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Long-term negative pressure wound therapy decreases a risk of diabetic foot amputation assessed in the university of Texas wound classification

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ABSTRACT

Background: The University of Texas Wound Classification is a tool assesing risk of amputation of patients with Diabetic Foot Ulceration (DFU). Negative Pressure Wound Therapy (NPWT) is a nonivasive system which was shown to be effective in healing chronic wounds. The aim of the study was to assess utility of long-term NPWT in healing diabetic foot wounds among Polish patients with diabetes.

Material & Methods: In the study, we retrospectively analysed data of patients of DFU ambulatory using NPWT. Collected data included sex, age, type of DFU, duration of NPWT, history of previous minor amputation and characteristic of the healed wound in The University of Texas Wound Classification before and after NPWT.

Results: Total number of participants counted 21 (male = 16, 76%). The wound significantly improved in 17 (81%) patients. Group with successful treatment reached median 92% decrease of risk of amputation (-8.5 to -92%; $p < 0.001$). Group with successful treatment differed from group with unsuccessful treatment in count of angiopathic DFU (Chi2, 4[24%] vs. 3[75%]; $p = 0.049$). No significant differences in age, sex, history of previous minor amputation, presence of infection, depth of the ulcer were found. No NPWT adverse effect were reported. Logistic regression model revealed significant relationship between unsuccessful outcome of NPWT and presence of ischemic ulcer adjusted to presence of infection, depth of a wound and sex (OR = 27.5; CI: 1.1–716.7; $p = 0.046$).

Conclusions: NPWT significantly decraeses risk of amputation in Texas Score. NPWT may not help in healing wounds simultaneously infected and ischeamic. Presence of ischemic wound decreases chance for successful outcome.

1. Introduction

1.1. Diabetic foot ulceration

Diabetes is a metabolic disorder of multiple etiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both [1]. Chronic hyperglycaemia, fluctuations of glucose serum levels lead to long-term tissue damage and developement of diabetic complications. One of the complications of diabetes is Diabetic Foot Ulceration (DFU). DFU has may arise as result of lower limb macroangiopathy leading to foot's ischemia, decreasing of skin blood supply resulting in foot ulceration. Another etiology of DFU is peripheral neuropathy leading to sensation disturbances which predispose to feet's injuries leading to feet's wounds. Diabetic ulcers are one the most important cause of nontraumatic lower limb amputations in developed countries [2]. The 5-year mortality rate after diabetic-caused amputation counts between 39 to 68% and is comparable to mortality rate of patients with malignancy [3].

1.2. The University of Texas wound classification

The University of Texas Wound Classification is a tool for assessing clinical condition of diabetic ulcers by their depth and comorbidities4. Authors of the tool shown that on the basis of the classification 6-month risk of amputation can be assessed (Supplementary 1.) [4].

1.3. Negative pressure wound therapy

Negative Pressure Wound Therapy (NPWT) is a nonivasive system that creates a localized controlled subatmospheric (negative) pressure environment [5,6]. NPWT allows drainage of exudation reducing of

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oedema, stimulate formation of granulation tissue and promotes angiogenesis. NPWT appears to be useful in healing of diabetic-associated foot wounds [7]. However, there are no reports of long-term NPWT in healing diabetic ulcers in Polish population.

The aim of the study was to assess utility of long-term NPWT in healing diabetic foot wounds among Polish patients with diabetes.

2. Material & methods

2.1. Study design

The study group consisted of patients of ambulatory for patients with DFU. Individuals were treated in 2015-2016.

All patients who met the following criteria: DFU, age 18 between 80 years old, unsuccesful previous DFU treatment were included to the study. Exclusion criteria were: history of complete foot amputation, non-revascularized ischaemic foot, untreated osteomyelitis, exposed blood vessels, dementia, psychiatric disorders, unstable rheumatological disorders, alcoholism, diagnosed malignancy.

2.2. Treatment

Patients at initial visit were counsulled about feet hygiene, proper wound offloading, cessation of tobacco products and close cooperation with diabetologist. Each wound were characterized according to University of Texas Wound Classification[4]. Wounds were surgically cleaned and NPWT were initialized. Bacterial cultures were taken and oral antibiotic were administered in patients with symptoms of wound infection (amoxicilin + clavulanic acid 2 x 1 g /daily). After obtaining bacterial cultures results, patients were treated accordingly to antibiogram. Antibacterial therapy last until no infection symptoms in wound were observed.

To perform NPWT the Vacuum Assisted Closure Therapy System (Smith and Nephew Renasys GO, San Antonio, TX, USA) were used. Control of the wound and exchange of the foam dressing were performed every four days. Pressure suction was set on 100–120 mmHg. NPWT were continoued until infection were cured and satysfying depth of ulcer allowing standard moisture wound therapy were reached. If there were no wound healing progress and patient developed septicemia, antibiotic-resistant wound infection or next lower limb arterial revascularization were need, NPWT were ended.

