



Vacuum-assisted wound closure in vascular surgery – clinical and cost benefits in a developing country

Zarastanje rane pomoću vakuuma u vaskularnoj hirurgiji – klinička i ekonomska korist u zemlji u razvoju

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Abstract

Background/Aim. Surgical and chronic wounds in vascular patients might contribute to limb loss and death. Vacuum-assisted closure (VAC) – Kinetic Concepts, Inc. (KCI), has been increasingly used in Western Europe and the USA clinical practice for 15 years. Advantages of this method are faster wound healing, wound approximation, lower wound related treatment costs and improved quality of life during treatment. Evidence related to the usage of VAC therapy in vascular patients and cost effectiveness of VAC therapy in a developing country are lacking. The aim of this study was to explore results of VAC therapy in vascular surgery comparing to conventional methods and to test cost effects in a developing country like Serbia. **Methods.** All patients with wound infection or dehiscence operated at the tertiary vascular university clinic in the period from January 2011 – January 2012, were treated with VAC therapy. The primary endpoint was wound closure, while secondary endpoints were hospital stay, the number of weekly dressings, costs of wound care, working time of medical personnel. The patients were divided into groups according to the wound type and location: wound with exposed synthetic vascular implant (25%), laparotomy (13%), foot ampu-

tation (29%), major limb amputation (21%), fasciotomy (13%). The results of primary and secondary endpoint were compared with the results of conventional treatment during the previous year. **Results.** There was one death (1/42, 2.38%) and one limb loss (1/12, 2.38%) in the VAC group, and 8 deaths (8/38, 21.05%) and 5 (5/38, 13.15%) limb losses in the patients treated with conventional therapy. In the VAC group there was one groin bleeding (1/12, 2.38%), one groin reinfection (1/12, 2.38%) and one resistance to therapy with a consequent limb loss. Costs of hospital stay ($p < 0.001$) and nursing time ($p < 0.001$) were reduced with VAC therapy in the group with exposed graft. **Conclusion.** VAC therapy is the effective method for care of complicated wounds in vascular surgery. Patients with infection of wound with the exposed synthetic graft significantly benefit from this therapy. Cost effectiveness of VAC therapy is applicable to a developing country scenario, however cautious selection of patients contributes to the effectiveness.

Key words:

surgical wound infection; surgical wound dehiscence; vascular surgical procedures; vacuum; socioeconomic factors; treatment outcome.

Apstrakt

Uvod/Cilj. Rane kod vaskularnih bolesnika, kao i komplikacije hirurških rana nakon vaskularnih procedura doprinose gubitku ekstremiteta i smrtnom ishodu. Zatvaranje rane vakuumom (*vacuum-assisted closure* – VAC) je metoda koja se sve više koristi u zapadnoj Evropi i Americi u poslednjih 15 godina. Prednosti ove metode su brže zarastanje rana, približavanje ivica rane, manji troškovi lečenja vezani za ranu i bolji kvalitet života bolesnika tokom lečenja. Dokazi koji se odnose na upotrebu VAC terapije kod vaskularnih bolesnika i njihovi ekonomski efekti u zemlji u razvoju do sada nisu objavljeni. Cilj ove studije bio je da se uporede rezultati lečenja metodom VAC kod vaskularnih bolesnika u

odnosu na dosadašnje metode, kao i da se ispita isplativost ove terapije u specifičnim ekonomskim uslovima u zemlji u razvoju kao što je Srbija. **Metode.** Svi bolesnici sa infekcijom ili dehiscencijom hirurške rane, operisani u tercijalnoj vaskularnoj ustanovi u periodu januar 2011 – januar 2012, lečeni su metodom VAC. Primarni cilj bio je zatvaranje rane, dok su sekundarni ciljevi bili da se utvrdi dužina hospitalizacije, broj previjanja, cena lečenja rane, radno vreme medicinskog osoblja potrošeno za tretman rane. Bolesnici su bili podeljeni u 5 grupa prema tipu lečene rane i njenoj lokaciji: rana sa ekspaniranim veštačkim krvnim sudom (25%); laparotomna rana (13%); rana nakon amputacije stopala (29%); rana nakon amputacije ekstremiteta (21%); fasciotomna rana (13%). Rezultati su poređeni sa rezultatima lečenja

