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Original Article

Study of the vacuum therapy influence on the wound process in patients with diabetic foot syndrome

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Abstract

An open, observational, multicenter, retrospective, randomized, controlled, comparative study of patients in the main and control groups of patients was carried out. Patients were assigned using a table of random numbers. The mixed form of the lesion was not isolated separately, and the patients of this group were divided between neuropathic (NF) and ischemic (IF) forms, respectively, with the peripheral hemodynamics rate. The participants were also divided into patients with acute and chronic wounds. In patients with NF SDS, the formation of healthy granulation tissue began at (4.61±0.96) days, and before (6.43±0.48), the wound surfaces were ready for plastic closure by one of the methods of plastic surgery (imposition of secondary sutures, autodermoplasty). In the control group, plastic wound closure was possible only from (9.42±1.46) days ($p<0.05$).In patients with IF SDS, the formation of granulation tissue began on (6.53±1.14) days ($p<0.02$), and the wounds were ready for plastic closure on (8.76±1.25) days (control group – 12.48±1.94 days) ($p<0.05$). This, in turn, allows to be prepared in a shorter time the wound for closure using one of the methods of plastic surgery or to create favorable conditions for its independent epithelialization. Vacuum therapy can be used in the local treatment of acute and chronic wounds in patients with different pathogenetic forms of DFS and a positive effect is highly expected. It allows the stabilization of the course of the wound process, improves local microcirculation, and stimulates regenerative processes in the tissue.

Keywords: vacuum therapy, wound process, diabetic foot syndrome.

Introduction

All over the world, diabetes mellitus (DM) is recognized by the medical community as one of the most important non-infectious diseases, the prevalence of which has reached the scale of a pandemic [1, 2]. According to the International Diabetes Federation (IDF), the number of patients with diabetes is now more than 415 million people on Earth, by 2030 it will increase to 439 million, and by 2035 – to 592 million [3–5].

Throughout life, 4.6–25% of patients with diabetes mellitus develop diabetic foot syndrome (DFS). According to IDF, from 25% to 47% of hospitalizations of patients with diabetes are associated with foot lesions. Treatment of this patients group consumes about 10% of the national health budgets, reaching 4.6–13.7 billion dollars in different countries [4, 6–9].

In the present stage, the treatment of patients with DFS is still not satisfactory, as in 15–25% of patients with diabetes, DFS is the direct cause of high amputations of the lower extremities.

Recently, in the local treatment of wounds, more and more importance is attached to the use of vacuum therapy, the positive effect of which has been described in a number of works. However, in patients with DFS, this method of local wound treatment has not been studied enough, especially in various forms of the disease. Therefore, the aim of this research was to study

the effectiveness of vacuum therapy in the treatment of acute and chronic wound processes in patients with complicated forms of DFS, depending on the pathogenetic form of the injury.

Material and methods

An open, observational, multicenter, retrospective, randomized, controlled, comparative study of patients in the main (during the treatment of wound defects, vacuum therapy of wounds was used) and control (vacuum therapy was not used) groups of patients was carried out. Patients were assigned using a table of random numbers.

The lesions of the lower extremities were classified according to the depth of the injury (Meggit-Wagner classification) and in accordance with the pathogenetic forms of the disease (classification of the 1st International Symposium on the Diabetic Foot, Netherlands, 1991). The mixed form of the lesion was not isolated separately, and the patients of this group were divided between neuropathic (NF) and ischemic (IF) forms, respectively, with the peripheral hemodynamics rate. The participants were also divided into patients with acute and chronic wounds.

The study included patients with complicated forms of diabetic foot syndrome with acute and chronic wound defects. Inclusion criteria: age from 24 to 78 years; diabetes mellitus type 2; the presence of diabetic foot syndrome with a foot injury of the II-IV degree according to the Meggit-Wagner classification. Exclusion criteria: lesions of the foot of 0 and V degree; critical ischemia of the lower extremities; patients who were recommended to revascularizing interventions on the lower extremities arterial vessels.

The study was carried out in a department of general surgery of the I. Horbachevsky Ternopil National Medical University (surgical department of the Ternopil City Municipal Emergency Hospital). At the time of admission, the patients underwent a complex clinical and laboratory study according to standard methods. Laboratory tests were carried out in the laboratory of the Ternopil City Municipal Emergency Hospital. The complex differentiated pathogenetic surgical treatment and conservative therapy were performed for all patients, using simple insulin administrations and unloading the affected limb until the healing of wound defects.

