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CLINICAL RESEARCH ARTICLE

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Preoperative medical treatment in patients undergoing diabetic foot surgery with a Wagner Grade-3 or higher ulcer: a retrospective analysis of 52 patients

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Diabetic foot ulcers (DFU) are one of the most important complications in people with diabetes mellitus. The present study was aimed to retrospectively review the efficacy of at least 1-week medical treatment before any surgical intervention in patients with Grade-3 and higher DFU according to Wagner's classification. A total of 52 patients (36 males and 16 females) hospitalized and treated between June 2006 and February 2009 and had initially received therapeutic treatment (local wound care, antibiotic therapy and blood glucose regulation) for a period of at least 1 week were included in the study. The level of amputation, rates of reulceration and mortality in both groups were recorded in the following period of 2 years. Group 1 (did not respond to preoperative medical intervention) included 16 patients where a surgical debridement, flap or skin graft surgery was performed in 2 (12.5%) patients, major amputation was performed in another 2 (12.5%) patients and minor amputation was performed in the remaining 12 (75%) patients. Of 36 patients in Group 2 (did respond to preoperative medical intervention), 5 (13.9%) patients underwent the surgical debridement, flap or skin graft surgery, 8 (22.2%) patients had a major amputation and the remaining 23 (63.9%) patients lead to a minor amputation. The ulcer recurrence and mortality rates were obtained as 2 (12.5%) and 2 (12.5%) in Group 1 and 2 (5.6%) and 1 (2.8%) in Group 2, respectively. Despite the lower rates of ulcer recurrence and mortality in patients having adequate responses to initial treatment before surgical procedures were performed, no statistically significant difference was observed between the 2 groups. In addition, there was no statistically significant difference between the levels of amputation in both groups.

Keywords: *diabetes mellitus*; *diabetic foot*; *amputation*; *medical treatment*; *mortality*

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Diabetic foot ulcers (DFU) are common complications in the diabetic population, resulting in significant associated morbidity and mortality (1). Long-term diabetes mellitus (DM), poorly controlled glucose levels, trauma and inadequate treatment are some of the risk factors for diabetic foot infections. The lifetime risk of DFU for patients with DM is approximately 15% (2). Major causes of amputations in patients with DM include minor trauma, cutaneous ulcerations and wound-healing failure most commonly found in association with infection and gangrene (3). Patients with DM have approximately 15–40 times greater risk of amputation throughout their lives than do individuals without DM (4–7). Another significant problem in patients with DFU is the high mortality rate (8, 9).

This present study was aimed to retrospectively review the efficacy of at least 1-week medical treatment consisted of local wound care, antibiotic therapy and glycemic control before any surgical intervention was performed in patients with Grade-3 and higher DFU according to

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the Wagner classification (Table 1) (10). The amputation levels, reulceration and mortality rates within 24 months of the treatment were compared between the responding and non-responding patients to initial 1 week of therapeutic treatment.

Patients and methods

A total of 52 patients with Wagner Grade-3 and higher DFU hospitalized and treated between June 2006 and February 2009 were included in the study. A preoperative treatment of local wound care, antibiotic therapy and blood glucose regulation was initially given to all patients for a period of at least 1 week. Exclusion criteria for the study included patients with amputation performed for other reasons such as trauma or tumor, associated with entrapment neuropathies or vascular disease. The clinical follow-up periods and the results of the patients were retrospectively assessed.

The local wound care consisted of a saline wet-to-dry dressing applied to all patients for at least once a day for 1 week, and, if necessary, wound debridement was also performed. In the patients with malodorous and infected wounds, their feet were kept in a mixture solution of 100-mL Betadine® (each 1 mL contains 100-mg povidone–iodine, equivalent to 10-mg available iodine) and 1,000-mL saline for 5 min. Immediately after this procedure, saline wet-to-dry dressings were applied to their respective wounds.

Intravenous antibiotic therapy of ampicillin sulbactam has been shown to be safe and effective in the treatment of diabetic foot infections (11) and our hospitalized patients received the empirical therapy of ampicillin sulbactam, 4 g per day for at least 7 days prior to undergoing any type of diabetic foot surgery.

