ABSTRACT

Aim To examine two modalities of surgical treatment of diabetic foot based on two different approaches, classical and multidisciplinary.

Methods A retrospective-prospective study including 120 consecutive patients with diabetic foot treated in the Department of Surgery, General Hospital Tešanj in the period 1999-2006. Since 2003 a new multidisciplinary approach to the treatment of diabetic foot based on a more conservative approach has been introduced. Two groups of patients were analyzed according to two treatment approaches: the first group included patients treated with classical method (in the period 1999-2002), and the second group included patients treated with multidisciplinary approach (in period 2003-2006). An age distribution, gender, local changes in the extremities, results of microbiological analysis of wound swabs, and modalities of surgical treatment of diabetic foot were analyzed.

Results Duration of the disease (p=0.24), the level of blood glucose (p=0.52) and glycosylated hemoglobin (p=0.10) had no statistically significant effect to the outcome of the treatment of diabetic foot, while the level of hematocrit (p<0.006), fibrinogen (p<0.003), cholesterol (p<0.000001), and the absence of a pulse in the peripheral arteries (p<0.000002), and the outcome of surgical treatment of diabetic foot had the influence to the outcome of the treatment of diabetic foot with statistical significance.

Conclusion Aggressive and appropriate medical and surgical treatment according to a grade of disease could improve the outcome and reduce the morbidity and mortality of diabetic foot. The results of this study showed the importance of proper diabetes treatment, prevention of complications and a multidisciplinary approach to the treatment of diabetic foot.

Key words: complications, diabetes mellitus, multidisciplinary approach, outcome.
INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic diseases in which a person has high blood sugar level. Incidence of DM is about 3.3% in human population with equal rates in females and males (1,2). Diabetes mellitus is classified into four broad categories: type 1, type 2, gestational diabetes, and other specific types. All forms of diabetes increase the risk of long-term complications, but most of them come from type 1 (1-4). Long-term complications typically develop after many (10–20) years, but they might also be the first symptom of diabetic disease (3). Diabetic angiopathy and neuropathy could result in diabetic foot complications (3,4). Diabetic foot is a foot with a constellation of pathologic changes affecting the lower extremity in diabetics, often leading to amputation and/or death due to complications; the common initial lesion leading to amputation is a non-healing skin ulcer, induced by regional pressure, pathogenically linked to sensory neuropathy, ischemia and infection (4). Diabetic foot complications are the most common cause of non-traumatic lower extremity amputations in the industrialized world (5). The risk of lower extremity amputation is 15 to 46 times higher in diabetics than in persons who do not have diabetes mellitus (3-6).

There is a two-fold aim of surgery, to control the infection, and to attempt to salvage the leg (3). The eventual goal is always to preserve a functional limb (3,4). The surgical treatment of the infection largely consists of draining of pus and removal of all necrotic and infected tissue (4). The outcome of the surgery mainly depends on the skills, care, and experience of the surgeon (3).

In the Federation of Bosnia and Herzegovina (FBiH) 120,000-190,000 people are estimated to have diabetes, with the prevalence of about 5.4% (7). Until January 2003 patients with diabetic foot had been treated according to the basic principles of surgery. The approach to the patient was more individual without any defined protocol. This period is characterized by a high frequency of high amputations (femoral and tibial) (8,9). Since 2003 we have been applying a standardized treatment protocol of diabetic foot (Armstrong, 2003). This protocol used diabetic wound classification system based on a grade on the horizontal axis and a stage on the vertical axis: grade 0 - pre/or post-ulcerative site that has healed, grade 1 - superficial wound not involving tendon, capsule, or bone, grade 2 - wound penetrating to tendon or capsule, and grade 3 - wound penetrating a bone or joint. Within each wound grade there are four stages: clean wounds (stage A), nonischemic infected wounds (stage B), ischemic noninfected wounds (stage C), and ischemic infected wounds (stage D) (10-12).

This protocol involves adequate control of blood glucose, glycolated hemoglobin, glycemic profile, treatment of wound infection, debridement of necrotic tissue, administration of antibiotics according to the antibiogram, gradual removal of necrotic tissue from the affected foot with a possible use of partial amputation. This protocol prohibits application of caustic antiseptics in the treatment of wounds (11,12).

