

**H.H. Kasrashvili, I.V. Ksyonz<sup>1</sup>, P.F. Hiulmamedov R.P. Klimanskyi, P.O. Andreev**  
**Donetsk National Medical University, Lyman**  
<sup>1</sup>**Ukrainian Medical Stomatological Academy, Poltava**

## RETROSPECTIVE ANALYSIS OF TREATMENT EFFICACY IN PATIENTS WITH CHRONIC WOUNDS

e-mail: Giga03@i.ua

It is estimated that in developed countries from 1 to 2 % of the population will suffer from chronic wounds throughout their life. The study included the retrospective analysis data on the case histories of 75 patients (40 (53 %) women and 35 (47 %) men who were divided into 8 groups depending on the etiological factor. The other determining factor was the use of local negative pressure in their treatment. In all groups active surgical intervention was used, the preparation of the wound for surgical intervention with the help of negative pressure was faster. As a result, the time of the patient's staying at the in-patient department reduced and the percentage of autotransplants survival increased. Results of the analysis showed that the use of local vacuum therapy caused statistically significant difference in the mean time of treatment between some groups of patients compared to other groups. The number of eliminated chronic wounds is also statistically significant.

**Key words:** chronic wounds, retrospective analysis, etiological factor, local negative pressure.

## Г.Г. Касрашвілі, І.В. Ксьонз, П.Ф. Гюльмамедов, Р.П. Кліманський, П.О. Андрєєв

### РЕТРОСПЕКТИВНИЙ АНАЛІЗ ЕФЕКТИВНОСТІ ЛІКУВАННЯ ПАЦІЄНТІВ З ХРОНІЧНИМИ РАНАМИ

За оцінками, в розвинених країнах від 1 до 2 % населення буде страждати від хронічних ран протягом життя. У дослідження увійшли дані ретроспективного аналізу історій хвороб 75 пацієнтів (40(53 %) жінок, 35(47 %) чоловіків), які були розділені на 8 груп в залежності від етіологічного фактора. Іншим визначальним фактором стало застосування в їх лікуванні локального негативного тиску. У всіх групах застосовували активну хірургічну тактику. Підготовка рани до оперативного втручання за допомогою негативного тиску відбувалося швидше, в результаті зменшувався час перебування пацієнта в стаціонарі, також поліпшувався відсоток приживлюваності ауто трансплантатів. Проведений аналіз показав що застосування локальної вакуумної терапії має статистично значущу, різницю між середнім часом лікування одних груп пацієнтів в порівнянні з іншими групами. Статистично значущим є і кількість ліквідованих хронічних ран.

**Ключові слова:** хронічні рани, ретроспективний аналіз, етіологічний фактор, локальний негативний тиск.

*The study is a fragment of the research project "Diagnosis and combined treatment of inflammatory-destructive and oncological diseases of organs and systems to substantiate the use of cell and tissue technology schemes", state registration No. 0116U008235.*

There is still no single definition for the term "chronic wound". It can be defined as one that has not undergone an orderly and timely reparative process to achieve anatomical and functional integrity within 3 months, or that has undergone a reparation process without establishing a stable anatomical and functional result.

These wounds are sometimes referred to as incurable wounds / ulcers, and the time required to form a chronic wound has been determined within the range of 4 weeks up to more than 3 months [8].

According to the definition approved at the special meeting of the European Tissue Repair Society (Cardiff, Wales, 1996), a wound is called chronic if it does not heal within a period that is normal for wounds of this type or localization [5].

Chronic wounds, frequently disguised as comorbid conditions, are a quiet epidemic that affects a large part of the world's population. In developed countries, as it is estimated, 1 to 2 % of the population will suffer from chronic wounds during their lifetime. And a sharp growth of the ageing population will increase these numbers as the ability of wounds to heal worsens with age. Chronic wounds have a negative impact on the health and quality of life in patients: causing pain, loss of function and mobility, depression, distress, and anxiety. Available data indicate that this pathology imposes a significant financial burden on the individual, the health care system and the society as a whole [7, 9, 10].

In addition, the urgency of this problem is due to the atypical course of the wound process: at the cellular and subcellular levels, long non-healing wound is characterized by the presence of chronic inflammation and simultaneous signs of all the wound process phases [2, 3, 6, 11].

Currently, various remedies are used for the treatment of chronic wounds, however, none of them provides a guaranteed clinical effect, and the proposed surgical closures for peptic ulcer defects have their limitations and disadvantages. They are often a complication of diseases, such as diabetes mellitus [1],

connective tissue diseases, vascular failure or neurological disorders, which causes not only personal but also social problems, threatens the extremities and life of the patient. One of the new promising methods for treating wounds of different etiology is the vacuum exposure method [4].

