



Original article

Vacuum assisted closure (VAC) in the treatment of advanced diabetic foot

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A B S T R A C T

Introduction: Deep diabetic foot lesions pose an enormous therapeutic problem. The purpose of this study was to present the experience of the use of vacuum assisted closure (VAC) in the treatment of advanced and complicated diabetic foot lesions.

Material and methods: Five cases of advanced diabetic foot that were treated with VAC were prospectively studied. Three patients were diagnosed with renal failure, including one with renal transplant, who were receiving immunosuppression therapy. Four patients had undergone local foot surgery. The foot lesions were classified as grade 3 or 4 according to the Wagner classification. In all patients extensive debridement was performed that resulted in open minor amputations in 4 cases and resection of the metatarsophalangeal joint in 1 case. The VAC was applied during the same procedure. The median follow-up period of the patients was 9 months.

Results: Foot salvage was achieved in all cases. The median number of changes of VAC was 16 within median period of 8 weeks. Half of the changes were performed as an outpatient procedure. There were no major complications or clinical signs of infection observed. In 1 case before treatment with VAC began, angioplasty of the iliac artery and superficial femoral artery was performed. Other interventions carried out after the treatment was started were, 2 distal revascularizations and 2 partial transmetatarsal amputations.

Conclusions: VAC appears to be very useful in the treatment of advanced diabetic foot lesions.

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El sistema de cierre asistido al vacío en el tratamiento del pie diabético avanzado

R E S U M E N

Introducción: Las lesiones profundas del pie diabético constituyen un importante problema terapéutico. El objetivo de este estudio es presentar la experiencia resultante de la utilización del sistema de cierre asistido al vacío (VAC) en el tratamiento del pie diabético avanzado y complicado.

Palabras clave:

Pie diabético

Sistema de cierre asistido al vacío

Desbridamiento

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Material y métodos: Se realizó un estudio prospectivo de 5 casos de pie diabético avanzado tratados mediante VAC. Del total, a 3 pacientes se los diagnosticó de insuficiencia renal, entre ellos uno que recibió tratamiento inmunosupresor debido a un trasplante renal. En 4 de los casos se habían realizado intervenciones quirúrgicas locales sin éxito. Conforme a la clasificación de Wagner, las lesiones se catalogaron como de grado 3 o 4. En todos los casos se realizó un desbridamiento extenso, que en 4 de los pacientes dio lugar a amputaciones menores abiertas a la altura del metatarso, mientras que en uno se tradujo en una resección de la articulación metatarsofalángica. En el mismo acto, en cada uno de los pacientes se colocó VAC. La mediana de seguimiento posprocedimiento fue de 9 meses.

Resultados: Se consiguió salvar la extremidad en todos los casos. La mediana de cambios de VAC fue de 16 durante un período mediano de 8 semanas. La mitad de los cambios se realizó de modo ambulatorio. No ocurrieron complicaciones mayores. En ningún caso se produjeron signos clínicos de la infección. En uno de los pacientes, antes de comenzar el tratamiento con VAC, se llevó a cabo una angioplastia de arteria ilíaca y femoral superficial. Se necesitaron otros procedimientos adicionales: 2 revascularizaciones distales y 2 amputaciones parciales del antepié, después de que se iniciara el tratamiento con VAC.

Conclusiones: El sistema VAC parece ser muy eficaz en el tratamiento del pie diabético avanzado.

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Introduction

Diabetic foot is still the most important cause of non trauma-related amputation of the lower extremities.^{1,2} Although it has been shown that proper prophylactic measures can prevent 85% of all amputations in this patient group, every so often there is a case of advanced ulcer or necrosis that signals immediate loss of the member. These cases always require complex treatment in which extensive surgical debridement is the most important procedure and results in serious damage to tissues in the affected foot, which generally means a slow and difficult healing process.

The vacuum-assisted closure system (VAC) uses continuous or intermittent sub-atmospheric pressure over the surgical wound, applied with a polyurethane sponge sealed with adhesive transparent plastic. This system came into clinical use ten years ago. It has been stated that treatment with negative pressure dressing can accelerate the healing of diabetic foot lesions.³⁻⁵ The action mechanism for this system has multiple factors and consists of evacuating excess fluid and reducing oedema in neighbouring tissues to therefore improve microvascular perfusion and decrease bacterial colonisation, while simultaneously protecting the lesion from external contamination.⁶ The purpose of this study is to describe our experience treating advanced, complicated diabetic foot using VAC.

Patients and method

We performed a prospective study of 5 cases of advanced diabetic foot treated using the VAC system between August 2007 and September 2008 in the University Clinic of Navarra. The average patient age was 65.2 years. One of the patients had type 1 diabetes. The others had type 2 diabetes that was treated with oral anti-diabetic drugs. Three patients

were diagnosed with renal failure, including one who underwent a regular haemodialysis programme and another on immunosuppressants as a result of having a kidney transplant. All patients presented deep lesions: three grade 3 lesions and 2 grade 4 lesions, according to the Wagner classification system.⁷ According to the University of Texas system, all were grade 3. One of the cases was considered stage A (with no infection and no ischaemia), another in stage B (infection, no ischaemia), 2 more in stage C (ischaemia, no infection), and 1 in stage D (infection and ischaemia).⁸

The required signs and symptoms for diagnosing the infection were suppuration, foul odour or such signs as erythema, tumefaction, heat or pressure sensitivity in the area around the ulcer (Figure 1). All had received previous treatment. Two patients had undergone amputation of a toe on the affected foot; another patient had undergone a forefoot amputation and an angioplasty of the posterior tibial artery; a fourth patient had received conservative treatment despite presenting partial necrosis of the forefoot, and the last patient presented an ulcer after partial amputation of the forefoot.