konvencionalnim metodama previjanja i lečenja rana kod bolesnika istih grupa lečenih u 2010. godini. **Rezultati.** U grupi bolesnika lečenih terapijom VAC jedan bolesnik je preminuo (1/42, 2,38%) i jedan je izgubio ekstremitet (1/12, 2,38%), dok je u prethodnoj godini preminulo osam bolesnika (8/38, 21,05%), a pet bolesnika (5/38, 13,15%) je izgubilo ekstremitet tokom lečenja konvencionalnim metodama. U grupi bolesnika lečenih metodom VAC zabeleženo je jedno krvarenje u preponi (1/12, 2,38%), jedna reinfekcija u preponi (1/12, 2,38%) i kod jednog bolesnika je infekcija bila rezistentna na terapiju, što je zahtevalo ekstirpaciju grafta i amputaciju noge. Cena lečenja i vreme koje je medicinsko osoblje provelo u lečenju i nezi rane bili su značajno manji u grupi bolesnika sa ekspaniranim veštačkim krvnim su-

dom tretiranih terapijom VAC. **Zaključak.** Zatvaranje rane metodom VAC je efikasna terapija za lečenje komplikovanih rana kod vaskularnih bolesnika. Bolesnici sa infekcijom rane u kojoj je ekspaniran veštački krvni sud imaju značajnu korist od ove metode. Isplativost terapije VAC opravdava primenu i u zemljama u razvoju, ali je pažljiv izbor bolesnika jedini način da se ta ekonomičnost zadrži i poboljša.

Ključne reči:

rana, hirurška, infekcija; rana, hirurška, dehiscencija; hirurgija, vaskularna, procedure; vakuum; socioekonomski faktori; lečenje, ishod.

Introduction

Chronic wounds are great burden to the health care system in every country. Vascular patients with peripheral arterial or vein insufficiency are frequently diagnosed with already developed chronic wounds. On the other side vascular procedures might be complicated with different wound complications. Most complicated wounds are related to usage of synthetic material, infected or dehisced laparotomy after complex procedures, extensive amputation in the malperfused area or advanced foot infections. Vacuum-assisted closure (VAC) – Kinetic Concepts, Inc. (KCI) has been increasingly used in the developed countries since 15 years ago for treatment of different wounds¹⁻³. The Serbian National Agency for Drugs and Medical Devices registered this method in 2009. Reported advantages of VAC therapy are related to general and gastrointestinal surgery; plastic and reconstructive surgery burns, trauma and cardiac surgery reporting faster recovery, granulation, and shorter hospital stay with lower costs of the therapy. Cost effects in countries with lower gross domestic product (GDP) might be different due to notably lower costs of hospital stay. Publications related to the usage of VAC in specific vascular patients are lacking as well as cost analysis related to the scenario of a developing country.

The aim of our study was to explore the results of VAC therapy in vascular surgery comparing to conventional methods and to test cost effects of this method in a developing country like Serbia.

Methods

We prospectively followed patients operated at the Clinic for Vascular and Endovascular Surgery of the Serbian Clinical Center in the period from January 2011 – January 2012. Out of 2,154 patients operated, 42 (1.95%) patients with complicated wounds were treated with VAC therapy and included in the study. These data were compared with retrospectively collected data from the history group of patients with complicated wound treated with the conventional methods of wound dressings in the period January – December, 2010.

According to the wound type patients were divided in five groups: the group 1 of groin wound with synthetic vascular implant (25%); the group 2 with infected or dehisced

laparotomy wound (13%); the group 3 with wound after foot amputation (29%); the group 4 with wound after major limb amputation (21%); the group 5 with fasciotomy wound (13%).