**The purpose** of the study was to carry out retrospective comparative analysis of chronic wounds treatment with the use of local negative pressure (vacuum therapy).

**Materials and methods.** The study included data from a retrospective analysis of medical histories for the period of 2015–2018. We summarized the results of 75 patients treatment who were hospitalized in the burn department of Kramatorsk. Patients were divided into 8 groups, depending on the etiological factor that eventually caused the formation of chronic wounds (table 2); Another determining factor was the use of local negative pressure in their treatment.

The mean age of patients in groups 1–2, joined by one etiological factor, was  $58.4 \pm 12.4$  years; among these, the mean age of men was  $51.4 \pm 8.1$  years and that of women was  $62.2 \pm 12.9$  years. Of the total number of patients in groups 1–2, women were 70 % and men 30 %, respectively. In group 1 comprising 10 patients, 9 had residual wounds (which amounted 90 %) as a result of surgical treatment, while in 1 (10 %) patient the wound healed completely. The mean number of bed–days was  $61.2 \pm 27.1$ . In group 2, with the use of vacuum therapy in 10 patients, the wound was managed in 7 (70 %) patients. Three patients with residual wounds amounted 30 %. The mean number of bed–days was  $23.0 \pm 10.0$ .

The mean age of patients in groups 3–4 was  $67.2 \pm 12.9$  years (men –  $63.8 \pm 14.4$  years (60 %) and women –  $72.3 \pm 9.3$  years (40 %)). In group 3, without the use of local negative pressure, out of 10 patients, only 3 (30 %) completely healed after surgery, and 7 (70 %) had residual wounds. The mean number of bed–days was  $37.2 \pm 12.3$ . In group 4, where local vacuum therapy was used, the mean value of bed–days was  $17.2 \pm 6.5$ . Out of 5 (100 %) patients, the wounds healed in all.

In groups 5–6 the mean age of the patients was  $60.0 \pm 22.3$  years: (men –  $69.0 \pm 17.6$  years (45 %) and women –  $61.4 \pm 21.6$  years (55 %)). In group 5 without vacuum therapy, among 10 patients in 2 of them (20 %) wounds healed, and in 8 patients (80 %) were residual wounds left. In group 6 using local vacuum therapy, in 9 patients out of 10 (90 %) after surgical treatment the wound healed, in 1 patient (10 %) residual wounds were determined. The mean number of bed–days in group 5 was  $44.6 \pm 11.0$ ; in group 6 –  $26.7 \pm 9.7$ .

In groups 7–8, the mean age of patients was  $53.3 \pm 16.2$  years (men –  $48.9 \pm 17.67$  years (55 %), women –  $58.6 \pm 13.3$  years (45 %)). In group 7, without vacuum therapy, among 10 patients in 3 (30 %) wounds healed, while 7 (70 %) had residual wounds. In group 8 of 10 patients, in 2 (20 %) were identified residual wounds after surgery, in 8 (80 %) patients wounds were eliminated. The average value of the number of bed–days group –  $85.1 \pm 19.0$ ; group 8 –  $20.7 \pm 10.5$ .

The following statistical criteria were used: to analyze the distribution for normality–critical assessment of excess and asymmetry, graphical method, namely normal–probability graph, and statistical criteria by Kolmogorov–Smirnov and Shapiro–Wilk test, the significance level  $\alpha = 0.05$ .

Non–parametric criteria, namely the Kolmogorov–Smirnov two–sample test and the Mann–Whitney U–test, were used to compare the mean values in different groups. The data obtained were assessed at the significance level  $\alpha = 0.05$ , and were considered significant if the probability of explaining the difference between the obtained values by different measurements and randomness did not exceed the significance level, i.e.  $p < 0.05$ . The  $\chi^2$ –squared criteria were used to compare the two groups of qualitative variables. The data obtained were assessed at a significance level of  $\alpha = 0.05$ , and were considered significant if the probability of explaining the difference in values obtained by different measurements and randomness did not exceed the significance level, i.e.  $p < 0.05$ .

Statistical analysis of the results obtained was evaluated using the StatSoft © Statistica version 12® computer software.

