly visited and assessed for one year and examined for any ulcer recurrence and infection. Furthermore, HbA1c was used to analyze blood sugar control.

Statistical analysis

Results were presented as mean ± standard deviation for quantitative variables and as frequency and percentage for categorical variables. The normality of the data was analyzed using the Kolmogorov-Smirnov test. Categorical variables were compared using a chi-square or Fisher's exact test. The quantitative variables were also compared with a t-test or Mann-Whitney U test. We assessed the relative risk for re-ulceration of the same toe, ulcers in other parts, increased HbA1c, and infection. We used SPSS Version 16.0 for Windows (SPSS Inc.) for statistical analysis. A $P \leq 0.05$ was considered statistically significant. The effect of confounding factors was eliminated by using stringent exclusion criteria.

Results

A total of 31 patients with diabetic foot ulcers were treated with toe amputation and 23 patients with toe-sparing surgery. Overall, 21 patients had dry, and 33 patients had moist wounds. In the toe-sparing group, 8, 12, and 3 patients had wounds with a diameter of < 1, 1-5, and > 5 cm, respectively. Among the 23 patients in the toe-sparing group, rays were completely resected in 3 patients, and two rays were resected simultaneously in 1 patient. Wounds,

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Table 1. The comparison of clinical characteristics between the toe amputation and toe-sparing surgery groups

Variable	Toe Amputation (n = 31)	Toe-sparing Surgery (n = 23)	*P* Value
Re-ulceration of the same toe	4 (12.9)	9 (39.1)	< 0.001
Ulcers in other parts	20 (64.5)	9 (39.1)	0.062
Increased HbA1c	19 (38.7)	10 (43.5)	0.193
Infection	9 (29.0)	4 (17.4)	< 0.001

Data presented as n (%).

Table 2. Risk estimation for each operation-related determinant (toe-sparing surgery versus toe amputation)

Item	Relative Risk (95% CI)	*P* Value
Re-ulceration of the same toe	2.401 (1.173 – 4.822)	< 0.001
Ulcers in other parts	1.162 (0.831 – 1.373)	0.092
Increased HbA1c	1.217 (0.668 – 1.794)	0.354
Infection	0.678 (0.542 –0.925)	< 0.001

skin fistulas, and necrotic tissues were removed in all patients. No patient was lost to follow-up.

Re-ulceration of the same toe, ulcers in other parts, increased HbA1c, and infections were compared in the two groups (Table 1). This table shows that re-ulceration of the same to was significantly higher in the toe-sparing surgery group, while the infection rate was significantly higher in the toe amputation group.

Also, a risk assessment for each variable was done (Table 2). This table indicates that toe-sparing surgery has a higher risk of re-ulceration of the same toe, while it has a lower risk of infection than toe amputation.

In the toe-sparing surgery group, three patients (with wounds > 5 cm) had ulcer recurrence, but in the patients with 1-5 cm wounds, the recurrence rate was the same as those with < 1 cm wounds.

Discussion

DM is a progressive disease associated with multiple complications, among which diabetic foot ulcer is among the most common, causing gangrene and even amputation, leading to high financial, emotional, and psychological burdens. A reason for the complexity of diagnosing and managing diabetic ulcers is the reduced immune responses in diabetic patients (16). Despite all efforts to manage diabetic foot ulcers, the condition is still one of the most devastating complications of DM (17). The economic and psychological burden of diabetic ulcers has challenged the introduction of novel approaches to more effective treatment and care protocols. Moreover, diabetic foot ulcers often result from chronic ulcers with slow healing due to numerous potential factors such as inadequate blood supply, neuropathy, long-term stress, prolonged ulcers, smoking, organ failure, and poor blood sugar control (18-20). The treatments include debridement, wound care, controlling infection, improving blood supply, reducing foot pressure, and managing comorbidities. In most guidelines, debridement is preferred over removing necrotic tissue from the wound (21). Besides, osteomyelitis, a complication after an untreated soft tissue infection, is a serious complication in diabetic patients and a significant cause of amputation (22, 23). The treatment of osteomyelitis includes resection of the affected bone and antibiotics. Also, evidence suggests that antibiotic administration alone can be effective in some cases, but partial amputation of the toes is of no benefit in such cases.

Our observations indicate that the rate of re-ulceration was significantly higher in patients with toe-sparing surgery than in the amputees in this study. However, patients undergoing toe-sparing surgery showed lower infection rates. Salvaging affected limbs in such patients may improve physical function and quality of life. In other words, higher gait efficiency for patients treated with toe-sparing surgery may suggest a superior level of physical function. Moreover, surgeons prefer reconstructing the affected limb by sparing interventions to minimize patient disability. Previous studies using objective measurements and comparing patients treated with amputation to those who had salvage surgery have shown conflicting results, with no difference in wound healing but better functional testing scores (24-26). In patients with osteosarcoma, limb-salvage surgery can result in higher long-term survival and better functional outcomes than amputation (27). Gait efficiency is better in patients undergoing limb-salvage surgery, and these patients can return to their everyday lives earlier than the amputees, but their perception does not improve their quality of life (28).

Several salvage techniques have been introduced to improve the function of the affected limb instead of complete limb amputation. Surgical debridement or limited amputation, in addition to antibiotics, was shown to be more effective in achieving clinical control and limb preservation than local amputation (29). Debridement and attempted fusion with an external fixator are reasonable alternatives to below-knee amputation, leading to clinical improvement in 86.7% of patients (30).

Similar results in several postoperative outcomes following amputation and salvage surgery in our study are consistent with the previous studies; however, our study was not without limitations. First, our small sample size could be a major limitation. Second, some baseline factors confounding our comparative analysis might have been overlooked. As previous studies indicated, some factors are significantly associated with the success or failure of limb salvage surgery that may affect our statistical analysis. These factors include underlying renal disease or other organ failures, limited activity before surgery, low hemoglobin level, high white blood cell count, high C-reactive protein level, and damage to 2 or more vessels in the preoperative computed tomography angiogram (31). These factors should be considered as probable confounders, and the comparison of

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the efficacy of the treatment approaches should be reassessed.

Conclusion

Our findings indicate that despite the lower rate of re-ulceration with the amputation method, infection rates were lower when toes were preserved. Also, toe-sparing surgery has a higher risk for re-ulceration of the same toe, while it has a lower risk of infection than toe amputation.

Authors' Contributions

AKM and AY presented the concept of the study. SA, SC, and SNT collected the data. MG and MS drafted the primary manuscript. All authors contributed to the study design, critical revision of the manuscript, and approval of the final version of the manuscript.

Ethical Considerations

This study was approved by our institute board and the ethics committee of the Iran University of Medical Sciences under code IR.IUMS.REC.1397.418.

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Conflict of Interests

The authors declare that they have no competing interests.

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