Primary endpoint of the study was wound closure, while the secondary ones were duration of hospitalization, the number of weekly wound dressings, costs of wound care, working time of medical nurse dedicated to the care of those with complicated wound. A positive primary endpoint was considered the moment of closing wound with secondary suture, or discharging patient with wound in a condition that allows home care. A negative primary endpoint was considered wound bleeding, reoperation, wound reinfection requiring new hospitalization and limb loss. Secondary suture or discharge of patient to home care was based on a decision of operated surgeon.

Groin wound with a synthetic vascular implant (the group 1) was considered as any wound in the groin after vascular reconstruction with a Dacron or polytetrafluorethylene (PTFE) graft that had signs of infection defined by Szilagyi (stage I, II or III). Infected laparotomy wound (the group 2) was considered as any wound with signs of infection that requires multiple daily dressings and positive microbacterial wound culture. The treatment strategy was to remove necessary sutures and the application of VAC. Dehisced laparotomy wound was considered as any laparotomy wound complicated with disruption of all layers in the abdominal wall. The patients in good general condition were treated with reoperation and were excluded from the study, while the patients in poor general condition, with previous major surgery and the presence of other cardiorespiratory complications were treated with VAC application. Wound after foot amputation (the group 3) was considered as every foot wound that required further hospital dressings after foot amputation or foot incision due to infection. Wound after limb amputation (the group 4) was considered as any wound after below knee, above knee or hip disarticulation that required intrahospital multiple dressings. Fasciotomy wound (the group 5) was considered as any fasciotomy with signs of ischemia or muscle devitalisation. In these patients, combined musclectomy and VAC application were performed. Clean and well-perfused fasciotomy wounds were excluded from the study and immediately referred to plastic surgeon. Each of the five groups of wounds was treated with VAC therapy in 2011 and with conventional methods (multi-

ple wound dressing) in 2010. The results of the two methods were compared.

Different types of wounds treated with VAC therapy are presented in Figures 1–3.

The number of weekly wound dressings was scored by a

treating nurse, as well as working time spent for the wound care. Cost of wound care was counted as a sum of spent gauze [100 m – 2,981 Republic of Serbia Serbian Dinars (RSD), 27 Euro], hydrogen (1,000 mL – 28 RSD, 0.32 Euro), chloramin (1,000 mL – 39 RSD, 0.35 Euro) and Octenisept (1,000 mL – 2,900

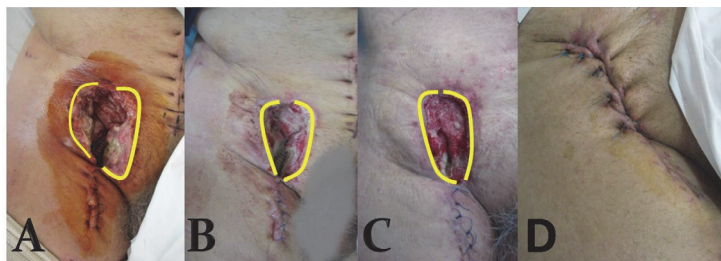


Fig. 1 – Treatment of infection of the polytetrafluoroethylene (PTFE) graft that exposed in the groin. During a two-weeks therapy wound retracted (A–C) with 5 dressings (15 days), and finally secondary suture was possible (D).