Table 1

**Distribution of patients depending on the duration of the wounds**

Duration of wounds	Number of patients n= 75	
	Abs.	%
5 –12 weeks	27	36
3 –6 months	24	32
6 –12 months	8	11
1 –3 years	8	11
3 –5 years	2	2
More than 5 years	6	8
Total	75	100

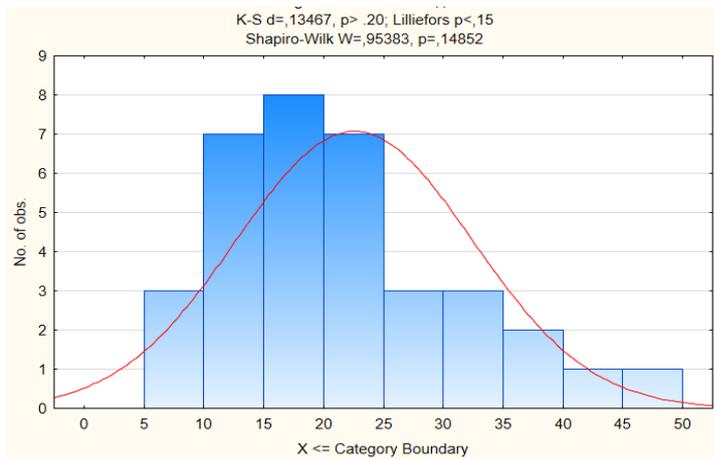


Fig. 1. Patients who were treated with local negative pressure.

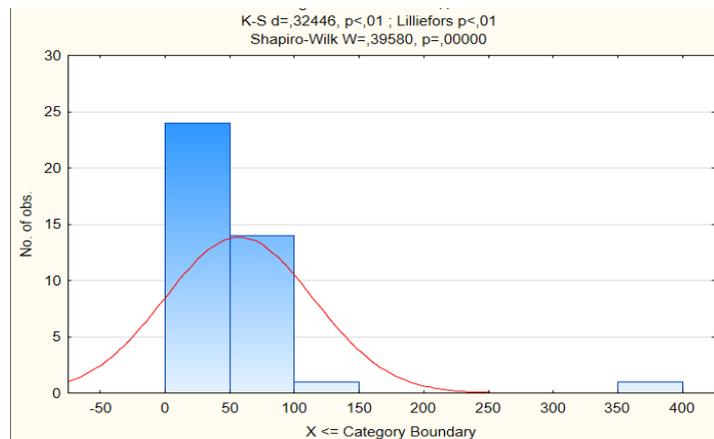


Fig. 2. Patients who were not treated with local negative pressure.

The histogram shows that the distribution center is shifted to the left. According to the Kolmogorov–Smirnov test, the probability of a normal distribution is higher than 0.2 ( $p > 0.20$ ), so the hypothesis of the distribution normality cannot be rejected. The probability of the normal distribution by the Shapiro–Wilk test is greater than 0.05 ( $p = 0.14852$ ). Thus, the hypothesis of the distribution normality cannot be rejected.

The histogram shows that the normal distribution center is shifted to the left. In general, the distribution does not differ from normal. However, according to the Kolmogorov–Smirnov test, the probability of a normal distribution is below 0.2 ( $p < 0.01$ ), thus the hypothesis of the distribution normality can be rejected. The probability of the normal distribution by the Shapiro–Wilk test slightly equals 0 ( $p = 0.00000$ ). Thus, the hypothesis of normality of distribution can be rejected.

In general, it can be said that, according to the tests results, the factor influences the response, i.e. the use of VAC therapy in the treatment of patients has an impact on the treatment time, and the difference between the mean treatment time of one group of patients and that of the other is statistically significant.

**Results of the study and their discussion.** Results of the wounds analysis, depending on their term of existence, which are presented in table 2, indicate that those who sought medical treatment most frequently were patients with the chronic wounds term of 5 – 12 weeks (36 %), as well as those with the term of 3–6 months (32 %). Meanwhile, the total number of patients, who had chronic wounds for more than 1 year, amounted to 32 %. This indicates a low number of patients seeking professional help. This may be due to the low level of patient awareness of new and modern treatment methods for chronic wounds. The age of patients, who sometimes find it difficult to adhere to mandatory doctor's recommendations, also play a significant role. An even more urgent problem is the lack of finances in patients, which is also due to the high cost of dressings.

In all groups active surgical tactics were used: after preparation of the wound for autodermoplasty with the help of local negative pressure (groups: 2, 4, 6, 8) and without it (groups: 1, 3, 5, 7), surgical treatment was carried out (fig. 1, 2).

Table 2

**Distribution of patients by nosological forms depending on the etiological factor**

Nosological form	Number of patients n= 75			
	With VAC therapy		Without VAC therapy	
	abs.	%	abs.	%
Chronic wounds against the background of venous outflow disturbance	10	29	10	25
Chronic wounds against the background of impaired arterial permeability (macroangiopathy)	5	13	10	25
Chronic wounds against microcirculatory disorders (microangiopathy)	10	29	10	25
Long non-healing wounds (post-traumatic, post-operative)	10	29	10	25
Total	35	100	40	100

Wound preparation for surgery with negative pressure was faster, resulting in a shorter stay in the hospital (fig. 3).