The aim of this research was to examine two modalities of surgical treatment of diabetic foot, using two different approaches, classical based on a radical surgical approach and a new multidisciplinary approach based on a more conservative approach. The application of this protocol resulted in a decrease of major amputations (femoral and tibial), and in an increase of the functionality and support of the leg. The results of this study should show the importance of proper diabetes treatment, prevention of complications and a multidisciplinary approach to the treatment of diabetic foot.

PATIENTS AND METHODS

Clinical trial design

The retrospective-prospective, non-randomized, controlled study included 120 consecutive patients with diabetic foot who were treated at the Department of Surgery, General Hospital Tešanj in the period 1999-2006.

Objective

The aim of this research was to examine two modalities of surgical treatment of diabetic foot, using two different approaches, classical based on the radical surgical approach and the new multidisciplinary approach based on a more conservative approach.

The outcome was defined by reducing the number of amputations and preserved foot support.

The patients were divided in two groups. The first group included 53 (retrospectively) patients treated with radical surgical approach characteri-
ized with higher incidence of major amputations, which was performed in 31 patients during the period January 1999 to December 2002. The second group included 67 (prospectively) patients treated with a doctrinal approach in the period January 2003 to December 2006.

The research was conducted with the approval of the Ethics Committee of the General Hospital Tešanj.

**Eligibility criteria**

Patients with diabetes treated with insulin or oral antidiabetics, of different age and gender, with proven unilateral or bilateral diabetic foot were eligible for this research. Patients with diabetes treated with insulin or oral antidiabetics, of different age and gender, without evidence of diabetic foot and who died during the study were excluded. All patients were followed to the complete wound healing. All subjects included in this study voluntarily agreed to participate and gave written signed informed consents.

**Study interventions**

Until 2002 the surgical procedures treatment of diabetic foot had not been standardized. This approach includes the treatment of a local change without clearly defined antiseptics, which meet the minimum toxicity to tissues and rapid elimination from the tissues (13,14). A characteristic of this approach is more frequent application of small and large amputations. Small amputations are performed at the level of the toes and feet: interphalangeal, metatarzofalangeal, intertarsal (Lisfranc, Schoport, Pirogov). Large amputations are femoral and tibial (14-16).

The doctrinal approach which was established in 2003 by Armstrong (11,12) involves multidisciplinary approach that includes prevention, conservative treatment and application of less extensive surgery. This protocol used diabetic wound classification system based on a grade on the horizontal axis and stage on the vertical axis: grade 0 - pre/postulcerative site that has healed, grade 1 - superficial wound not involving tendon, capsule or bone, grade 2 - wound penetrating to tendon or capsule, and grade 3 - wound penetrating the bone or joint. Within each wound grade there are four stages: clean wounds (stage A), nonischemic infected wounds (stage B), ischemic noninfected wounds (stage C), and ischemic infected wounds (stage D) (10-12).

The prevention of diabetic foot is related to the adequate control of the disease: glycaemia control, blood count, glycosylated hemoglobin, lipidograms, body mass reduction, adequate therapy, physical activity, etc. The treatment of local changes is conditioned by their size, type and depth (10-13). Local treatment of wound includes antiseptic (3% hydrogen peroxide) application and irrigation with sterile saline solution, partial necrectomy and wound debridement, and administration of antibiotics according to microbiological analysis and susceptibility testing. Amputation is maximally delayed (11,12).

Diabetic foot is defined as a foot with pathologic changes affecting the lower extremity in diabetics. Phlegmon represents a spreading diffuse inflammatory process with formation of suppurative/purulent exudate or pus. Ulcers are wounds or open sores that will not heal or keep returning, and are often complicated with infections. Expanding ulcers and spreading infection on a bone occur as osteomyelitis. Gangrene is the most serious form of diabetic foot. There is necrosis or decay of the affected foot (17,18).

Microbiological analysis of swabs of wound infections were performed at the Department of the Laboratory Diagnostics, General Hospital Tešanj, by standard microbiological methods (19). Antibiotic susceptibility testing of isolated Gram-positive and Gram-negative bacteria was performed according to the Clinical Laboratory Standard Institute (CLSI) (20).