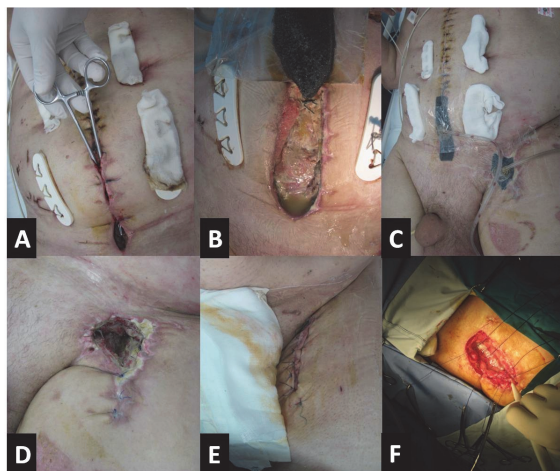


Fig. 2 – Concomitant infections of laparotomy, and groin wound (A, B, D) in a 125 kg weighted patient treated for ruptured abdominal aortic aneurysm. Extensive secretion from both wounds required multiple daily dressings (more than 15 per day), the patient was unmotivated in the Intensive Care Unit. Vacuum-assisted closure dressing was applied to both wounds (C) and with only 3 dressing *per* week the patient’s general condition improved, his self esteem improved too and the patient was then motivated for treatment. Finally, the patient was transmitted to the semi-intensive care unit where the patient was prepared for secondary suture of the groin and later of the infraumbilical laparotomy wound (E, F).

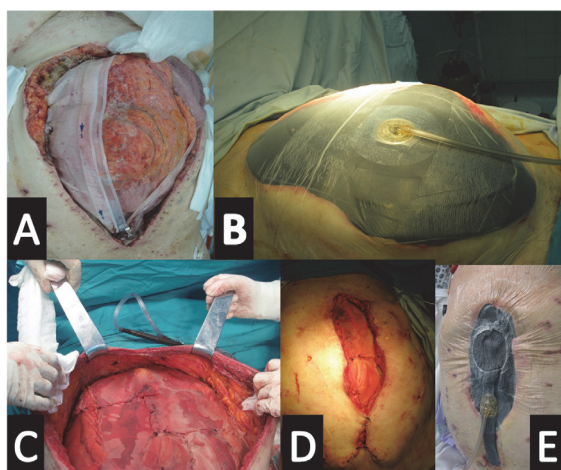


Fig. 3 – Abdominal compartment syndrome after repair of ruptured abdominal aortic repair was treated initially with “zip” abdominal suture (A), and due to dehiscence of the “zip”, vacuum-assisted closure (VAC) abdominal set was applied (B), for 15 days when synthetic mesh was used to reconstruct abdominal wall (C, D). Later, smaller VAC dressings were used to support healing of the skin and subcutaneous tissue (E). Wound was in such condition that the patient was able to be discharged and treated in the regional hospital. However, the patient suffered sudden death due to pulmonary embolism so no final wound image was available.

RSD, 26.60 Euro) for each patient during conservative treatment. For the patients treated with VAC therapy a sum of spent material was considered as wound care costs (small, medium or large wound set and VAC canister). Antibiotic therapy was expressed as the number of days under antibiotic therapy.

All wounds treated with VAC therapy were initially managed by removing all removable necrotic layers and devitalized tissue. Negative pressure of 125 mmHg in continuous fashion was applied. Wounds were dressed every 48–96 h until home care or the feasibility of secondary suture. Foot wounds with surrounding phlegmona were dressed every 24–48 h until the improvement of local state was visible, when dressing was prolonged (48–96 h) since secondary suture or home care was possible. Antibiotic therapy was selected according to wound culture findings and applied until secondary suture or home care.

Each wound in the history group was treated with multiple dressings using hydrogen, chloramin and Octenisept until home care or secondary suture. Antibiotic therapy was selected according to wound culture findings and applied until secondary suture or discharge to home care.

Statistical analysis

All continuous variables are represented with the median (range). The χ^2 was used to determine the association between a categorical outcome and a categorical factor. A $p < 0.05$ was considered as a statistically significant. SPSS Version 12.0 was used for statistical computing.

The study was approved by the local Ethical committee.

Results

Out of 80 patients, there were 42 (52.5%) in the VAC group treated between January 2011 and January 2012, and 38 (47.5%) patients treated with conventional methods in the period January–December, 2010. There were 72 (90%) males and 8 (10%) females, without statistical difference between the groups (39/3 and 34/4 in the VAC and conventional group, respectively). The distribution of wound types in both groups is given in the Table 1.