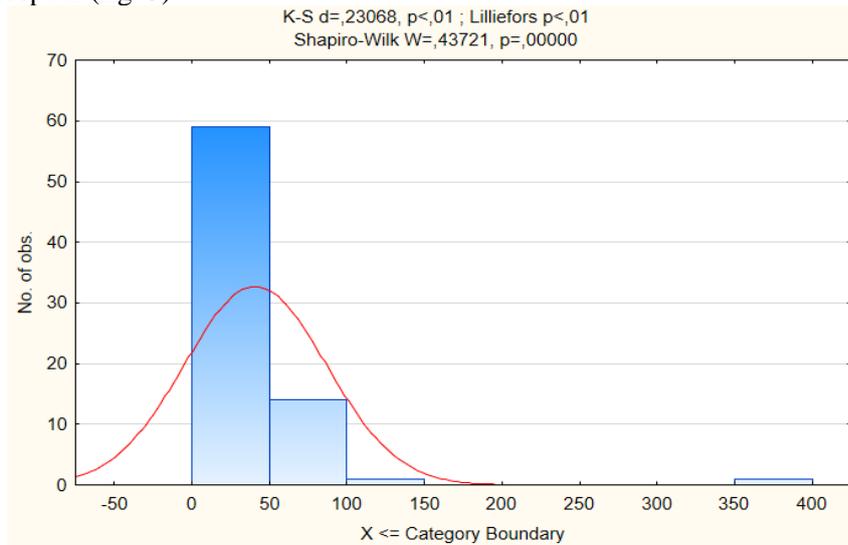


Fig. 3. Time of stay in hospital for the patient who was treated with local negative pressure.

The histogram shows that the center of normal distribution is slightly shifted to the left. In general, the distribution does not differ from normal. According to the Kolmogorov–Smirnov test, the probability of a normal distribution is below 0.2 ( $p < 0.01$ ), thus the hypothesis of the distribution normality can be rejected. The probability of a normal distribution by the Shapiro–Wilk test is 0 ( $p = 0.00000$ ). Thus, the hypothesis of the distribution normality can be rejected.

The autograft transplantability rate was also analyzed depending on the pathogen cultivated from the wound secretions (table 3). As a result, it was found that the best transplantability and the least number of autodermoplasty was required when cultivating *Staphylococcus saprophyticus*, and the reverse results were obtained when *Staphylococcus haemolyticus* and *Escherichia coli* were cultured. Patients receiving local vacuum therapy also improved the transplantability rate of autografts, which reduced the number of autodermoplasty performed and had a positive effect on the treatment outcome.

Table 3

**Microbiological characteristics of wounds**

Pathogen	Number of patients n= 75	
	Abs.	%
Microbial growth was not detected	5	7
<i>Staphylococcus aureus</i>	7	9
<i>Staphylococcus haemolyticus</i>	5	7
<i>Staphylococcus epidermidis</i>	24	32
<i>Staphylococcus saprophyticus</i>	11	15
<i>Streptococcus haemolyticus</i>	1	1,5
<i>Escherichia coli</i>	4	5
<i>Klebsiella pneumoniae</i>	3	4
<i>Proteus mirabilis</i>	1	1,5
<i>Acinobacter baumannii</i>	3	4
<i>Pseudomonas aeruginosa</i>	7	9
<i>Providencia rettgeri</i>	4	5
Total	75	100

Thus, there is a worldwide tendency to increase the number of chronic wounds. Difficulties and features of the wound process course in chronic wounds necessitate the search for new treatments and improvement of the existing ones. One of the best methods to date is the application of negative local pressure. It is believed that vacuum therapy accelerates the course of wound process. The advisability of using this method of treatment is based on its various effects which include: maintenance of moisture balance in the wound bed; active removal of excessive discharge from a wound; elimination of local interstitial edema; activation of neoangiogenesis. Also the use of vacuum therapy has the following properties: acceleration of wound tissue debridement; activation of proliferation and deformation of the wound area; increase of local blood circulation and tissue oxygenation; prevention of hospital infections associated with a wound; decrease in the volume and area of a wound; reducing the time and cost of treating patients; enhancing the effects of systemic drug

therapy [3, 5]. The use of this method improves the course of the wound process, which has a general positive effect on the final treatment result. The results obtained confirm the above and are consistent with the data of studies performed both in Ukraine and abroad. VAC therapy is also an effective and safe modern method of treatment when it's used correctly, however, larger clinical trials are needed to obtain more accurate data on the effectiveness of its application. In addition, we have also found that many existing methods of treating chronic wounds as well as negative pressure wound therapy can be used in combination with other methods and it improves their effectiveness [1, 4, 9, 10]. As wound characteristics change such multimodal therapies can be applied simultaneously or sequentially to provide optimal therapy for any chronic wound.

