



Comparison of vacuum-assisted closure therapy and debridement with primer surgical closure for Fournier's gangrene treatment: 10 years' experience of a single centre

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ABSTRACT

Objective: Fournier's gangrene is a type of necrotizing soft tissue infection of the perineal, genital and perianal region that has a rapidly progressive and potentially fatal course. In the present study, our goal was to compare the patients submitted to surgical debridement for Fournier Gangrene with Vacuum-assisted Closure (VAC) and without VAC therapy after debridement.

Materials and Methods: We retrospectively analyzed 313 patients underwent surgical debridement for FG in our hospital. Patients were divided into two groups as patients performed surgical debridement with VAC therapy and surgical debridement with primer closure and without VAC therapy. Demographic characteristics, hospitalization time, requirement of re-constructive treatment, area of necrosis and localization, requiring per-operative colostomy, percutaneous cystostomy or orchiectomy status, presence of septic shock, etiology of Fournier Gangrene (FG) and Fournier gangrene severity index score were recorded for statistical analysis.

Results: 111 (35.5%) patients received vacuum-assisted closure therapy and remained 202 (64.5%) patients did not receive vacuum - assisted closure after surgical debridement due to Fournier's gangrene. Mortality rate was calculated as 15.7%. Mean hospitalization time of patients were 23.7 ± 1.1 days. The requirement of reconstructive surgery, septic shock, Fournier gangrene severity index, requirement of colostomy, mortality rate and hospitalization time was significantly lower in patients who received VAC therapy.

Conclusions: Vacuum-assisted closure therapy is suggested for the treatment of Fournier gangrene. Early implementation of vacuum - assisted closure therapy can decrease mortality rate and hospitalization time of patients with Fournier gangrene and increase the recovery time.

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INTRODUCTION

Fournier's gangrene (FG) is a type of necrotizing soft tissue infection of the perineal, genital and perianal region that has a rapidly progressive

and potentially fatal course (1). It is characterized by an obliterating endarteritis that leads to thrombosis of subcutaneous tissue blood vessels, ultimately leading to both skin and vessel gangrene (2). Treatment of FG entails treating sepsis,

stabilizing medical parameters and urgent surgical debridement. Despite timely and aggressive management, the condition is life threatening as most studies report mortality rates of between 20% and 40% with a range of 4-88% (3, 4). Predominantly affects males (at a 10 to 1 ratio) with an average age of 50 years (5). Several predisposing factors have been identified: diabetes, alcoholism, arterial hypertension, renal and hepatic insufficiency, obesity, dementia, tobacco consumption and diseases that affect the immune system such as human immunodeficiency syndrome (HIV), chemo and radiotherapy, cancer and surgical interventions. Concerning etiology, the source can be in the urogenital tract, anorectal region and skin infections (6, 7).

Regarding local cares, the vacuum - assisted closure (VAC) device (KCI Inc., San Antonio, Tex., USA) demonstrated to lead to remarkable improvement, useful to achieve a successful one-step surgical closure. It is considered that these devices stimulate angiogenesis and lead to an improvement of nourishment and tissue formation. Granulation tissue depends on neovascularization for a sufficient supply of proteins and immunological factor. Noticeably, the draining role removes stagnant fluid and the debris that impair wound closure (8).

There are limited studies about the use of VAC therapy for FG treatment after first debridement in the literature. We performed a systematic review of all cases of FG at our hospital over a 10-year period. In the present study, our goal was to compare the patients submitted to surgical debridement for Fournier Gangrene with and without VAC therapy after debridement.

MATERIALS AND METHODS

We retrospectively analyzed 313 patients underwent surgical debridement for FG in our hospital between 2005 and 2015. All patient's data were collected from hospital patient's record system. Demographic characteristics, hospitalization time, requirement of reconstructive treatment, area of necrosis and localization, requiring per-operative colostomy, percutaneous cystostomy or orchiectomy status, presence of septic shock,

etiology of FG and Fournier gangrene severity index score were recorded for statistical analysis. Patients were divided into two groups as patients performed surgical debridement with VAC therapy and surgical debridement with primer closure and without VAC therapy. All patients were operated by different urologist or general surgeon. Debridement area was calculated from the patient's operation note according to the description of surgeon from the patient record system. All patient's surgeon decided the need of VAC or non-VAC therapy for his/her patients. VAC therapy was performed for 3-4 days and 3-4 times after the first surgical debridement. Between each session, patients were evaluated for further debridement. After debridement and with or without VAC therapy all patients were consulted by plastic and reconstructive surgeon to determine the need of free skin flap reconstruction. After first debridement of all patients with and without VAC therapy, all were evaluated after 3-4 days from first debridement for further debridement. Standard VAC therapy was performed with VAC-Ulta device at 150-200mmHg negative pressure and continuous irrigation with saline solution including 250mg rifampicin to prevent the contamination of wound. Fournier Gangrene severity index score for all patients were calculated.