The patients with groin wound infection were treated due to lymphorhea with conventional or VAC methods in five out of six (83.33%) patients and four out of 12 (33.33%) patients, respectively. Synthetic graft was exposed in only one patient (1/6, 16.66%) treated with conventional treatment, while eight out of 12 (66.66%) patients in VAC group had exposed synthetic graft. Conventional treatment was used only for infected laparotomy wound, while VAC was used for dehisced (2/6, 33.33%) and infected (4/6, 66.66%) laparotomy. In other wound types there was no specific difference between the two groups.

The length of treatment was counted in hospital days and compared between the different wound types (Table 2).

The number of wound dressings *per* week was significantly lower in all but fasciotomy wounds when VAC treatment was applied. The greatest difference was in the group of patients with exposed graft. The number of wound dressings is presented in Table 3. The greater the difference between the number of weekly dressings, the greater the saving of nursing time: 165, 45, 50, 35 and 25 min/week were

Table 1

Distribution of different wound types in the two compared groups

Wound type	Conventional treatment, n (%)	VAC treatment, n (%)	<i>p</i> values
Groin with synthetic vascular implant	6 (15.78)	12 (28.57)	0.003
Infected or dehisced laparotomy	4 (10.52)	6 (14.28)	0.077
After foot amputation	14 (36.84)	12 (28.57)	0.254
After major limb amputation	11 (28.94)	9 (21.42)	0.084
Fasciotomy	3 (7.89)	3 (7.14)	0.216
Total	38 (100)	42 (100)	

VAC – vacuum-assisted closure.

Table 2

Length of hospital stay

Wound type	Length of stay (days), median (range)		<i>p</i> values
	Conventional treatment	VAC treatment	
Groin with synthetic vascular implant	45.3 (25–60)	25.1 (20–35)	< 0.001
Infected or dehisced laparotomy wound	20 (15–30)	17 (13–32)	0.806
After foot amputation	13.8 (9–20)	7.6 (5–15)	0.191
After major limb amputation	22.2 (15–32)	12.1 (7–22)	0.783
Fasciotomy	12.4 (9–15)	8.3 (4–18)	0.978

VAC – vacuum-assisted closure.

Table 3

Number of weekly wound dressings and the amount of medical nurse time saved due to the lower number of dressings

Wound type	Wound dressing, number/week		<i>p</i> values	Saved time (minutes/week)
	Conventional treatment	VAC treatment		
Groin with synthetic vascular implant	35	3	< 0.001	165
Infected or dehisced laparotomy	12	2	0.065	45
After foot amputation	9	2	0.030	50
After major limb amputation	10	2	0.038	35
Fasciotomy	7	3	0.182	25
Mean	14.6	2.4	0.022	53.33

VAC – vacuum-assisted closure.

saved for groin, laparotomy, foot, limb and fasciotomy wound, respectively.

The total cost of treatment was lower in the VAC group of patients with the greatest difference in patients with exposed synthetic grafts. The costs of patients with laparotomy dehiscence were higher when VAC treatment was used. The costs of treatment are shown in Table 4.

Chronic wounds do not heal satisfactory even after long lasting conventional treatment. Infection, secretion, malperfusion and slow granulation are the usual causes of prolonged healing process due to lower concentration of growth cytokines, increased level of inflammatory cytokines and proteolytic enzymes^{4, 5}. Also mechanical forces in the wound bed have been shown to influence the healing pro-

Table 4
Cost of hospital treatment included hospital day, antibiotic therapy and dressing material (due to diversity of vascular procedures costs of primary procedure were not calculated)

Wound type	Total cost of treatment, RSD		
	Conventional treatment	VAC treatment	<i>p</i> values
Groin with synthetic vascular implant	212,000	145,000	< 0.001
Infected or dehisced laparotomy	38,000	195,000	0.025
After foot amputation	33,000	22,000	0.055
After major limb amputation	58,000	42,000	0.034
Fasciotomy	27,000	18,500	0.047

VAC – vacuum-assisted closure; RSD – Republic of Serbia Dinar.

