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Comparison of orthopaedic reconstruction of diabetic Charcot foot Eichenholtz stages 1-2 and conservative treatment

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Abstract

The objective was to evaluate the efficacy and safety of closed transosseous osteosynthesis in the treatment of patients with diabetic Charcot neuroosteoarthropathy at the acute radiographically positive stage (Eichenholtz 1-2) with hindfoot and midfoot deformity and immobilization using Total Contact Cast. **Material and methods** Eight patients of the treatment group underwent closed deformity correction and Ilizarov external fixation. The frame was removed with radiographic signs of consolidation and conservative methods of fixation and off-loading employed. The control group consisted of 11 patients who received outpatient conservative treatment with Total Contact Cast combined with crutches. **Results** The treatment length of surgical patients prior to the use of orthopaedic shoes was shorter than that of patients treated conservatively. Foot ulcers seen in the conservative group during the observation period were not detected in the surgical cases and were associated with the lack of deformity correction. **Discussion** The advantage of operative reconstruction includes more stable foot and lower risk of ulcers. Reduced rehabilitation period improves the patient's quality of life. Complications that developed in the treatment group were resolved and had no effect on the outcome. **Conclusion** Closed deformity correction using transosseous osteosynthesis can be an option for patients with diabetic Charcot neuroosteoarthropathy at the acute radiographically positive stage as compared to the conservative treatment.

Keywords: diabetic foot syndrome, Charcot foot, arthrodesis, transosseous osteosynthesis, Ilizarov apparatus, immobilization

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INTRODUCTION

Diabetic neuroosteoarthropathy (Charcot's osteoarthropathy, DNOAP, Charcot's foot) is a relatively painless, progressive, destructive arthropathy of one or more joints accompanied by neurological deficit [1]. The pathology remains a completely unexplored problem at the intersection of specialties and requires a multidisciplinary approach. The condition is associated with pathological fractures due to decreased BMD, osteolysis and destruction of the foot joints. The risk of fractures in patients with diabetes mellitus (DM) is 30-70 % higher than in individuals having no DM [2, 3]. Although DM is the most common cause of neuroosteoarthropathy there are "non-diabetic" cases of neuroosteoarthropathy being associated with tertiary syphilis, syringomyelia, alcoholic neuropathy, inflammatory and metabolic diseases [4-6]. Aseptic inflammation combined with destructive changes in the osteoarticular apparatus is associated with the condition. The nature of the inflammation is poorly understood, but can be ascribed to impaired ratio of osteoprotegerin (suppresses the osteoclast activity) and a ligand, an activator of the nuclear factor kappa-b receptor (increases the osteoclast activity), and the associated increase in the synthesis of a number of pro-inflammatory cytokines. Activation of the interrelated cytokine cascades leads to the stimulation of osteoclasts, their prevalence at the site of the pathological process and avalanche-like osteolysis. DNOAP should be considered as an impaired integrity of the bone resulting in fractures) and as a result of inflammatory and degenerative processes that affect the timing of consolidation. This would have an impact on the treatment strategy [7, 8].

There is a sufficient evidence indicating the effectiveness of conservative treatment with complete immobilization of the limb using a custom-made Total Contact Cast (TCC) in combination with non-weight-bearing mode. This is registered in foreign agreements

