THE USEFULNESS OF TOPICAL NEGATIVE PRESSURE (TNP) AS A SUPPORTING METHOD FOR THE SURGICAL TREATMENT OF VENOUS ULCERS WITH THE USE OF MIDDLE-SPIT THICKNESS SKIN GRAFT

MACIEJ ZIELIŃSKI, FRYDERYK PUKACKI, GRZEGORZ O SZKINIS, MARCIN GABRIEL, KRZYSZTOF WALISZEWSKI, WACŁAW MAJEWSKI

Department of General and Vascular Surgery, K. Marcinkowski Medical University in Poznań
Kierownik: prof. dr hab. W. Majewski

The most effective method of treatment for venous ulcers resistant to conservative therapy is operation. The surgical procedure consists of resection of the entire ulceration followed by perforated middle-split thickness skin graft transplant. Postoperative treatment requires both long term elevation of the patient’s leg and frequent dressing changing.

The aim of the study was to assess the effectiveness of TNP as a method supporting surgical treatment.

Material and methods. From 2004 to 2006 in the Poznań Clinic of General and Vascular Surgery of Medical University, 25 patients (16 women and 9 men) were treated for venous ulcers resistant to conservative treatment. The patients’ ages varied from 50 to 82 years (average: 69), and the time of ulceration presence ranged from 6 months to 6 years (average: 2 years and 5 months). Patients were divided into two groups: all patients in group I (n=14) underwent surgical treatment with the use of middle split thickness skin grafting, whereas all patients in group II (n=11) underwent surgical treatment with support of TNP –VAC® Subsequent parameters, including the time of hospitalization, time and effectiveness of skin graft healing, and patient’s subjective comfort of the therapy, were analyzed.

Results. The average hospitalization time was significantly shorter in group II than group I (18 vs 24 days, p<0.0005). The average healing time in group II was significantly shorter than that in group I (31 vs 42 days, p<0.00002). Additional skin grafting was necessary in four cases from group I but none from group II. Subjective therapy comfort was higher among patients from group II than group I.

Conclusions. TNP is a useful method supporting the surgical treatment of venous ulcers that are resistant to conservative treatment.

Key words: ulceration, skin graft, VAC therapy, topical negative pressure

Despite the fact that the conditions necessary for successful healing of autogenic skin grafts were described long ago, skin grafts are frequently rejected. This may be related to incorrect wound preparation, inadequate graft adhesion, and/or graft immobilization on the defect surface (1). Incorrect wound preparation arises from either inadequate exposure of the vascularized tissue or lack of vital granulation (2, 3). On the other hand, incorrect wound surfaces are described as wounds containing deposits of necrotic tissue. These wounds contain fibrin depots and inflammatory exudate or high bacterial inoculum in the tissue or exudates (4). This situation results in low healing potential and subsequent inadequate neovascularization of the transplanted tissue. Finally, this can lead to skin graft death.

Inadequate skin graft adhesion is usually the consequence of the collection of exudates and/or blood under the graft surface. Mechanical separation and liquid collection can promote infection and thereby decrease the effectiveness and rate of the healing process (5). Proper skin graft immobilization on a defect site is also highly important for the process of healing.
Preventing movement of the skin graft protects delicate new vessels that grow into the transplant (5).

Different surgical and pharmacological techniques are commonly used in order to 1) improve debridment and wound bed preparation and 2) enable better skin graft adhesion. Despite ongoing progress, however, a certain percentage of skin graft transfers result in failure (6). The above mentioned analysis of both the effectiveness of middle split-thickness skin grafting and the risk factors for this therapy is of great importance for the surgical treatment of venous ulcers. These ulcers are typically chronic, fibrotic wounds that develop in the process of lipodermosclerosis. These wounds are anergic and infected, and they contain a large amount of exudate due to venostasis and microcirculatory changes (1, 7). Therefore, venous ulcers present many features that are undesirable with respect to skin graft healing.