The mean fasting blood glucose level of the total of 52 patients with a long history of DM (14.9 years $\pm$5.1) was 309 mg/dL during hospitalization. Long-lasting hypoglycemic treatments for all patients were stopped, and intensive insulin treatment (subcutaneous injections of regular human insulin for three times a day and insulin glargine for a single dose) was started via the calculation of total insulin dose with the formula of 0.5 IU/kg. After at least 7 days, the mean fasting blood glucose level of all patients was reported at 183 mg/dL.

Table 1. Wagner's classification for foot ulcers

Grade 0	Preulcerative lesion, healed ulcers, presence of osseous deformity
Grade 1	Superficial ulcer without subcutaneous tissue involvement
Grade 2	Penetration through the subcutaneous tissue (bone, tendon, ligament or joint capsule)
Grade 3	Osteitis, abscess or osteomyelitis
Grade 4	Gangrene of the forefoot
Grade 5	Gangrene of the entire foot

Blood glucose levels less than 200 mg/dL, leukocyte counts in the reference ranges and C-reactive protein less than 10 mg/L were accepted as the criteria for adequate responses to 1 week of the preoperative medical intervention. Decrease in wound size and drainage, non-progressive necrosis and onset of granulation tissue were considered as clinical improvement of the preexisting DFU.

Patients were divided into two groups according to the responses of 1-week medical and local wound care treatment. Group 1 consisted of the patients without clinical improvement and who did not respond well to medical treatment. The patients having adequate responses to 1-week medical treatment were included into Group 2. The patients were followed for a mean period of 2.4$\pm$0.5 years. The demographic and clinical data of the patients, levels of amputation, reulceration and mortality rates were retrospectively reviewed.

Statistical Package for the Social Sciences (SPSS) 15.0 was used for statistical analysis, and the variables were compared by using Chi-square and Mann–Whitney *U* tests. Values less than 0.05 were considered as significant.

Results

Demographic and clinical data of all patients are shown in Table 2. No adequate responses to the pre-operative 1-week medical intervention were obtained in 16 (30.8%) patients (Group 1). Of total 52 patients, 36 (69.2%) patients had been medically treated with adequate responses (Group 2). The healing rate without amputation in Group 1 was 12.5%, whereas in Group 2, complete wound healing was achieved in 5 of 36 feet (13.9%). These wounds were completely healed by surgical debridement, flap or skin graft surgery.

Out of 16 patients in Group 1, 2 patients (12.5%) had major amputations. One patient was amputated above the knee and 1 patient required a Syme's amputation. In Group 1, 12 patients received minor amputations; where 1 patient (6.2%) had a transmetatarsal, 4 (25%) patients had a ray and 7 (43.8%) patients had toe amputations (Table 3). In Group 2, major amputations were performed in 8 patients (22.2%); 5 (13.9%) patients were amputated above the knee and 3 (8.3%) patients had a Syme's amputation. Twenty-three (63.9%) patients had minor amputations; 12 (33.3%) patients had a transmetatarsal, 2 (5.6%) patients had a ray and 9 (25%) patients had toe amputations (Table 3).

There was no statistically significant difference between Groups 1 and 2 when comparing the minor and major amputation rates ($p = 0.32$, $p = 0.09$). The rates of ulcer recurrence and mortality were obtained as 2 (12.5%) and 2 (12.5%) in Groups 1 and 2 (5.6%) and 1 (2.8%) in Group 2, respectively. The comparison of both groups with respect to the ulcer recurrence and mortality

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Table 2. Patients' demographic and clinical data

	Group 1 ($n=16$)	Group 2 ($n=36$)
Female/male *n* (%)	5 (31.2)/11 (68.8)	11 (30.6)/25 (69.4)
Age, mean ± (year)	66.7 ± 5.7	62.6 ± 10.6
Duration of diabetes, mean ± (year)	14.8 ± 4.9	15.0 ± 5.2
Follow-up time, mean ± (year)	1.6 ± 0.7	1.6 ± 0.0.3
Peripheral neuropathy (+), *n* (%)	9 (56.2)	24 (66.7)
Peripheral vascular disease (+), *n* (%)	10 (62.5)	14 (38.9)
Osteomyelitis (+), *n* (%)	14 (87.5)	25 (69.4)
Etiologic factors of forefoot diabetic ulcers, *n* (%)		
Unknown	3 (18.7)	10 (27.8)
Trauma	4 (25)	6 (16.7)
Shoe	3 (18.7)	5 (13.9)
Nail wound	3 (18.7)	5 (13.9)
Burns	1 (6.25)	6 (16.7)
Foot deformity	2 (12.5)	4 (11)
Wagner's classification, *n* (%)		
Grade 3	5 (31.25)	14 (38.9)
Grade 4	9 (56.25)	14 (38.9)
Grade 5	2 (12.5)	8 (22.2)

rates also showed no statistically significant difference ($p=0.06$, $p=0.09$). However, less ulcer recurrences and mortalities were clinically detected in Group 2.