and in Russian algorithms for specialized medical care for patients with diabetes mellitus and relevant clinical guidelines [9, 10]. The conservative treatment is mostly effective at the radiographic negative stage of arthropathy [11]. The effectiveness of a conservative approach to the treatment of patients with active DNOAP at the radiographic positive stage (Eichenholtz 1 and 2) is still a matter of debate. The duration of immobilization and the timing of the transition to orthopaedic shoes at these stages is significantly longer than in the radiographic negative stage. The foot remains deformed with impaired supporting abilities in this case, and the biomechanics changes dramatically leading to unstable bone and joint structures and the progression of deformities [12]. A conflict between a deformed, insusceptible foot due to polyneuropathy and shoes is likely to result in ulceration with a high risk of amputation [10]. Evaluation of the results of conservative treatment is also complicated by the lack of consensus regarding the possibility of weight-bearing on the affected limb with use of offloading devices. Low commitment to treatment, which is typical for patients with diabetic foot syndrome, leads to a decreased motivation among the attending physicians, who can allow weight-bearing being contrary to reason [13]. Studies on the conservative treatment of DNOAP patients showed a high rate of foot injuries with use of TCC (29.41 %), progression of deformities in 14 % of patients, and longer immobilization periods [14, 15]. There is a high risk of injury with TCC itself and a high risk of purulent-necrotic complications [16, 17]. Conservative treatment of severe lesions of the midfoot and the ankle joint with prolonged immobilization may result in the loss of a supporting ability of the limb due to severe deformities and extensive total defects of the foot. A more traumatic surgical intervention may be required to restore the supporting ability of the foot using different fixation options and another long-term immobilization, risks of complications, and difficulties with the manufacture of orthopaedic products for rehabilitation [18]. One of the largest studies evaluating long-term follow-up of conservative treatment of DNOAP patients reports 42.4 % of patients undergoing a surgery after reaching the inactive stage with amputation rate of 19 % over 6 years [19]. Recurrence of arthropathy was more common for baseline 3 or 4 types lesions as classified by Sanders with stability of the affected area being problematic with conservative treatment.

There is a consensus regarding indications to surgical treatment of DNOAP patients in the literature based mainly on the experience of different multidisciplinary teams. Non-plantigrade foot or a severe deformity leading to inability to support the foot or the limb, progression of the deformity due to failed conservative treatment, and recurrent ulcer at the point of maximum pressure are indications for foot reconstruction [20-23]. The approach is appropriate for DNOAP Sanders types 3 and 4 since the lesions are accompanied by severe deformities that cannot be accommodated by orthopaedic products and have a high risk of amputation [24, 25]. Early surgical correction and fixation of the deformed Charcot foot continues is being discussed [26-33]. The lack of definitive recommendations is caused by insufficient evidence due to difficulties in recruiting patients, rare pathology, and the low life expectancy of the patients with 5-year mortality of 41 % using an external fixation device (EFD) [34]. Russian guidelines for the treatment of Charcot's foot outline principle directions of treatment, giving priority to conservative methods [9]. The problem of choosing between conservative and surgical treatment of severe deformities of the middle and hindfoot in DNOAP has not been resolved.

The objective was to evaluate the efficacy and safety of transosseous osteosynthesis in the treatment of patients with Charcot neuroarthropathy in the active radiological positive stage (Eichenholtz 1-2) due to diabetes mellitus with involved hindfoot and midfoot in comparison with conservative treatment.

MATERIAL AND METHODS

The study included 19 DM cases complicated by DNOAP. Inclusion criteria included a history of DM prior to the detection of DNOAP, foot involvement Sanders types 2 to 5 [35], clinical and radiographic signs of arthropathy activity, consent to surgical or conservative treatment. Exclusion criteria included genesis of Charcot arthropathy being different from diabetes mellitus, isolated Sanders 1 lesion, refusal from treatment. The treatment group with the localization of the pathological process in the bones that make up the ankle, subtalar joints and the Chopart joint (n = 8) was treated at the Center for Foot and Diabetic Foot Surgery of the City Clinical Hospital named after S.S. Yudin, Moscow and at the Department of Purulent Surgery of City Clinical Hospital No. 13, Moscow between 2020 and 2022. Closed reduction using transosseous osteosynthesis with the Ilizarov frame (EFD) was performed for the patients. The duration of the follow-up ranged from 1 to 2 years. The control group included patients with Charcot's diabetic neuroosteoarthropathy

who underwent outpatient conservative treatment with TCC in combination with crutches at the "Diabetic Foot" room of the St. Petersburg Territorial Diabetology Center (St. Petersburg) between 2018 and 2020. Controls were selected based on medical records according to the "case-control" principle. The selection parameters included gender, age, and the nature of the lesion. The duration of follow-up in controls ranged from 2 to 4 years. The characteristics of the patients are presented in Table 1.

