

THE EXPERIENCE IN DIABETIC FOOT MANAGEMENT

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ABSTRACT:

Objective: to improve therapeutic outcomes in patients with neuropathic diabetic foot and mixed forms of diabetic foot syndrome (DFS), including the use of the Lacerta[®] material.

Materials and methods: A total of 53 patients with DFS, age 23 to 65 years (mean age 44 years) have been treated in the clinical setting of the Department of Disaster Medicine, Military Medicine, Anaesthesiology and Critical Care of Zaporozhye State Medical University between 2010 and 2013. There were 32 (60.4 %) female and 21 male (39.6 %) patients.

Results and Discussion: Most patients (44 or 83%) had mixed forms of DFS. The medical management was aimed at stabilizing the ischaemic limb syndrome. The surgical management in this group of patients was mostly organ-sparing. Thirteen (24.5 %) patients with Grade 1 of Wagner Grading System for Diabetic Foot had a post-surgery plastic closure of a wound defect with a split-thickness skin graft. In addition to medical management and intra-arterial injections of drugs, 17 (32 %) patients with Grade 2 of Wagner Grading System for Diabetic Foot the following treatment modalities were employed: debridement of the inflammation focus, drainage, time-phased sequential necrectomies, local dressings with antiseptics and enzymes and physical therapy as assigned. Split-thickness graft technique was employed to close the defect after the granulating wound was obtained. Eight (15.09 %) patients with Grade 3 of Wagner Grading System for Diabetic Foot had emergency necrectomies with a wide drainage of a focus of inflammation on the foot. During the 'cold period' after demarcation line on the foot had been formed, 3 patients had exarticulation of the toes, 4 patients had an atypical resection of the foot (in two of the latter patients the postoperative wound has healed by secondary intention). One patient had Sharp's foot amputation. Alongside with medical management, surgical treatment was undertaken in 6 (11.3 %) patients with Grade 4 of Wagner Grading System for Diabetic Foot. Two patients had lumbar sympathectomy, profundoplasty and peri-arterial sympathectomy with a single-step resection of the foot. A new treatment technique, developed in our clinic, was used in 9 (16.9 %) patients. The technique is based on using the Lacerta[®] material. All patients had a positive outcome manifested as complete healing of the ulcerative defect.

Conclusions: Therefore, the suggested diagnostic and therapeutic algorithm combining assessment of circulatory and neuropathic disorders and optimisation of surgical and local treatment techniques improves the outcomes of multi-modality treatment of DFS.

Key words: diabetic foot syndrome, ischaemic ulcer (trophic ulcer), neuropathy, autologous skin graft, Lacerta[®] material.

In the recent decades diabetes mellitus (DM) has become a global non-infectious epidemics; its incidence doubles every 10 – 15 years [5].

The diabetic foot is a clinical and morphological syndrome driven by the development of DM-associated progressive changes in the anatomical structures of the foot, including polyneuropathy, microangiopathy, macroangiopathy and osteoarthropathy, accompanied by necrotic and septic complications [1].

The formal diagnosis of diabetic foot syndrome (DFS) is made in 4 – 10 % patients with DM; this syndrome is one of the leading causes of disability and mortality. The syndrome contributes to 30% of all diabetes-related in-patient days [3].

According to literature reports, approximately 10 – 20 % patients with DFS develop ischaemic ulcers. Also, almost 40 – 50 % of all non-traumatic lower limb amputations are performed in this patient population [2].

Whereas there is a substantial number of literature reports concerning the treatment of ischaemic DFS, the treatment of patients with isolated neuropathic and mixed forms of the syndrome are legitimate subjects of discussion. In this patient population, ischaemic ulcers are characterised by lengthy presence at typical locations, such as sole and/or heel and are virtually not healed or recur after restorative surgery.

Objective: to improve therapeutic outcomes in patients with neuropathic diabetic foot and mixed forms of diabetic foot syndrome (DFS), including the use of the Lacerta® material.

Materials and methods: A total of 53 patients with DFS age 23 to 65 years (mean age 44 years) have been treated in the clinical setting of the Department of Disaster Medicine, Military Medicine, Anaesthesiology and Critical Care of Zaporozhye State Medical University between 2010 and 2013. There were 32 (60.4 %) female and 21 male (39.6 %) patients. A total of 9 patients among the overall quantity were treated using the technique developed at our clinic.