The research was carried out from September 2020 to November 2023. For patients with acute purulent-necrotic lesions of the feet surgical debridement with (if indicated) amputation of toes or foot segments was performed. Surgical debridement was done in patients with chronic wounds. After treatment of the pathological focus, the patients were divided into study groups.

Main group. The patients were given with continuous vacuum therapy of wounds in the negative pressure range from -80 to -120 mm Hg using the apparatus of vacuum therapy "AGAT-DNEPR" (Ukraine) and standard dressing sets V.A.C. GranuFoam Dressing (USA). Bandaging were performed every 3–5 days, depending on the degree of exudation and the dynamics of the wound process course.

Control group. The patients were made with local treatment of wounds according to the phases of the wound process, using antiseptics (dioxidine, chlorhexidine, povidone-iodine) and ointments on a hydrophilic basis (levosin, levomekol, oflokain), with daily dressings. Main research outcome. During the research, the dynamics of the wound process were assessed by the observation of change in the area of wounds, the cytological picture, the nature of the microflora, morphological changes in the wound tissues and indicators of microcirculation in the area around the wound.

Changes in the clinical picture and integral hematological indices of endogenous intoxication were also studied in dynamics. Additional research outcomes. A study of the effect of vacuum therapy on the dynamics of the clinical course of the wound process was carried out. Analysis in subgroups. In order to form groups, the following criteria were used: age, sex, type, severity, compensation and duration of diabetes mellitus, pathogenetic form of diabetic foot syndrome, type and depth of the wound process.

Outcome registration methods. The study of the dynamics of changes in the area of wounds during treatment was carried out using a planometric method according to the method of L.N. Popova. The dynamics of the granulation tissue growth and the size of the wound defect was studied by the hydrometric method [10].

Cytological examination of smears-prints from the wound was carried out using the method of M.P. Pokrovskaya, M.S. Makarov modified by M.F. Kamaeva [11, 12]. Microbiological examination of wound exudate with the identification of microorganisms and the study of their sensitivity to antibacterial drugs was carried out at the Department of Microbiology, Virology and Immunology of I. Horbachevsky Ternopil National Medical University [13–15].

Morphological examinations of wound tissues were performed at the Department of Pathological

Anatomy, which included a sectional course and forensic medicine of I. Horbachevsky Ternopil National Medical University.

Research material was obtained by incisional biopsy during surgery or dressings. The production and staining of histological preparations with hematoxylin and eosin was performed according to conventional methods, followed by optical examination. The study of microcirculation in area around the wound was performed by laser doppler flowmetry using the device "LACC-02" ("LAZMA") and data processing using a specialized computer program.

At the meeting of the local ethical committee of the I. Horbachevsky Ternopil National Medical University (Protocol No. 4 of March 26, 2014), this study was approved, and when considering the results of its effectuation, no violations of the rules of bioethics were found (Protocol No. 33 of January 11, 2016). Written informed consent was obtained from all patients included in the research for the proposed methods of examination and treatment.

Statistical data analysis methods: All the obtained numerical results were statistically processed using the S-plus 2000 and Excel software packages. Assessment of the nature of the characteristics distribution in each of the sorted groups was performed with the help of The Shapiro-Wilk and Kolmogorov-Smirnov tests. Taking into account the absence of significant differences in the indicated tests ($p>0.05$), the distribution was considered normal. Descriptive statistics are presented as M±m, where M is the mean, and m is the standard deviation. Categorical variables are presented in percentages.

The statistical reliability of indicators in patients of the main and control groups was determined by calculating the Student's t-criterion. Differences were considered significant at a significance level of $p<0.05$.

Results

The research is based on the results of a complex clinical examination and treatment of 231 patients with complicated forms of diabetic foot syndrome. According to the main clinical indicators, which are presented in Table 1, the patients of the main and control groups did not differ among themselves ($p>0.05$).

The analysis of the presented studies showed that the use of vacuum therapy in the treatment of acute and chronic wounds in patients with DFS has a positive effect at the local and systemic levels.

In patients with NF SDS, the formation of healthy granulation tissue began at (4.61±0.96) days, and before (6.43±0.48), the wound surfaces were ready for plastic closure by one of the methods of plastic surgery (imposition of secondary sutures, autodermoplasty). In the control group, plastic wound closure was possible only from (9.42±1.46) days ($p<0.05$). In patients with IF SDS, the formation of granulation tissue began on (6.53±1.14) days ($p<0.02$), and the wounds were ready for plastic closure on (8.76±1.25) days (control group – 12.48±1.94 days) ($p<0.05$).