2.3. Statistical analysis

A statistical analysis was performed with STATISTICA 12.0 (StatSoft, USA). Normality of a distribution of the variables distributions was tested using Shapiro-Wilk test. Wilcoxon test was used to compare differences in risk of amputation before and after NPWT. Mann-Whitney U test and Chi^2 were used to compare group with successful and unsuccessful treatment outome. Differences with p-value < 0.05 were considered statistically significant.

3. Results

There were 21 participants (male = 16, 76%) included to the study. Nineteen patients were afflicted with diabetes type 2, one type 1 and one type 3. General characteristics of the group is contained in Table 1.

The wound significantly improved in 17 patients, 4 patients (initial Texas score: two 3D, 1 one 3B, one 2C) had no improvement to the endof treatment. Three of them had to undergo foot amputation (two developed septicemia, one drug resistant infection) and one patient with initial 2C score had to undergo following revascularization. The duration of NPWT in unsuccessful group lasted between 12–34 days. Effects of therapy are presented in Supplementary 2. Group with successful treatment median reached 92% decrease of risk of amputation counts (-8.5 to -92%; $p < 0.001$). Group with successful treatment differed from group with unsuccessful treatment in count of angiopathic DFU (Chi^2, 4[24%] vs. 3[75%]; $p = 0.049$). No significant differences in age, sex, history of previous minor amputation, presence of infection, depth of the ulcer were found. No NPWT adverse effect were reported.

Table 1
General characteristics of the study group.

Feature [unit]	median(IQR) / n(%)
Age [years]	60 (52–64)
Angiopathic DFU	7 (33)
Neuropathic DFU	14 (67)
Infected Wound at the Beginning of Therapy	16 (76)
History of previous minor amputation	5 (24)
Risk of amputation at the beginning of NPWT [%]	92 (92–100)
Risk of amputation at the end of NPWT [%]	0 (0–20)
Duration of NPWT [days]	39 (20–61)

DFU – Diabetic Foot Ulcers, NPWT – Negative Pressure Wound Therapy.

In multivariate regression model revealed a significant relationship between unsuccessful end of NPWT and presence of ischemic ulcer adjusted to presence of infection, depth of a wound and sex (male count as 1, female 0) (Table 2).

4. Discussion

Presented results confirm utility of NPWT in healing DFU in ambulatory treatment. Most of the patients significantly improved healing the wound and decreased risk of amputation. However, patient with ischaemic DFU was at increased risk of unsuccessful treatment. Five patients with ischaemic DFU improved wound healing but three of them remained ischaemic character of the ulcer (Figure 2.). Possible rationales for differences in healing ischaemic wounds may include features and quality of revascularisation procedure preceeding NPWT, lipid profile, diabetic control, concomitant diseases and smoking history and taking drugs. These data were unavailable. Current evidence are strongest for using NPWT in non-ischaemic DFU, 2 or 3 in Texas Grade [8]. NWPT may be considered as an ischaemic wound therapy only after revascularisation [8], because in not well-revascularised wounds. NWPT may cause necrosis at the wound edge with foam dressing and delay healing of a wound [9]. Currently, there is no randomized clinical trial comparing NPWT vs. conventional therapy in healing ischaemic-DFU.

This study has several limitations. Firstly, it is a retrospective study, we have not created a control group with randomized assign. Secondly, since long-term NPWT is relatively high cost treatment, number of individuals included into the study was limited. Thus this results should be interpreted with caution. Finally, data such as laboratory results, ankle-brachial index were not collected.

In conclusions, NPWT significantly decraeses risk of amputation in Texas Score. NPWT may not help healing wounds simultaneously infected and ischeamic. Presence of ischemic wound decreases chance for successful outcome. First month of NPWT treatment seems to be critical for wound healing.

Table 2
Multiple Regression Model. Dependent Variable: Unsuccessful End of Negative Pressure Wound Therapy.

	OR	CI -95%	CI + 95%	p
Ischemia	**27.5**	**1.1**	**716.7**	**0.046**
Infection	8.4	0.3	242.1	0.21
Wound penetrates to bone / joint	1.9	0.1	38.1	0.67
Sex	0.8	0.03	17.7	0.86

CI – Confidence Index, OR – Odds Ratio.

Ethical statement

"Long-term Negative Pressure Wound Therapy Decreases Diabetic Foot's Risk of Amputation Assessed in the University of Texas Wound Classification" is a retrospective study and no ethical review board agreement was required. All procedures were performed using medical equipment approved for humans in European Union.

Financial disclosure

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Disclosure

All authors approved a submitted version of the article.
None of the authors declared any potential conflict of interests.

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Declarations of interest

None.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.wndm.2019.02.004.

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