This study was undertaken to assess the efficacy of a novel method of improvement for factors influencing skin graft healing in patients treated surgically for venous ulcers. This method, known as topical negative pressure (TNP) therapy, is based on the creation of local subatmospheric pressure with the use of a VAC (vacuum assisted closure) device. VAC devices enable continuous control of the hypobaric pressure level inside the wound, and they isolate it from both the surrounding environment and active drainage of the exudates (8).

**MATERIAL AND METHODS**

In the Department of General and Vascular Surgery at the Medical University in Poznań, 25 patients (16 women and 9 men) underwent surgical treatment due to venous ulceration resistant to conservative treatment between 2004 and 2006. Patients’ ages varied from 50 to 82 years with an average of 69 years. The average duration of ulceration was 2 years and 5 months (range: 6 months to 6 years). Each patient was submitted to an initial clinical evaluation as well as Doppler ultrasound analysis. The purpose of this analysis was 1) to confirm venous etiology of the ulceration and 2) to exclude arterial insufficiency, diabetes mellitus, dermatological diseases, and infective diseases as possible causes of the defect. Patients were divided into two groups. Patients in the first group (n=14) were treated surgically with the use of middle split thickness skin grafts, whereas those in the second group (n=11) underwent surgical treatment supported with the TNP therapy device VAC® (Hartmann, Kinetic Concepts Inc, San Antonio, Texas, US).

**Description of the topical negative pressure therapy device**

The topical negative pressure therapy device consists of portable subatmospheric pressure generator equipped with a touch-pad panel control enabling programming of a pressure value within the range of -50 mm Hg to -200 mm Hg. There is also a possibility of continuous or intermittent suction action of the device. Because of the integrated rechargeable battery, the device can work for several hours without an electric supply. The generator has a slot to install a sealed container for exudate collection, and this container is subsequently connected with the dressing via a special drainage system. The dressing consists of a polyurethane sponge that permits shaping to adjust to the contour of defect. The end of the suction drain is located on this sponge, and the entire dressing is sealed with the use of a transparent adhesive dressing (fig. 1).

**Therapeutic procedure**

At the moment of admission, each patient (6/25) presenting extensive skin and subcutaneous tissue inflammation and exudate production was initially treated with frequent dress-
These patients also received nonsteroidal antiinflammatory drugs and antibiotics until their symptoms regressed (average: 4 days). Subsequently, the surgical procedure was performed. In group I, the entire ulceration up to the level of the fascia was first resected; at the same time, a middle split-thickness perforated skin graft procedure was applied. The donor site was always the lateral aspect of the thigh, and the skin grafting technique was conducted in accordance with the description published earlier (1). In group II, the VAC system was applied for a period of 3 to 6 days (average: 5) after the ulcer’s resection. The duration of negative pressure therapy was determined by the time required for vital granulation tissue to grow over the defect surface. The VAC device was programmed for continuous suction with a pressure of -125 mm Hg. Subsequently, the skin grafting procedure was performed similarly to the protocol from group I. The skin graft was covered with a VAC dressing separated from the polyurethane sponge surface by one-layer gauze soaked in sterile paraffin. In this way, the secured transplant was left for 2-3 days with application of continuous negative pressure of -75 mm Hg. The donor site was covered for 10 days with gauze dressing with betadine solution mixed with sterile paraffin (fig. 2). Each patient from the first

Fig. 2. Surgical procedure supported with TNP: A – chronic venous ulcer, B – situation after surgical debridement, C – TNP – wound bed preparation, D – vital granulation tissue, situation after VAC removal, E – skin grafting, F – skin graft covered with one-layer gauze soaked with paraffin, G – graft initial healing with the use of TNP, H – healed graft, situation after VAC removal, I – healed skin graft, J – long term result.
Topical negative pressure (TNP) in treatment of venous ulcers with the use of skin graft
group was required to stay in bed with the leg elevated for 10 days; when necessary, this time was prolonged to a maximum of 16 days. During this period, patients received low molecular heparin prophylaxis. From the fourth postoperative day, daily dressing changes with the use of sterile gauze were performed to eliminate excess exudate. After the initial skin graft, healing patients were permitted to leave bed with compressive stockings. Patients from group II, on the other hand, were not required to stay in bed with their legs elevated, and they were allowed to walk from the first postoperative day. In cases of incomplete graft healing, supplementary skin grafts were placed in the defect area. These grafts were taken either from those stored in a refrigerator (temperature: 5-8°C) on the day of harvesting or from additional skin grafts performed according to the Riverdin method under local anesthesia (9). After complete or almost complete ulceration healing, patients were discharged home with the recommendation of permanent compressive therapy and weekly control visits in order to assess healing progress and perform dressing changes.