Condition of the foot bones in the groups was assessed according to radiological changes described in the Eichenholtz classification [36]:

stage 1 (dissolution, resorption): local demineralization, periarticular fragmentation, joint dislocation;

stage 2 (consolidation): periosteal reaction, bone fragments in soft tissues, areas of osteonecrosis, osteoproliferation, newly formed bone tissue, signs of destruction consolidation;

stage 3 (remodelling): smoothing of the edges of bone fragments, osteosclerosis, bone or fibrous ankylosis.

Clinical guidelines suggest that the activity of the arthropathic process can be assessed by clinical signs (edema, hyperemia and hyperthermia). Local non-contact thermometry (infrared non-contact thermometer Berrcom JXB-178, China) was used to calculate the temperature gradient between the area of interest on the affected and contralateral limbs to objectify hyperthermia during conservative treatment. A temperature gradient of less than 2 °C, measured with an interval of 2 weeks was considered as a clinical sign of arthropathy transition to an inactive stage in the absence of edema and hyperemia of the foot. The removal of the TCC and the use of a removable orthosis or shoes were carried out only with the use of temperature gradient [9, 37]. Magnetic resonance imaging (MRI) without contrast was used to confirm the completion of the active stage with no clinical signs of the active process, the temperature gradient being less than 2 °C and Eichenholtz stage 3 determined radiographically. The absence of bone marrow edema at the site of interest on MRI in combination with the above clinical signs served as an indication to complete immobilization and the transition to walking. Comparison of qualitative parameters was produced using the chi-square test. The Mann-Whitney test was used to compare quantitative parameters. Differences were considered significant at $p < 0.05$.

Description of medical interventions

Closed reduction using transosseous osteosynthesis was produced for patients of the treatment group. The Ilizarov frame with two rings was applied to tibia with involved ankle joint and one ring was used for deformity at the level of Sanders 2-3, with pairs of wires placed in the middle and lower thirds of tibia and three calcaneal and two metatarsal wires added [38]. The deformity was corrected using image intensifier. Compression was provided with the parafracture rings and aseptic dressings applied at the pins. Hinges were used in the early postoperative period (starting from the third day) to eliminate residual deformity performing control radiographs. Maintaining compression was performed once a month with the rate of 1 mm with parafracture rings to stimulate osteoreparation. Systemic antibiotic therapy with an average duration of 10.1 ± 1.1 days (7-21 days) for the patients using the group of protected penicillins empirically and therapy correction after receiving microbiological results. The duration of antibiotic therapy varied depending on ulcers and clinical manifestations. Ulceration (50 % of patients) was treated with curettage and povidone-iodine solution with aseptic dressings applied. The patient was examined physically and radiologically every 1.5 months during fixation with EFD. The device was taken off with positive radiological signs and clinical testing of fusion, and posterior plaster cast or a custom-made TCC was used to fix the limb. Custom-made orthopaedic shoes were manufactured in addition to a removable splint or TCC, and custom-made braces were used for bilateral involvement in one case.

Table 1

Comparative characteristics of patients receiving surgical and conservative treatment

Description		Treatment group (EFD), n = 8		Control group (TSS), n = 11	
		abs.	%	abs.	%
Type of DM	type 1	3	37,5	4	36.4
	type 2	5	62,5	7	63.6
Gender	males	7	87,5	6	54.5
	females	1	12,5	5	45.5
Age		52.6 ± 4.3 (41-63), median 50		48.5 ± 4.7 (23-68), median 50	
Duration of DM, years		23.5 ± 6.4 (5-43), median 21.5		15.8 ± 3.1 (3-35), median 13	
Number of patients with an ulcer at the beginning of treatment		4	50.0	0	0

A non-removable custom-made TCC was replaced with a new device with decreasing edema of the limb in controls [32]. Crutches were used to provide a full non-weight bearing effect. Radiographs were produced in the same manner as in the treatment group. Thermometry was performed every 1.5 months to calculate the temperature gradient. The patient could use a standard removable orthosis and walk with radiographs showing Eichenholtz stage 3 in combination with a temperature gradient of less than 2°C. The duration of orthotic use was determined by the temperature gradient and magnetic resonance imaging in fat suppression modes. Approaches to the use of orthopaedic shoes were the same as in the treatment group. The main stages of the study are shown in Figure 1. The total duration of treatment as the main parameter of the study was measured in the treatment group as the sum of the time with EFD on (primary fixation) and the foot fixation after removal of EFD before using the shoes (secondary fixation).