All of the patients were informed about the technique to be performed, and they signed informed consent documents. All of these patients underwent radical surgical debridement consisting of the resection of all dead and infected tissue, including toe amputation and partial amputation of the forefoot in the applicable cases (Figure 2). Four patients underwent minor open amputations at the metatarsal level, and there was one case of radical debridement of the perforating foot ulcer with resection of the metatarsal-phalangeal joint.

For all cases, a VAC system was used during the procedure, beginning with continuous aspiration during the first 6-12 hours, after which it changed to intermittent mode (Figure 3). The VAC changes were performed in an operating theatre using sterile technique every 3 to 4 days,

Figure 1 – Deep infection in a diabetic foot following amputation of the fourth toe (Wagner 3, University of Texas 3D). Note the suppuration in the wound and the signs of infection (erythema and tumefaction) on the plantar surface of the foot.

Figure 2 – The same patient. State after radical debridement resulting in minor open amputation extending to the metatarsus.

or with shorter intervals where indicated. The foot was inspected daily to identify inflammation symptoms in the tissues surrounding the lesion. VAC treatment continued until the ulcer filled completely with granulation tissue and

Figure 3 – The vacuum-assisted closure system in place.

the decision was made to implant a partial thickness skin graft, continue with conventional dressings, or perform a smaller closed amputation. During the initial debridement procedure, we collected samples for culturing in all cases. All patients received antimicrobial treatment while they were hospitalised.

To save the extremity, we considered preserving the part of the foot that would permit prosthesis-free standing and walking, in accordance with published criteria.⁹ The mean length of patient follow-up was 9 months, ranging from four to 13 months.

Results

There were no deaths. We managed to save the extremity in all cases. The mean number of VAC changes was 16 (range, 2-19) during a median period of 8 weeks. Half of the procedures were performed on an outpatient basis. The hospital stay due to VAC treatment ranged from 2 to 23 days. The median was 21 days.

One patient presenting partial necrosis of the forefoot and pain at rest received an ileal and superficial femoral artery angioplasty to eliminate the pain three days before receiving radical debridement and beginning VAC treatment. Three patients underwent other procedures after beginning VAC treatment. Two cases presented slow granulation tissue growth and required revascularisation procedures despite absence of pain at rest. The revascularisations that were performed were, in one case, angioplasty of the anterior tibial artery four days later, and in the other case, popliteal angioplasty and a popliteopaedic derivation, occurring 13 and 29 days after beginning VAC treatment respectively. This last

Figure 4 – The same patient. Following debridement, the wound is completely covered with granulation tissue after eight weeks of treatment with a vacuum-assisted closure system.

patient had already undergone iliac and superficial femoral artery angioplasties.

One patient completed only 2 VAC changes during 6 days, after debridement of the infected perforating ulcer including resection of the metatarsal-phalangeal joint, as we proceeded to amputate the forefoot due to extensive deep tissue involvement. After the amputation, the forefoot healed three weeks later and presented no complications. At that time, the patient was able to resume walking with no need of a prosthesis. After 29 days on VAC treatment, another patient with an open amputation of the medial part of the forefoot underwent closed amputation of the remaining lateral part of the forefoot. VAC treatment continued for the lesion on the medial part. The amputation on the lateral part healed in 21 days. The lesion on the medial part was treated with VAC over an additional ten days, after which it was treated with Betadine® gel until completely healed 7 months after beginning treatment. After 56 days of VAC treatment, 1 patient received a partial-thickness skin graft to accelerate definitive healing (Figure 4 and 5).

The last 2 patients did not need additional procedures and their wounds were completely healed 3 and 4 months after treatment, which involved 66 and 31 days of VAC treatment for each patient.

Pathogenic microorganisms were identified in 4 cases. The isolated bacterial cultures were *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bacteroides fragilis*, *Klebsiella pneumoniae*, and *Serratia marcescens*.

No serious complications arose. Complications related to the technique included loss of dressing seal or blockage of the

Figure 5 – Closed wound with a partial-thickness skin graft.

aspiration system caused by blood clots. This last complication occurred in 2 patients who were on double antiaggregant treatment due to previous revascularisation. There were no cases of oedema, erythema, pain or suppuration. None of the patients refused treatment or expressed a wish to discontinue VAC treatment before the doctor so indicated.

Discussion

This study has shown that using VAC system treatment on extensive wounds after debriding deep diabetic foot lesions, whether ischaemic or infected, is safe and effective, even in patients with renal failure and immunosuppressants. Furthermore, it showed that the treatment can be given on an outpatient basis without causing complications.