Discussion

Long-term effects of DM on the microcirculation and on dermal collagen eventually result in skin disorders in almost all diabetic patients (4). These skin disorders cause a full-thickness penetration of the dermis of the foot, infection and ulceration in people with DM (12). Severity is classified using the Wagner's classification system, which grades it from 1 to 5. Grade-3 ulcers are deep ulcers with cellulitis or abscess formation, often complicated with osteomyelitis. Ulcers with localized gangrene are classified as Grade 4, and those with extensive gangrene involving the entire foot are classified as Grade 5 (10). Grade 3 and higher DFU are usually serious infections requiring surgery. In this retrospective study, the rates of ulcer recurrence, mortality and amputation levels were not statistically different between Groups 1 and 2. One of our major limitations of the present study was the lack of glycosylated hemoglobin levels of the patients in both groups.

Table 3. Amputation and complication rates

	Group 1, $n=16$ (%)	Group 2, $n=36$ (%)
Healing without amputation	2 (12.5)	5 (13.9)
Minor amputation	12 (75)	23 (63.9)
Toe amputation	7 (43.8)	9 (25)
Transmetatarsal amputation	1 (6.2)	12 (33.3)
Ray amputation	4 (25.0)	2 (5.6)
Major amputation	2 (12.5)	8 (22.2)
Syme amputation	1 (6.25)	3 (8.3)
Above the knee amputation	1 (6.25)	5 (13.9)
Reulceration	2 (12.5)	2 (5.6)
Mortality	2 (12.5)	1 (2.8)

The relative risk of major amputation in people with DM compared with the population without DM is approximately 15 times higher (13–15). Targeting more-intensive glucose lowering modestly reduced major macrovascular events and increased major hypoglycemia over 4.4 years in persons with type 2 DM (16). Another study showed that good quality of life is significantly related to good diabetes self-management and fasting blood sugar control in type 2 diabetic patients with foot ulcers. Therefore, these patients should be encouraged to perform self-management for controlling their blood sugar and improving their quality of life (17). Imran et al. determined that the frequency of minor and major amputations increases with the higher grades of diabetic foot pathology. Poor glycemic control is a significant risk factor for amputation in diabetic patients (18). Together with early detection and treatment of foot lesions, normal blood glucose levels and early management of systemic complications such as nephropathy and arteriosclerosis are considered important to avoid major amputations (19–22). Most of the patients with Grade-3 and higher DFU usually undergo amputation or major surgery. The higher the level of amputation in the lower extremity, the greater the energy required for walking (23). In our study, there was no statistically significant difference between the rates of major amputations in both groups.

The reappearance of a foot lesion after the primary ulcer had healed is considered as an ulcer recurrence, and is mostly seen in patients with DM (24). The DFU recurrence can be prevented by instituting the multi-disciplinary approach in the overall management of the diabetic patient. Additional preventive measures such as osseous and soft tissue reconstructions during the infection-free period together with education and routine follow-ups provide the basis for a long-term reduction of ulcer and infection recurrence with progressive deterioration of the prognosis (25). In the present study, the preoperative medical intervention was found to be effective clinically for reducing the ulcer recurrence rates, but this showed no statistical significance.

After a major amputation, patients with DM have an increased mortality rate compared with patients without

DM (15). Lee et al. (27) concluded that, in patients with DM, the mortality rate among amputees was two times higher than in non-amputees, and that the 5-year survival rate after first amputation was 40.4% (26). In another study, there was an 8.7% mortality rate in patients with DM. In addition, it was also found that the mortality rate in major amputations was approximately three times higher than in minor amputations (28). In our study, the mortality rates between the two groups were not statistically different.

Conclusion

The reulceration and mortality rates were not statistically different between the two groups, but were found to be clinically lower in patients having an adequate response to preoperative medical intervention before undergoing any diabetic foot surgery.

Conflict of interest and funding

The authors have not received any funding or benefits from industry to conduct this study.

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