At 4-6 weeks from the time of complete graft healing, 11 patients (seven from group I and four from group II) were subjected to either operations to remove insufficient superficial veins or cruroscopic perforator ligation.

Statistical analysis

Statistical analysis was performed to compare study groups with regard to both hospitalization time and healing time. The Shapiro-Wilk test of multiple comparisons revealed no statistically significant differences between groups and a normative results distribution. Therefore, a Student t-test was employed to assess the average differences in relevant variables. Correlations of these variables were assessed with the use of a multivariate linear regression model. All data were analyzed using CCS STATISTICA v.7.1. software.

RESULTS

For all evaluated patients, complete ulceration healing was observed. The average healing time was 42 days in group I and 31 days in group II; this difference was significantly significant (p<0.00002, fig. 3). Similarly, the average hospitalization time was significantly (p<0.0005) shorter in group II than group I (18 vs 24 days, respectively, fig. 4). Four patients receiving conventional treatment in group I required additional skin grafting, whereas no additional procedures were needed for patients in group II. The average time of postoperative leg elevation and immobilization with antithrombotic prophylaxis was 13 days in group I; patients treated with topical negative pressure in group II did not require these procedures. This difference is reflected in the higher comfort level of therapy reported by patients from the second group. In the conservatively treated group I, initial graft healing was present after 11 days; in the VAC treated group II, initial graft healing was present after 5 days. Initial graft healing was defined as

![Fig. 3. Comparison of the average healing time for conventionally treated patients (group I) and patients undergoing surgery with the addition of TNP (group II)](image)

![Fig. 4. Comparison of the average hospitalization time for conventionally treated patients (group I) and patients undergoing surgery with the addition of TNP (group II)](image)
a moment of healing when 1) no liquid concentration was observed under the graft and 2) there was no longer a need for liquid removal during dressing changes.

Patients were monitored during control monthly visits the first 12 months of the postoperative period. At this time, ulceration recurrence was observed in five patients (three from group I and two from group II). The average recurrence time was 10 months (range: 7 to 12 months) from the date of operation. These recurrences were related to patients' refusal to use compression, and no statistical differences between groups were observed.

DISCUSSION

A better understanding of the pathophysiology of chronic venous disease and progression of operative techniques has improved the efficacy of the venous ulceration operation using middle split-thickness skin grafts. It is currently believed that this is the most effective method for treatment of this disease (1, 10, 11). In some cases (particularly for refractory ulcers resistant to conservative treatment), however, the results of operative therapy are still unsatisfactory. This is mostly related to the complexity of the procedure, which requires precise wound bed preparation, meticulous postoperative care of transplanted tissue, and long-term immobilization of the patient. All of these problems make the therapy time- and cost-consuming and burdensome for the patient and medical staff (12, 13).

In this study, the use of a VAC device for topical negative pressure therapy significantly shortened the hospitalization time and improved the efficacy of graft healing. The diminished postoperative care complexity associated with VAC usage allowed for a decrease in patient immobilization and also in the number of everyday dressing changes that involved mechanical exudate evacuation.