### Conclusions

1. The results of the treatment analysis in patients with chronic wounds showed that the use of local vacuum therapy in the treatment of patients with chronic wounds has a significant effect on the statistically significant difference between the mean treatment time of one group of patients (22.6+/-9.9 bed days) compared to other groups (57.0 +/-7.6 bed days).

2. The number of chronic wounds eliminated is statistically significant in the groups where local negative pressure was applied (eliminated wounds –29 (39 %), residual wounds – 6 (8 %)) than in the compared groups (eliminated wounds –9 (12 %), residual wounds – 31 (41 %)).

This proves that the use of vacuum therapy significantly effects the final result of chronic wound healing.

### References

1. Herasymchuk PO, Deykalo IM, Vlasenko VH, Fira DB, Pavlyshyn AV. Vykorystannya vakuuum-terapiyi v likuvanni ran u khvorykh na syndrom diabetichnoyi stopy. *MÉZH*. 2016; 2(74):124-9. [in Ukrainian]
2. Gain YuM, Gerasimenko MA, Shahraj SV, Hryshchanovich VYa, Gain MYu, Bordakov PV. Innovatsionnye printsipy kompleksnogo lecheniya khronicheskikh ran. *Innovatsionnye tekhnologii v meditsine*. 2017; 5(4):223-42. [in Russian]
3. Glukhov AA, Aralova MV. Patofiziologiya dlitelno nezazhivayushchikh ran i sovremennyye metody stimulyatsii ranevogo protsessa. *Novosti khirurgii*. 2015; 23(60):573-9. [in Russian]
4. Nor NM, Slesarenko SV, Trofimov MV, Slesarenko KS, Korpusenko OI. Zastosuvannya vakuuum-terapiyi u kompleksni likuvannya khronichnykh ran nyzhnikh kintsivok. *Klinichna khirurgiya*. 2017; 3: 39-41. [in Ukrainian]
5. Obolenskiy VN. Sovremennyye metody lecheniya khronicheskikh ran. *Meditsinskiy sovet*. 2016; 10:148-154. [in Russian]
6. Slavnikov IA, Dundarov ZA, Yarec YuI. Otsenka effektivnosti sposobov podgotovki k plasticheskomu zakrytiyu khronicheskikh ran u patsientov s sakharnym diabetom. *Zhurnal Grodnenskogo gosudarstvennogo meditsinskogo universiteta*. 2018; (6):735-9. DOI: 10.25298/2221-8785-2018-16-6-735-739 [in Russian]
7. Cwaliński J, Paszkowski J, Banasiewicz T. New perspectives in the treatment of hard-to-heal wound. *Negative Pressure Wound Therapy Journal*. 2018; 5(4):10-2.
8. Demidova-Rice TN, Hamblin MR, Herman IM. Acute and impaired wound healing: pathophysiology and current methods for drug delivery, part 1: normal and chronic wounds: biology, causes, and approaches to care. *Adv Skin Wound Care*. 2012 Jul; 25(7):304-14. doi: 10.1097/01.ASW.0000416006.55218.d0.
9. Järbrink K, Ni G, Sönnergren H, Schmidtchen A, Pang C, Bajpai R, Car J. Prevalence and incidence of chronic wounds and related complications: a protocol for a systematic review. *Syst Rev*. 2016 Sep 8; 5(1):152. doi:10.1186/s13643-016-0329-y.
10. Maruccia M, Onesti MG, Sorvillo V, Albano A, Dessy LA, Carlesimo B, et al. An alternative treatment strategy for complicated chronic wounds: Negative Pressure Therapy over Mesh Skin Graft. *Biomed Res Int*. 2017; 8395219. doi: 10.1155/2017/8395219.
11. Uccioli L, Izzo V, Meloni M, Vainieri E, Ruotolo V, Giurato L. Non-healing foot ulcers in diabetic patients: general and local interfering conditions and management options with advanced wound dressings. *J Wound Care*. 2015; 24(Suppl 4b):35-42. DOI: 10.12968/jowc.2015.24.Sup4b.35

Стаття надійшла 14.01.2020 р.