The development of active marginal epithelialization of wounds on the background of vacuum therapy in patients with NF was noted from (4.64±1.12) days. The epithelialization rate on 3–4 days was 2.9% and on days 6–7 – 3.9% daily ($p<0.05$). In patients with IF, this indicator was as follows: the appearance of active marginal epithelization was noted on (6.15±0.47) day, and the epithelialization rate on days 3–4 was 1.8%, and from 6–7 days – 2.8% daily ($p<0.05$). The volume of wound defects also significantly decreased. In the case of NF lesions, this indicator was respectively: after surgery (18.96±0.46) cm^3, on days 4–5 – (11.14±0.24) cm^3 (by 41.24%), at 7–8 day – (5.28±0.12) cm^3 (by 72.15%) ($p<0.05$).

In patients with IF lesions, the dynamics of reduction in the volume of wounds was as follows. After surgery – (16.92±0.18) cm^3, on days 4–5 – (10.28±0.24) cm^3 (by 39.24%), on days 7–8 – (7.82±0, 68) cm^3 (by 50.63%) ($p<0.05$). At the time of admission, all patients in the control and main groups had a necrotic or degenerative-inflammatory type of cytogram. Already on the third day of treatment with the use of vacuum therapy, an inflammatory type of cytogram appeared in 36.8% of patients with NF and in 20.3% with IF SDS. On the sixth day, 50.0% with NF and 3.6% with IF showed the appearance of regenerative types of cytograms, which made it possible to perform wound plasty. On the 9th day, the percentage of regenerative types

Table 1: Development of granulation tissue and readiness of the wound for dermoplasty.

	Patients with NF SDS	Patients with IF SDS
Formation of healthy granulation tissue	4.61±0.96 days	6.53±1.14 ($p<0.02$) days
Readiness of the wound for dermoplasty	6.43±0.48 days	8.76±1.25 days

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of cytograms was 83% for NF, and 67.9% for IF (control was 53.9% and 41.6%, respectively). On the 14th day, the regenerative type of cytograms was observed in 94.5% and 78.6% of patients in the main groups (control – 69.3% and 62.7%), respectively ($p<0.05$).

Along with this, positive changes were noted on the part of microbial contamination of wounds. At the time of admission, in patients of all groups, staphylococci, micrococci, corynebacteria, streptococci, enterobacteria, pseudomonas were most often isolated, with a total average wound colonization of 7.42 lg CFU/g.

On the 3rd day of vacuum therapy, there was a decrease in the density of microorganisms, which had no statistical significance. Only the number of staphylococci decreased at a significant level ($p<0.05$). Starting from the 6th day of treatment, the total density of microorganisms in the patients of the main groups was (3.69±0.45) lg CFU/g, which was significantly lower than in the control groups (5.88±0.66) lg CFU/r ($p<0.05$). A significant decrease in the species composition of microflora in wounds was also noted.

The use of continuous vacuum therapy in the treatment of wound defects made it possible to significantly improve the indices of local microcirculation. Already on the 3rd day, in patients with NF lesions, the main indicators increased, on average, two times in comparison with the control values ($p<0.001$). In patients with IF lesions, with chronic arterial insufficiency of I-III degrees, the increase in these indicators was also statistically significant and depended on the severity of the latter ($p<0.01–0.001$). Even before the 6th day of treatment, the microcirculation indices in this group of patients were significantly higher than the critical indices ($p<0.05$), which made it possible to resolve the issue of plastic wound closure.

During the morphological study of tissues taken from the sites of wound defects, it was found that already on the 5th day of using vacuum therapy, there were positive changes in the tissues, which indicated the transition of the wound process from the phase of inflammation to the phase of regeneration. On the 10th day of treatment, an array of granulation tissue with a high density of thin-walled vessels and predominant infiltration with leukocytes and lymphocytes was formed. In general, the morphological picture of the granulation tissue at this stage corresponded to the changes that were observed in the patients of the comparison groups only on the 15th day of treatment.