These changes positively influenced patients' subjective comfort assessments. As mentioned in the introduction, appropriate wound bed preparation prior to skin grafting is one of the most important conditions for venous ulcer treatment success. In the conventional method, this condition can be met by the utilization of dressings with antiseptic agents combined with antibiotics given systematically. This procedure improves ulceration cleaning and provides infection and inflammation control inside the wound and in its vicinity. The next step is the surgical excision of fibrotic, infected, and anergic tissue, including entire bottom of the ulceration, through the level of the fascia. In this way, the prepared wound bed can be used as a recipient site for a middle split-thickness skin graft. The described procedure was employed in patients from group I.

Despite significant inadequacy of graft thickness relative to defect depth following total ulceration resection, graft healing was observed. However, the time of healing was significantly longer for group I than group II, in which five days of TNP-therapy with the use of a VAC system was applied prior to grafting to improve wound bed condition. The explanation for the use of VAC-therapy for this purpose lies in the literature. Topical negative pressure creation improves tissue vascularization and stimulates mitotic cellular divisions, leading to faster granulation (8, 14, 15). By the third day of VAC therapy, vital granulation tissue completely covering the fascia surface was observed. It is very likely that a skin graft transplanted on a wound prepared in this way is more prone to healing than one transplanted straight onto the fascia. As we have already mentioned, the grafts heal after two days of diffusion because of the growth of new vessels coming from the wound bed area. The number of vessels is much higher in granulation tissue than in the fascia. We believe that this might be an explanation for the observed differences in graft healing effectiveness and rapidity; grafts transplanted on a wound surface initially prepared with the use of VAC healed faster than others.

Another justification of TNP use in wound bed preparation prior to skin grafting lies in its well documented ability to reduce the bacterial titre in the wound area (17). Venous ulceration is a chronic wound and thus must be considered infected. Conservative treatment of venous ulcer infection seems to be ineffective due to the infections’ extended fibrosis, weak vascularization, and massive colonization of different bacterial strains frequently resistant to antibiotics. TNP therapy has great potential to reduce bacteria because it actively drains the tissue, improves tissue vascularization, and preserves moist environments without restriction oxygen access. Even the most accurate surgical excision of old infected, fibrotic granu-
Topical negative pressure (TNP) in treatment of venous ulcers with the use of skin graft

Ligation tissue performed on patients from group I cannot guarantee aseptic wound conditions. Therefore, several days of TNP therapy in addition to the surgery seems to elevate the probability of graft acceptance as a result of more efficient purification of the recipient site.

According to the authors, another factor contributing to faster graft healing in group II was the application of a negative pressure dressing for a 2-3 day period immediately after skin graft transplantation. Graft fixation with accurate adhesion, which protects against movement, also improves the success of skin grafting. In the traditional method, this condition can be obtained by confining the patient to bed and both elevating and immobilizing the patient’s legs. Daily dressing changes are also required to evacuate the excess of exudate separating the graft from its bed. In group II, a VAC dressing was applied on the skin graft after the transplant was covered with one layer of gauze soaked with paraffin. Because this manipulation created a constant negative pressure of –75 mm Hg, it enabled exact graft adhesion as if the graft were pressed into the wound bed (18). Continuous suction by the VAC device causes graft immobilization and thus protects it from movement. This also has a positive impact on the rapidity and effectiveness of graft healing. Moreover, VAC therapy eliminated the need for patients to remain in bed with their legs immobilized for long periods of time. Locally exerted negative pressure in the skin graft area stimulates new vessel formation, and the growth of these vessels into the transplanted tissue improves healing.

Negative pressure, however, can cause the undesirable effect of graft contraction when the polyurethane sponge contracts. In order to avoid this situation, the authors used single 5-0 stitches for graft fixation. Sponge separation from the graft surface by a single layer of gauze soaked with paraffin was of great value as it enabled unconstrained sponge movements against the graft surface, while also protecting the delicate graft structure from mechanical damage. Finally, it facilitated the removal of the negative pressure dressings without the danger of graft separation.

Induction of continuous negative pressure by use of a VAC dressing enabled effective exudate elimination from the wound area, which protected against both exudate deposition under the graft and the eventual separation of the transplant. These findings are in accordance with observations reported by other authors (18,19). TNP therapy also did not require the frequent dressing changes with mechanical exudate removal that are necessary when using the traditional method.