The research included patients with neuropathic and mixed form of the condition (DFS Classification, the 1st International Symposium in Diabetic Foot, the Netherlands, 1991). The neuropathic form was represented by the neuropathic ischaemic ulcer and osteoarthropathy (the Charcot foot). The mixed or neuroischaemic form (after Wagner's classification of the depth of foot involvement in DFS) is represented by Grade 1-4 lesions.

All patients had infected forms of the diabetic foot, that is, inflammatory or destructive changes in the soft tissues of the foot (pyogenic cellulitis, ischaemic ulcers and gangrene).

The following diagnostic tests were performed in the patients: general clinical assessments, angiology assessments, neurological assessments, clinical laboratory tests, including blood glucose, glycated haemoglobin, cholesterol, triglycerides, lipoproteins, microbiological monitoring of wound contents, radiography of feet and ankle joints (in two projections), electroneuromyography, ultrasound duplex scan and Doppler scan, laser Doppler flowmetry and angiography with photographic documentation.

Results and Discussion: most patients (44 or 83%) had mixed forms of DFS. The medical management was aimed at stabilizing the ischaemic limb syndrome, namely at:

- 1) compensation of DM symptoms (diet, oral hypoglycaemics and conversion to insulin therapy);
- 2) metabolic therapy (Tivortin, Solcoseril);
- 3) angioprotecting agents (Doxium, nicotinic acid derivatives);
- 4) antiplatelet agents (pentoxifylline, alprostadil, curantil, ticlopidine, sulodexide);
- 5) anticoagulants (heparin, low molecular weight heparin, warfarin, Xarelto, pentosan);
- 6) neuroprotectors (B1 and B6 vitamins, Milgamma, α -lipoic acid derivatives);
- 7) antibacterial therapy taking into account the susceptibility of cultured microorganisms;
- 8) extracorporeal detoxification (plasmapheresis);
- 9) intra-arterial administration of vasoactive substances and antibacterial agents according to the following schedule: The following mixture was administered into common femoral artery as a bolus injection: 2 mL of papaverine, 5000 IU of heparin, 10 mL of

pentoxifylline, 1 mL of lincomycin and 2 mL of xantinol nicotinate dissolved in normal saline. The duration of the therapeutic course was 7-10 days.

The surgical management in this group of patients was mostly organ-sparing.

After a course of medical therapy 13 (24.5 %) patients with superficial ischaemic ulcers and with no signs wound infection (Wagner Grade 1) had a plastic closure of the wound defect with a split-thickness skin graft 0.25 – 0.3 mm thick; 3 patients with wound area not larger than 3 cm² had Tirsch autologous skin graft. There were no recurrent ulcers or complications in early postoperative period.

In addition to medical management and intra-arterial injections of drugs, 17 (32 %) patients with deep ulcers (lesions involving subcutaneous fat, ligaments, tendons and soft tissues without damage to the bones or Wagner Stage 2) and with wound infections at the onset of treatment had debridement of the inflammation focus, drainage, time-phased sequential necrectomies, local dressings with antiseptics and enzymes and physical therapy as assigned. Split-thickness graft technique was employed to close the defect after the granulating wound was obtained. In 3 (5.66 %) cases the early postoperative period was marked by a partial lysis of the skin graft with further repeated surgery.

Eight (15.09 %) patients with Wagner Grade 3 lesions (pyogenic cellulitis of the foot and involvement of bony tissue) had emergency necrectomies with a wide drainage of a focus of inflammation on the foot. During the 'cold period' after demarcation line on the foot had been formed, 3 patients had exarticulation of the toes, 4 patients had an atypical resection of the foot (in two of the latter patients the postoperative wound has healed by secondary intention). One patient had Sharp's foot amputation.

Alongside with medical management, surgical treatment was undertaken in 6 (11.3 %) patients with limited gangrene of the foot or toes (Wagner Grade 4).

Followed by the findings of angiography and ultrasound duplex scanning (the status of distal blood flow), 2 patients had lumbar sympathectomy, profundoplasty and peri-arterial sympathectomy with a single-step resection of the foot. Due to circulatory decompensation in the extremity, at day 16 one of these patients had a limb amputation at the level of the lower third of the thigh.

Nine (16.9 %) patients with neuropathic DFS had multiple full treatment courses at other clinics without any tangible results. Therefore a decision was made to use a new method of treatment developed at our clinic in this patient population [4].