Additional research findings. In patients with NF SDS, soft tissue edema was reliably stopped on average by (2.46±0.84) day ($p<0.01$), tissue hyperemia by (2.16±0.48) day ($p<0.01$), tissue infiltration around the wounds on (3.25±0.82) day ($p<0.01$). In patients with IF SDS, soft tissue edema reliably stopped on (2.52±0.42) day ($p<0.01$), tissue hyperemia on (3.12±0.64) day ($p<0.01$), infiltration of tissues around the wounds on (3.96±0.84) day ($p<0.05$). In the same period of time, the phenomena of lymphangitis and lymphadenitis disappeared in all patients. Patients noted an improvement in their general condition, a decrease in pain syndrome, a normalization of body temperature, an improvement in sleep and appetite, while in the control group these indicators stabilized only on the 5–6th day of treatment ($p<0.001$).

In 19 patients with ischemic lesions (chronic arterial insufficiency of the III degree), the use of vacuum therapy according to the standard technique led to an increase in the pain syndrome. This made it necessary to establish an initial negative pressure in the system of 70–80 mm Hg, which, together with the intake of analgesics, made it possible to relieve pain within 24 hours. On days 2–3 of the postoperative period, negative pressure was set at standard values, without the subsequent development of side effects.

Discussion

Summary of the main research results. The research made it possible to establish an expressed positive effect of vacuum therapy on the course of acute and chronic wound processes in patients with SDS, which was manifested by the stimulation of regeneration processes, a decrease of the area and depth of wounds, a decrease in microbial contamination and an increase of local microcirculation in patients with both neuropathic and ischemic SDS forms.

Discussion of the main research result. All patients who were included in the study were comparable in area and depth of the lesion. According to the indications, the patients underwent surgical treatment, which made it possible to carry out the maximum possible surgical treatment of the purulent-necrotic process for acute wounds, and to carry out surgical stimulation of reparative processes in chronic wounds. Subsequent application of vacuum therapy in local wound treatment made allowed to distinctly activate regenerative processes, which did not have impressive differences in acute and chronic wounds ($p<0.5$).

Vacuum therapy of wounds has a definitely stimulating effect on the regenerative processes in wounds. On average, 3–5 days earlier, the cytological picture of smears-prints stabilizes with the prevalence of regenerative

types of cytograms, the processes of healthy granulation tissue formation and marginal epithelialization are forced, and area of wound defects is reduced.

A significant microbial decontamination of wounds was also noted, as well as a decrease of the level of microbial contamination below the critical mark and the disappearance of streptococci, micrococci and aerobic bacilli. The indicators of microcirculation in the wound are improved, that almost doubled compared to the initial indicators. Moreover, in patients with NF lesions, these changes occur earlier and become more expressed than in patients with IF SDS. This can be explained by the better blood supply to the tissues, on which the regeneration processes depend.

Similar data were obtained in the works of other researchers, who note the positive effect of vacuum therapy on the course of the wound process [7–9]. The positive effect of vacuum therapy of wounds on the wound process makes it possible to prepare the wound for closure in a shorter time by one of the methods of plastic surgery (on average by 3.5±1.4 days), or to create favorable conditions for its independent epithelialization.

This combination of peculiarities reduces the average duration of inpatient treatment of patients with acute wounds by (4.3±1.7) bed-days with NF lesions and by (4.8±2.4) bed-days with IF SDS. In chronic wounds, the terms of inpatient treatment are reduced in patients with NF lesions by (4.6±0.3) bed-days, with IF – by (3.4±1.4) bed-days, which has not only medical but also social significance.

Research limitations. Taking to attention the average sample size of patients and the short follow-up period, it is necessary to continue research in order to develop optimal differentiated schemes and parameters of vacuum therapy in the treatment of wound defects in patients with DFS, depending on the pathogenetic shape, area and depth of the lesion.

Conclusions

The results of this studies allow us to conclude that vacuum therapy can be used in the local treatment of acute and chronic wounds in patients with different pathogenetic forms of DFS and a positive effect is highly expected. It allow to stabilize the course of the wound process, improve local microcirculation, and stimulate regenerative processes in the tissue. This, in turn, allows to prepare in a shorter time the wound for closure using one of the methods of plastic surgery or to create favorable conditions for its independent epithelialization.

The results of this studies allow us to conclude that vacuum therapy can be used in the local treatment of acute and chronic wounds in patients with different pathogenetic forms of DFS and a positive effect is highly expected. It allow to stabilize the course of the wound process, improve local microcirculation, and stimulate regenerative processes in the tissue. This, in turn, allows to prepare in a shorter time the wound for closure using one of the methods of plastic surgery or to create favorable conditions for its independent epithelialization.

Conflict of interests

The authors declare no conflict of interest.

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