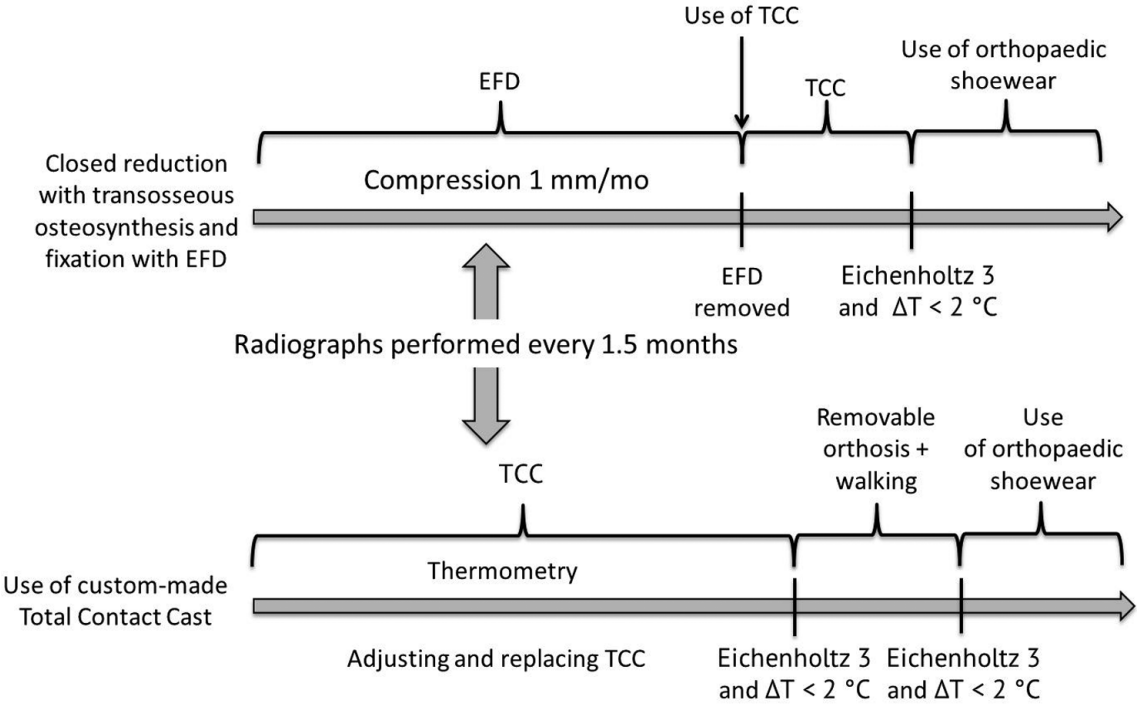

Fig. 1 Stages of examination

RESULTS

The nature of the foot lesions in the treatment and control groups is presented in Table 2. Although the nature of the destruction differed between the groups, there was a close proportion of lesions Sanders 2-3 and 3-4, the localization of lesions in the mid-foot and the nature of the deformity. The absence of deformity in a control patient could be ascribed to an early stage of DNOAP with minimal radiographic manifestations. Patients with advanced radiological manifestations (Eichenholtz 2) predominated in the conservative group and indicated a delayed diagnosis of DNOAP. and in of treatment, Five patients of the surgical group were diagnosed with radiological positive stage 1 that was detected earlier. The patients of the treatment group had severe deformities that resulted in ulceration in half (without involving the foot bones). The duration of primary and secondary fixation and the total length of treatment in both groups are presented in Table 3.