Primary endpoint in patients treated with VAC

There was one death (1/42, 2.38%) in the VAC group in a patient after foot amputation with severe cardiorespiratory comorbidity. Death was not related to VAC treatment. There was one groin bleeding (1/12, 2.38%) in the patients with groin infection. Bleeding was related to VAC treatment. There was one groin reinfection (1/12, 2.38%) treated with reoperation and extra-anatomical reconstruction. In one patient with a groin infection (1/12, 2.38%) no improvement in local condition was recorded demanding synthetic graft extirpation with consequent limb loss. All the other 38 patients (38/42, 90.47%) were successfully treated with positive primary endpoint.

Primary endpoint in patients treated with conventional therapy

There were 8 deaths (8/38, 21.05%), in 2, 3 and 2 patients with laparotomy, groin and limb amputation wounds, respectively. In 6 out of 8 (75%) patients the cause of death was sepsis. There were 5 (5/38, 13.15%) limb losses in the patients with groin infection (two patients) or foot amputation (3 patients). All the other 25 patients (25/38, 65.38%) were successfully treated with conventional measures in the prolonged and costlier manner as described above.

Discussion

This study shows clinical benefits of VAC therapy compared to conventional everyday dressings of chronic or surgical wounds in vascular patients. A reduced length of hospital stay and cost reduction in the subgroup of the patients with extensive wound secretion was found to be significant comparing to conventional therapy. The results of VAC therapy were prospectively collected and compared with retrospectively analysed data of conventionally treated patients during previous year.

cess, as well⁶. VAC therapy provides effective influence on both of these factors¹⁻³. Continuous evacuation of interstitial fluid and mechanical influence on wound edges shortens, wound healing time significantly. In addition, this vacuum effect improves cell migration, mitosis and microcirculation with consequent better wound perfusion being of significant help in malperfused wounds. The result of all these actions are higher rate of granulation tissue formation. Advantages of VAC therapy are shown in different wound types, however in this study we were focused on vascular patients operated due to different vascular pathology.

In all kinds of vascular procedures or interventional cardiovascular interventions groin is the most frequent site of access. For these reasons complication in the groin area are most frequent. Complications of percutaneous groin interventions, such as false aneurysms and hemathoma inducing hemodynamic instability of the patients requiring urgent surgical procedure, are more frequent in obese patients. Obesity, emergency procedure and secondary cavity in the wound increase infection rate in the postoperative time. Such a complicated polyvascular disease patients requires fast recovery after complicated treatment and prolonged groin wound healing might postpone treatment of the main disease (mostly coronary).

Groin infection after procedures when synthetic material is used jeopardizes performed procedure and exposes a patient to high risk of bleeding, sepsis and death. Persistent lymphorhea and superficial infections are usually treated with repetitive wound dressings and antibiotic therapy increasing hospital stay and costs. Such a conservative treatment in deeper infections with already exposed synthetic material is not justified. It requires aggressive surgical treatment with replacement of synthetic graft with autologous or with a new extra-anatomical reconstruction. These procedures are extensive and bare significant risks especially in patients with already performed extensive surgery. In our study, among the patients from the history group, treated with conventional methods,

there were only two patients with such extensive infection and due to severe comorbidity they were not treated aggressively as described. Both of them died during the conservative treatment due to bleeding or sepsis. Other patients with more superficial infection and lymphorrhea were treated with significantly longer hospitalization time and cost comparing to the group of patients treated with VAC therapy as shown in our results. In addition, among the patients treated with VAC therapy there was a significant number of them with deep infection and exposed synthetic graft. One of them is presented in Figure 1. There is a low number of reported cases with such extensive infection treated with VAC, however results of other authors are similar to ours^{7,8}. This group of patients has highest benefit from VAC therapy.