All of the facts mentioned above resulted in 1) earlier initial and complete healing of the grafts in group II and 2) 100% healing success without the need for additional grafting.

Other important issues include the economic and psychological aspects of the therapy. The use of topical negative pressure permitted a significant reduction in the hospitalization time, dressing changes, and anti-thrombotic prophylaxis period. It also precluded the need for additional transplantation procedures that were necessary for four patients treated in the classical manner. The reductions in the number of medical staff work days, dressings, and medications used compensate for the expenses of VAC therapy. Due to the expected growing costs of medical workers’ salaries, these reductions seem to economically justify the use of TNP as a method supporting surgical treatment of venous ulcers. From the psychological point of view, the use of the VAC system made therapy more acceptable for the patient as it eliminated the need for long-term bed stay with leg elevation after the procedure. Patients did not report that connection to the VAC device, which allows full mobility, decreased their quality of life. Rarely-reported pain sensations of low intensity were well controlled with the use of oral non-narcotic analgesics.

CONCLUSIONS

Topical negative pressure therapy with the use of a VAC system confirmed its efficacy as a method supporting surgical treatment of venous ulcers that are resistant to conservative treatment. It significantly improved the effectiveness of the therapy and shortened its time, thereby enhancing patients’ subjective therapy comfort sensation. Particularly in the most severe cases, therefore, the authors consider TNP to be a method of choice for supporting surgical treatment of chronic ulcers.
REFERENCES


Received: 13.11.2007 r.
Address correspondence: 61-848 Poznañ, ul. D³uga 1/2

COMMENTARY

The European Society in Wound Management issued several documents on wound treatment (the so-called Position Document) with the most recent study: “Topical negative pressure in wound management”; concerning the clinical application of hypotension, which is evidence of the actuality of the mentioned issue. Experts highlight the fact that the use of a VAC device accelerates the process of healing, reduces costs, and improves the quality of treatment.

The study lacks reference to the venous pathology before treatment: How many cases of isolated superficial venous insufficiency were present? How many cases of deep venous insufficiency? How many cases of mixed pathology? One can only guess that 11 patients were diagnosed with superficial and perforating venous insufficiency, whereas the remaining presented deep venous system defects. Although the thesis formulated by the Authors that VAC therapy is effective was proved, it would seem clearer to present precise data concerning the type of venous pathology.

Lack of reference concerning the simultaneous surgical elimination of the reflux, excision of the ulceration, and by-pass grafting are missing. The Authors of the study corrected the venous pathology after termination of the healing process. In view of current literature data, both foreign and domestic, such management lacks justification. In the study „Operative treatment of venous ulcerations” (Journal of Phlebography, 2005; 13(6): 247-53), Machyñska-Buêko
and co-authors performed simultaneous correction of the venous reflux and skin grafting (without VAC therapy) and achieved a shorter period of the healing process. In the 72% of patients with superficial venous system reflux, complete recovery (healed ulcer) was observed after 7 days. In the case of patients with deep venous system reflux, 10-20 days were needed to achieve healing.

The study Z. Rybak, G. Krasowski, A Tukiendorf: “Is early surgical intervention in case of crural venous ulcerations justified?” (2004, Wound Management; 1(1):5-8) demonstrated that surgery performed on the venous system eliminating retrograde blood flow of the superficial or perforating systems significantly reduces the duration of healing.

The presented remarks do not belittle the value of the study, which shows the utility of VAC therapy, especially in cases of patients who do not consent to surgical intervention. This modern approach to the management of wounds is relevant not only to venous pathology but also to diabetic angiopathy, treatment of bedsores, and complicated surgical wounds. Many times, this is the only effective method of therapy in cases of infected and oozing wounds.

Prof. dr hab. Zbigniew Rybak
Katedra i Klinika Chirurgii Naczyniowej, Ogólnej i Transplantacyjnej AM we Wrocławiu