There were no observed cases of necrosis progression or reinfection, both of which are frequent with conventional treatment. Most published studies on the use of VAC in treating diabetic foot refer to more minor ulcers than those presented by our patients.^{4,5} A recently published multi-centre study only selected patients with grade 2 and

3 ulcers (according to the Wagner system), meaning that our patients' ulcers were more advanced.¹⁰ Additionally, it excluded patients with osteomyelitis, ischaemia, or on immunosuppressants. Due to the depth of the lesions and the extensiveness of the debridement, our observations coincide with the results of the Armstrong and Lavery study. This study randomly assigned 162 diabetic patients with open post-amputation lesions to either a VAC treatment group or a conventional treatment group.¹¹ This study showed a higher healing rate and faster evolution of granulation tissue in the group treated with VAC than in patients in the conventional care group. However, this study also excluded patients with ischaemic diabetic foot, as well as those undergoing immunosuppressant treatment.

Determining whether or not there is sufficient blood perfusion in the diabetic foot is difficult. Due to calcification of the medial arterial layer, the ankle-arm index is not always reliable. Oedema present in cases of deep infection can affect transcutaneous oxygen pressure results. It is true that in the case of a deep diabetic foot ulcer with no pulse, the extremity should be revascularised. However, there are many factors involved in the pathogenesis of diabetic foot and there may be cases of deep infections with infrapopliteal arterial lesions whose clinical importance is unclear. Logically, evaluating the development of granulation tissue can clear up this uncertainty. In the case of open amputations on the ischaemic diabetic foot, however, the delay from revascularisation tends to make the local condition worse and can lead to loss of the extremity. Factors such as dehydration and reinfection of the wound contribute to this situation. The VAC system maintains a humid environment and protects against potential extrinsic infections. In addition to this, it decreases the oedema, which optimises blood circulation on a microcirculatory level. We observed that, in the event of oedema, VAC treatment permitted proper evaluation of the development of granulation tissue, and in 2 cases of slow evolution, it allowed us to proceed with more radical revascularisation techniques, such as infrapopliteal angioplasty or popliteopaedic derivation, that effectively accelerated healing and permitted conservation of the extremity. Therefore, especially with ischaemic diabetic foot, VAC treatment can be considered a safe treatment which permits proper evaluation of irrigation in dubious cases, but it is certainly not the only treatment.

As we saw in one of the cases, VAC treatment can also help control inflammatory state and infection, permit us to evaluate affected foot tissues and perform definitive closed forefoot amputation, a treatment that makes independent walking possible quickly and with no need for a prosthesis.

Before this, most of our patients were surgically treated with success. We believe that one of the main causes of ulcer healing failure in diabetic patients, apart from ischaemia, is insufficient debridement. It must be stressed that for all cases of deep diabetic foot lesions, it is necessary to eliminate all dead and infected tissue before beginning local treatment, including VAC treatment. A wish to conserve as much foot tissue as possible or fear of radical debridement can affect this

fundamental principal in treating diabetic foot. A comparison of the results from the 2 above mentioned studies seems to support this idea. The healing rate of diabetic ulcers at 16 weeks after debridement was lower (43%) than the healing rate for lesions following open amputations (56%).^{10,11}

VAC is not a haemostatic dressing. For this reason, haemostasis must be guaranteed before applying it, particularly for patients on anticoagulant medication. If this is not done, blood clots can occur that clog up the sponge or the drainage tube. The latter situation occurred with two patients. Furthermore, a lack of haemostasis at the moment when the VAC dressing is applied can often prevent its proper application. If the skin surface bordering the wound is not dry, the adhesive plastic will not stick well to the skin surface, which can cause a loss of seal in the dressing and expose healthy skin around the wound to negative pressure, which can cause maceration.

Using VAC treatment is not necessary until the wound is completely closed. In our study, the median length of VAC use was eight weeks, coinciding with the study by Clare et al. which describes a mean VAC treatment length of 8.2 weeks.¹² Once we observe that the wound has filled with granulation tissue or that irrigation is satisfactory, we can proceed to insert a partial-thickness skin graft or closed amputation.

All of the VAC dressing changes for patients in our study were performed in the operating theatre to ensure sterile technique. Additionally, using the operating theatre allows us to perform debridement and facilitates gaining haemostasis should it be necessary. However, we feel that in most cases, this can be done in a procedure room.

One of the important facts is that VAC treatment decreases dressing change frequency. In our patients, dressings were changed every three or four days, while with conventional treatments they are changed 2 or 3 times daily. If the procedure is done outside the operating theatre, this can lead to a cost reduction, as shown in the study by Apelqvist et al.¹³ According to that study, the mean cost of healing was \$25.954 in patients treated with VAC and \$38.806 in patients treated with conventional methods.

Another interesting factor in our study is patient satisfaction. Although patients had to carry an aspiration device and come to the hospital to have their dressings changed in the operating theatre, none of them wanted to abandon the treatment.

Conclusion

VAC system treatment appears to be very useful as an adjuvant treatment for advanced diabetic foot. However, this does not relieve us of the need to perform radical debridement and revascularisation if they are indicated.

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