Extended aortic vascular procedures require laparotomy that may complicate with infection or dehiscence. These complications are not related to vascular reconstruction however they might jeopardize outcome of treatment, prolong hospital stay, antibiotic therapy. Our study showed benefits in all these attributes when VAC treatment was concerned. The advantage of VAC therapy was immense in patients operated emergently whose postoperative general condition precluded any additional procedures, like patient shown in the Figure 2. There was significantly higher costs of treatment with VAC therapy in this group due to discrepancy between the number of patients and severity of complication in this group. All conservatively treated patients had mild wound infection, while those treated with VAC had abdominal compartment syndrome of wound dehiscence. They were treated with costly abdominal VAC set. There are no publication comparing conservative and VAC treatment of laparotomy wound dehiscence or compartment syndrome due to ethical issues. Abdominal compartment syndrome (ACS) is complication of open or endovascular repair of ruptured abdominal aortic aneurysm. Immediate decompression in some advanced stages is life saving. VAC open abdomen set provides treatment of ACS without intensive care unit stay as shown in Figure 3. Still higher costs of this method are justified due to the life saving results⁹.

The main impediment for healing after foot amputation is malperfusion and infection. In our group of patients VAC therapy improved limb salvage in the patients with foot amputation and also significantly reduced hospital stay and treatment costs. Limb salvage was improved in those patients who were admitted with already present extensive foot infection. Radical incision, debridement and subsequent VAC therapy was the strategy that gave obvious effects. In patients with simple amputation of foot finger that had demarcated necrosis VAC therapy decreased time until home care was possible. Still the patients did not recognize that and the majority of them complained on worse quality of care since they were fixed to bad. We did not examine quality of life with standard questionnaires; however we asked patients if they felt any improvement after our care or not. The majority of the patients with foot amputation complained on being fixed to bad. Other patients that experienced much extensive

surgery and those with extensive secreting wounds reported a significant improvement and better motivation since the number of daily dressings were reduced and hygienic conditions improved. Vuerstaek et al.¹⁰ found similar results in 2006. In this study the authors found decrease in quality of life during the first week of treatment while at the end of the therapy the quality of life was improved. We did not notice this improvement since in our series the mean treatment length was one week.

Infection and malperfusion after limb amputation is usually found in patients with previous vascular surgery. These patients are frequently found after synthetic graft infection in the groin when extirpation is necessary without an option to restore flow. Atypical reconstruction with viable tissue is made after previous open treatment of stump wound. In both situations, VAC therapy might be used to reduce the number of weekly dressings and improve perfusion. For these reasons, survival in this group of patients was better when VAC is used. With VAC therapy, patients avoid uncomfortable and annoying everyday dressings.

This study has some limitations. It compared the results of VAC therapy with the control history group that might bring some flaws. However, the patients in the history group were treated just one year before. The groups of patients were heterogenous and it was not possible to compare the results between the different wound types. On the other side, all the groups of wound types were present in both VAC and history group. The patients treated with VAC therapy were in worse general condition with more complex complications. For example, groin infections were more superficial in the history group while the graft was more frequently exposed in the VAC group. Laparotomy infections and dehiscence were also in a more advance stage in the VAC group. All these increase the strength of the results favoring VAC therapy.

Conclusion

Vacuum-assisted wound closure is the effective method for care of complicated wounds in vascular surgery providing limb or life salvage, shorter hospital stay and less nursing time to patient. Cost effectiveness of VAC therapy has been confirmed in the scenario of a developing country in particular groups of patients where longer hospital care is necessary. Due to the fact that patients with foot wound might feel less satisfied with VAC therapy outpatient modes of VAC therapy should be considered. VAC treatment of wound with synthetic graft should be considered as a first line therapy especially in superficial infection and high risk patients.

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