Neuropathy had the following clinical presentation: the absence of pain, constant temperature of skin with usual colour thereof, preserved pulsation of the arteries of the foot, hyperkeratosis on the sole and the characteristic deformity of the fingers, feet and joints. Ischaemic ulcers were located at sites of extensive pressure on the sole, that is, the heel, the heads of metatarsal bones and the lateral aspect of the foot. Electroneuromyography has confirmed the diagnosis in all cases; namely, there was no electrical conductivity along the peripheral nerve endings of the shin.

The new method of treatment of ischaemic ulcers of the lower extremities of vascular aetiology is based on using the Lacerta[®] material, which improves the efficacy of treatment of patients with noncompensated forms of chronic venous insufficiency and diabetic foot.

Lacerta[®] was applied by intra-cutaneous injections of 1.0 mL of 1.5% solution around the ulcerative defect once a week for 5-7 weeks. The dimensions of the ulcerative defect were measured as they changed in course of treatment.

All patients managed using this technique, were discharged with positive outcomes, that is with complete healing of the ischaemic ulcerative defects.

This therapeutic technique may be used in an out-patient setting as well, which substantially reduces treatment time and hospital stay.

Although this technique requires a dedicated training, its further use does not require any special instruments, anaesthesiological support or an operating room.

Weekly measurements of the ulcerative defect allow evaluating therapeutic outcomes with time and provide for an option to adjust the treatment, which, likewise, requires no special instruments apart from measuring tape or tracing paper.

Therefore, the aggregate of the aforementioned positive influences allowed increasing the efficacy of treatment, accelerating patient recovery, reducing the number of complications and reducing hospital stay.

Besides, the use of this technique requires no special hardware and resources or the help of other healthcare specialities; the technique may be used in an out-patient setting to manage the long-existing ischaemic ulcers of vascular aetiology in conjunction with surgical treatment modalities.

A clinical instance. Female patient S., born 1955, case No. 17145 was admitted to the Department of Thermal Injuries and Plastic Surgery with the following diagnosis: Diabetes mellitus (Type 2). Decompensated stage. DFS (neuropathic form). Date of hospitalisation: 16.10.2012. Date discharged: 16.11.2012.

At hospital admission, the patient complained of long-existing ischaemic ulcer on the sole of the left foot, paraesthesia and burning pain in both shins.

Medical history: the patient has been ill since 1980, when insulin-dependent diabetes was first diagnosed. The patient had multiple courses of medical therapy with angioprotecting and metabolic agents, antiplatelet agents, α -lipoic acid; the patient had her 4.5 fingers on both feet amputated due to gangrene. Effective 2008 the patient's condition deteriorated when the aforementioned complaints had appeared. The patient had a course of medical treatment at an in-patient setting using a traditional therapeutic schedule; no anticipated results were obtained. The complaints have persisted. The patient has been hospitalised to undergo a course of treatment.

Local inspection findings: the skin and the temperature of both low extremities are conventional; the peripheral sensitivity is reduced, the pulse on both feet is peripheral; the feet and ankle joints are deformed, there is a trophic ulcerative defect 4 x 3 cm in diameter with callous edges and surrounding hyperkeratosis in the centre of the left sole. The defect was debrided, hyperkeratosis was excised and antiseptic dressing was applied.

Effective 17.10.2012 a course of injections with Lacerta® material was initiated. The area of the ulcerative defect was rinsed with an antiseptic solution in a surgical dressing room setting. A measuring tape was used to measure the size of the defect prior to the onset of therapy. Ready-to-use Lacerta® material was used. A single intra-cutaneous injection of 0.1-0.2 mL of the solution is performed 0.5 cm away from the edge of the ulcer using a tunnel technique. The injections are made at intervals of 0.5 cm. A sterile gauze dressing was applied to the wound defect. The procedure was repeated 2 times a week with obligatory measurement of the ulcerative defect and its photographing. The duration of the course of treatment was 4 weeks.

Full epithelisation of the ischaemic ulcer was noted after the course of treatment. It was recommended that the patient wore a protective gauze bandage and fully disengaged the foot by wearing orthopaedic shoes and using a pair of crutches for the period of two weeks.

Conclusions: Therefore, the suggested diagnostic and therapeutic algorithm combining assessment of circulatory and neuropathic disorders and optimisation of surgical and local treatment techniques improves the outcomes of multi-modality treatment of DFS.

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