Although the total length of treatment compared prior to the use of orthopaedic shoes showed significant differences between the groups at $p < 0.05$ the critical U-value of 18.5 was slightly less than the critical U-value for the samples (critical value of 19). The differences were at the limit of reliability. The 4 ulcers in 4 patients of the treatment group healed due to local treatment and antibiotic therapy. The ulceration of one patient was not surgically treated, and the healing occurred 2 months after operative procedure due to non weight-bearing regime and daily dressings with antiseptic solutions. Complications developed in three patients of the treatment group and were associated with the treatment process; there were adverse events in four controls developed after immobilization during the observation period (Table 4).

Table 2

Comparative characteristics of groups by localization and severity of pathology

Classification	Treatment group (EFD), n = 8		Control group (TCC), n = 11	
Grading	abs.	%	abs.	%
Sanders 2	0	0	1	9.1
Sanders 2,3	5	62.5	5	45.4
Sanders 3	0	0	1	9.1
Sanders 3,4	2	25.0	3	27.3
Sanders 3,4,5	1	12.5	0	0
Sanders 4,5	0	0	1	9.1
Eichenholtz 1	5	62.7	4	36.4
Eichenholtz 2	3	37.5	7	63.6
No deformity	0	0	1	9.1
Rocker bottom foot	3	37.5	6	54.5
Valgus deformity	3	37.5	2	18.2
Varus deformity	2	25.0	0	0
Dome-shaped deformity without dislocation	0	0	2	18.2
Wagner 0	4	50.0	11	100
Wagner 1	1	12.5	0	0
Wagner 2	3	37.5	0	0

Table 3

Length of treatment in the groups

Description	Treatment group (EFD), n = 8	Control group (TCC), n = 11
Primary fixation, mo.	7 (4-8)	8 (7-14)
Secondary fixation, mo.	3 (2-8)	3 (0-10)
Total length of treatment, mo.	9 (6-15)	12 (7-14)*

*$p < 0.05$

Table 4

Characteristics of complications and ways of treatment

Group	Complication	Time	Number	Way of treatment
Treatment (EFD), n = 8	Pin tract infection	< 3 mo.	1	Wires re-inserted
	DNOAP of the ankle	8 mo.	1	TCC for 2 mo.
	Dislocated fragment of the cunei bone	6 mo.	1	Planar resection of a fragment and a primary suture
Control (TCC), n = 11	Ulceration at the site of greater deformity	> 8 mo.	4	Local treatment, immobilization

Pin tract infection was detected as moderate hyperemia and discharge at the pin sites in a patient who received renal replacement therapy using hemodialysis with infected catheter for systemic dialysis and a septic condition. Wires were re-inserted twice at the early stages (at 3 months). A patient with involved midfoot developed an acute DNOAP of the distal tibial metaepiphysis after removal of EFD and limited weight-bearing with the removable orthosis and had to stop bear weight using a shoe and the limb was fixed with a removable TCC for 2 months. The new DNOAP was diagnosed at the radiological negative stage and active arthropathy was arrested with a short period of immobilization. Subsequently, the patient returned to the use of orthopaedic shoes.

A dislocated cunei bone to under the skin resulting from excessive compression was detected radiographically and physically in another outpatient during admission for the frame removal. The migration was not detected at the fixation stage due

to the patient's residence in another region. A planar resection of the fragment was produced to prevent ulceration and skin perforation with orthopaedic shoewear. The wound healed with primary intention. No non-unions, progression of osteoarthropathy in the primarily affected area of the foot treated surgically, no relapses were seen in the treatment group at two years. Ulceration at the site of maximum deformity developed after immobilization in four control patients. Conservative local treatment was produced in combination with immobilization using a removable TCC. The defects healed with the treatment of 9 to 13 weeks prior to epithelialization. No progression of osteoarthropathy was observed in the group at 4-year follow-up period (Table 4).

With identical positive outcomes, the total length of treatment in the EFD group was shorter (median 9 months) than in the control group using TCC (12 months), with arthropathy developed in the EFD patients having been arrested conservatively.