In cases with superficial infection topical antibiotics (garamycin) were used until signs of the infection were resolved and the wound healed. For mild to severe infections, cephalosporins of the third and fourth generation and imipenem were used: for mild infections throughout the period of 12 weeks, for moderate and severe infections in the period of 24 weeks.

The decision on a modality of the treatment was based on the prevalence of infection and necrosis size, signs of vasculopathy and a lack of pulse in the arteries of the foot and neuropathic changes. All patients had a very bad medicament control of diabetes with high blood glucose (mean value 18.2mmol/L), glycosylated hemoglobin (mean value 11.2%), sedimentation (mean value 60.7), fibrinogen (mean value 5.6) and cholesterol (mean value 8.4).
Follow up

All patients were followed until the complete wound healing. The study did not follow up the patients after the healing of local changes, which is a significant limitation of this study.

Statistical methods

The results are presented in tables and expressed by relative values and mean value. The level of statistical significance was $p<0.05$.

RESULTS

Patients’ characteristics

This study included 120 patients with diabetic foot treated at the Department of Surgery, General Hospital Tešanj, during the period 1999-2006. The patients were divided in two groups. In the first group 53 patients were treated using radical surgical approach (January 1999 to December 2002) and in the second group 67 patients were treated with multidisciplinary approach (January 2003 to December 2006).

The gender ratio was 67 females (55%) and 53 males (45%). The youngest patient was 33 and the oldest aged 85 (mean value 64.2).

Local changes

All patients had inflammatory and necrotic changes in the foot.

In the first group 14 (28.30%) patients had phlegmon, 12 (22.64%) had ulcers, six (11.32) had both, 10 (18.86%) had ulcers with osteomyelitis and 11 (20.75%) had gangrene. In the second group 22 (32.38%) patients had phlegmon, 15 (22.38%) had ulcers, 10 (14.92%) had both, eight (11.94%) had ulcers with osteomyelitis and 12 (17.91%) had gangrene (Table 1).

Table 1. Local changes in patients with diabetic foot

<table>
<thead>
<tr>
<th>Local changes</th>
<th>Patients with radical surgical approach</th>
<th>Patients with multidisciplinary approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlegmon</td>
<td>14 (28.30)</td>
<td>22 (32.83)</td>
</tr>
<tr>
<td>Ulcer</td>
<td>12 (22.64)</td>
<td>15 (22.38)</td>
</tr>
<tr>
<td>Phlegmon and ulcer</td>
<td>6 (11.32)</td>
<td>10 (14.92)</td>
</tr>
<tr>
<td>Ulcer with osteomyelitis</td>
<td>10 (18.86)</td>
<td>8 (11.94)</td>
</tr>
<tr>
<td>Gangrene</td>
<td>11 (20.75)</td>
<td>12 (17.91)</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>67</td>
</tr>
</tbody>
</table>

Bacterial flora and antibiotics

The most common isolated bacteria were *Escherichia coli*, in 49%, *Staphylococcus aureus* in 28%, *Proteus* spp. in 25%, *Pseudomonas aeruginosa* in 10.8%, *Klebsiella* spp. in 3.3%, and *Clostridium perfringens* in 13.33% of the patients (data not shown).

In all patients an appropriate antibiotic treatment according to the antibiogram was prescribed. The most commonly used antibiotics in gram-positive and gram-negative bacteria were cephalosporins and imipenem.

Surgical treatment

The first group included 53 patients who were treated with classical approach (more individualized approach and it was not clearly adopted protocol of the treatment of diabetic foot) in the period 1999-2002 and only one patient was treated by conservative approach. The major amputation (femoral and crural) was performed in 31 (25.83%) patients, while small amputation (limited to foot) was performed in 11 (9.16%) patients. The first group included patients with poor control of the disease and higher incidence of complications (phlegmon, ulceration, osteomyelitis and gangrene) (Table 2).

Table 2. Modalities of treatment of diabetic foot

<table>
<thead>
<tr>
<th>Modality of treatment</th>
<th>Patients with radical surgical approach</th>
<th>Patients with multidisciplinary approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral amputation</td>
<td>17 (32.1)</td>
<td>6 (8.9)</td>
</tr>
<tr>
<td>Crural amputation</td>
<td>24 (45.5)</td>
<td>12 (17.1)</td>
</tr>
<tr>
<td>Minor amputation</td>
<td>11 (20.75)</td>
<td>-</td>
</tr>
<tr>
<td>Finger amputation</td>
<td>-</td>
<td>13 (19.4)</td>
</tr>
<tr>
<td>Foot amputation</td>
<td>-</td>
<td>15 (22.4)</td>
</tr>
<tr>
<td>Conservative treatment</td>
<td>1 (2)</td>
<td>21 (31.3)</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>67</td>
</tr>
</tbody>
</table>

The second group included 67 (prospectively) patients who were treated in the period 2003-2006. In these patients, we used the doctrinal approach in the treatment of patients with diabetic foot according to Armstrong (Table 2). A significant decrease of the incidence of major amputations and an increase in the number of patients with preserved function of foot has been found.

Laboratory parameters

In the second group relevant laboratory parameters were controlled in all patients. They all had a very bad medicament control of diabetes with high blood glucose (mean value 18.2 mmol/L), glycosylated hemoglobin (mean value 11.2 %), sedimentation (mean value 60.7), fibrinogen (mean value 5.6) and cholesterol (mean value 8.4) (Table 3).
In this research, the results of the treatment of diabetic foot were significantly different in relation to the approach. Prior to the adoption of a single multidisciplinary approach to the treatment of diabetic foot, there had been a much higher frequency of amputations compared to the second period, which is in relation with results of other authors (5-8). In the second group of patients percentage of large amputations was significantly reduced, thereby increasing the number of patients with conservative treatment and minor amputations. This is also in relation with results of other authors (3,15-18).

According to our research, there was no statistical significance between the duration of the disease, level of glucose, level of glycosylated hemoglobin and the outcome of the surgical treatment of diabetic foot in the second group of patients. These data did not correlate with other studies (3, 16-18). These results could be explained by an introduction of the conservative approach and better control of the disease with medicaments and insulin. These data are missing for the first group of patients.

Diabetic foot is a significant complication of diabetes. Aggressive and appropriate medical and surgical treatment according to a grade of the disease can improve the outcome and reduce morbidity and mortality due to diabetes.

In conclusion, this study was conducted with the principal aim to evaluate results of the surgical treatment of diabetic foot using two different approaches. The first group included patients treated with classical approach which had higher incidence of major amputations. The second group included patients treated with doctrinal approach which characterized more the conservative approach, with delayed large amputations. Aggressive and appropriate medical and surgical treatment according to a grade of the disease could improve the outcome and reduce morbidity and mortality of diabetic foot. The results of this study have shown the importance of proper diabetes treatment, prevention of complications and a multidisciplinary approach to the treatment of diabetic foot.

**FUNDING**

No specific funding was received for this study.

**TRANSPARENCY DECLARATIONS**

Competing interest; none to declare.
Evaluacija hirurškog liječenja dijabetičnog stopala
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SAŽETAK
Cilj Ispitati modalitete hirurškog liječenja dijabetičnog stopala zasnovane na dva različita pristupa – klasičnom i multidisciplinarnom.


Rezultati Dužina trajanja bolesti (p=0,24), nivo glukoze u krvi (p=0,52) i glikoliziranog hemoglobin-a (p=0,10), nisu imali značajan utjecaj na ishod liječenja dijabetičnog stopala, dok su vrijednost hemokrit-a (p=0,006), fibrinogen-a (p=0,003), holesterola (p<0,00001) i odsutnost pulsa u perifernim arterijama (p<0,000002), te ishod hirurškog liječenja dijabetičnog stopala, sa statističkom značajnošću imali utjecaj na ishod liječenja dijabetičnog stopala.

Zaključak Agresivni i odgovarajući medicinski i hirurški tretman prema stadiju bolesti može poboljšati ishod liječenja i smanjiti morbiditet i mortalitet dijabetesa. Rezultati ove studije pokazali su važnost odgovarajućeg liječenja dijabetesa, prevenciju komplikacija i multidisciplinarnog pristupa u liječenju dijabetičnog stopala.

Ključne riječi: komplikacije, dijabetes, multidisciplinarni pristup, ishod

REFERENCES