DISCUSSION

Foot reconstruction and stabilization using EFD is aimed at preventing changes in the foot shape and ulcerations posing a threat to the limb if untimely treated. A severe deformity and unstable foot are indications for surgical treatment of DNOAP [1, 4, 5].

In our series, the control group included patients with severe deformities who sought help 5-6 years ago, when surgical treatment was unavailable for them for organizational reasons. Although tailored orthopaedic shoewear was provided for the patients, 4 out of 11 patients developed ulceration at the sites of protruding bone deformities during the observation period. This could be caused by a shape of the foot gradually changing into an inactive stage that occurred imperceptibly for a patient with reduced sensitivity and could be verified radiologically [39]. Ulceration is the most common adverse event in patients with radiological positive (Eichenholtz 2) DNOAP after conservative treatment at a long term and our outcomes were quite predictable [19, 20, 34]. Patients with Charcot arthropathy and severe deformities Sanders types 3, 4 treated with prolonged immobilization are at extremely high risk of foot ulcers [10, 18, 19]. The surgical treatment we used allowed for the foot deformity correction providing foot support and adequate shape for the manufacture of orthopaedic footwear. Ulceration could be avoided due to the procedure after removal of EFD during the observation period, which was not as long as in the control group. Conservative treatment was practical for stabilization of the deformity, which being severe, created great difficulties for orthopaedic support.

A comparison of the outcomes and observation in the treatment and control groups poses a question: is it worth treating active DNOAP conservatively with a severe deformity diagnosed at the time of the first examination of the patient, or is surgical treatment more strategically beneficial for the patient? The answer to the question is still ambiguous and is influenced by many factors associated with the severity of the deformity and with the general condition of the patient, activities of daily living, social, family and other aspects that would be essential for the prognosis [34].

In our series, we tried to compare the results of surgical and conservative treatment based on the timing from the start of treatment to the transition to orthopaedic shoewear. With the focus on the total length of treatment the treatment group (surgery-immobilization-shoes) showed less duration of limb incapability than in the conservative group (immobilization TCC-orthosis-shoes). The support ability of the limb could be restored due to surgical treatment improving the quality of life [40, 41]. Conservative treatment at the radiological positive stage of DNOAP appeared to be longer and led to a decrease in the patient's adherence to treatment and worse outcomes [16, 17, 42].

Complications are to be considered evaluating results of the treatment. Complications were recorded in 3 out of 8 patients (38 %) of the treatment group. DNOAP patients are characterized by a high risk of systemic and local postoperative complications and can reach 50 % [20, 21, 30, 34]. The treatment group showed a high complication rate, but they were not critical for the final positive outcome. Development of a new Charcot arthropathy indicated an unfavorable prognosis for the second limb, and the complication is reported to result in disability in 15 % of cases [19].

Our study had a number of limitations. Those include an insufficiently long period of observation in the treatment group to allow a long-term evaluation, adverse events associated with the operated and contralateral limb. Second, despite an attempt to select an adequate control group, we were unable to achieve matching groups in terms of the nature and severity of the deformity. Finally, there were limited number of participants, in the treatment group, in particular. The shortcomings can be ascribed to particular pathology and technical difficulties in conducting comparative studies on the treatment of Charcot's arthropathy reported by international task force of experts [10].

CONCLUSION

Closed foot deformity correction using transosseous osteosynthesis can be advocated for patients with deformity of the hindfoot and midfoot in the active stage of diabetic Charcot osteoarthropathy in comparison to conservative therapy. The advantage of the approach over conservative treatment includes the possibility of correcting severe foot deformities within a shorter treatment period. More representative prospective and multicentre studies are needed to explore the effect of the surgical approach on long-term outcomes.

Conflict of interest *The authors declare the absence of obvious and potential conflicts of interest when working on the article.*

Financing *Patients were treated within the framework of the treatment process, provided by medical organizations-bases of the study in accordance with the programs of the Territorial Compulsory Medical Insurance Funds. The preparation of the article was not funded.*

Ethical expertise *Since the study is a retrospective comparative assessment of the results of usual clinical practice, ethical review was not considered appropriate.*

Informed consent *All patients signed informed consent for the study and treatment.*

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