All statistical analyses were conducted by SPSS v.22.0 package program. Categorical variables were described by frequencies and percentages; continuous variables were described by means and standard deviations. Kolmogorov-Smirnov test was used to evaluate the normality of the distributions. Parametric independent t-test was chosen to compare two independent means. Ki-square test was used to compare two categorical variable and Pearson correlation test was used to compare two continuous variables. Kaplan-Meier analyses were performed for survival analyses. A p value less than 0.05 was chosen as the criterion for statistical significance.

RESULTS

Mean age of patients was 59 ± 15.6 years. Totally, 313 patients were included in the study. 237 (75.7%) patients were male and 76 (24.3%)

patients were female. 111 (35.5%) patients received VAC therapy and 202 (64.5%) patients were submitted only to surgical debridement and primary closure without VAC therapy. Postoperatively, reconstructive surgery was required in 111 (35.5%) patients. 49 (15.7%) patients died because of sepsis or multi organ deficiency and 264 (84.3%) patients were alive. Mortality rate was calculated as 15.7%. Age, hospitalization time, septic shock, Fournier Gangrene severity index score and size of the necrotic area, presence of comorbidities and colostomy were mortality related factors on multivariate cox regression analysis. On survival analyze, 5yrs. general survival was 82.5% (std error: 0.025) and disease specific 5yrs. survival was 85.7% (std error: 0.021). Mean post-operative follow-up time was 50.19 ± 33.68 (range: 4-120) months. Etiological causes of FG are summarized in Table-1. Mean debridement area was $86.3 \pm 8.2 \text{ cm}^2$ and hospitalization duration of patients was 23.7 ± 1.1 days. Necrotizing area was observed in 192 (61.3%) patients on scrotum and vulva, 236 (75.4%) patients in perineum, 76 (24.3%) patients in inguinal region, 32 (10.2%) patients in penis, 79 (25.2%) patients in gluteal region, 45 (15.4%) in the wall of ab-

domen and 5 (1.1%) back side, respectively. Colostomy application was required in 76 (24.3%) patients and orchiectomy was performed in 8 (2.6%) patients. Percutaneous cystostomy was performed in 7 (2.2%) patients whose urethra was effected from the FG. Although reconstructive surgery was required in 42 (37.8%) patients, 69 (72.8%) patients did not require reconstructive surgery and recovered by debridement and primary closure in patients with VAC therapy. In patients without VAC therapy, reconstructive surgery was performed in 69 (34.1%) patients and 133 (65.9%) patients were recovered by primary closure. Statistically significance was observed about the requirement of reconstructive surgery between two groups ($p=0.03$). Mean hospitalization time of patients who performed VAC therapy was 20.4 ± 17.3 days and 25.6 ± 22.6 days in patients who did not received VAC therapy. Statistically significance was observed again about the hospitalization time between two groups ($p < 0.001$). In patients with VAC therapy, mortality rate was 8.1% but in patients without VAC therapy was 19.8% and there was statistical significance between groups ($p=0.006$). Comparison of two groups is summarized in Table-2.

Table 1 - Etiology of Fournier's Gangrene.

Etiology	N	%
Urogenital abscesses	118	37.7
Colorectal abscesses	115	36.7
Infections after surgery	34	10.9
Compression wound	25	8

Table 2 - Comparison of two groups.

Etiology	VAC therapy	Non-VAC therapy	p Value
Reconstructive surgery	42 (37.8%)	69 (72.8%)	0.03
Hospitalization duration	20.4 ± 17.3	25.6 ± 22.6	< 0.001
Mortality rate	8.1	19.8	0.005
Fournier gangrene severity index	9.3 ± 2	11.5 ± 2.7	0.001
Colostomy requirement	29 (26.1%)	47 (23.3%)	0.03

DISCUSSION

In present study, we compare the efficiency of VAC therapy and non-VAC therapy after surgical debridement in patients with FG. We revealed that mortality rates, hospitalization time and reconstructive surgery requirement such as skin flap or graft are lower in patients submitted to VAC therapy for FG than patients that did not performed VAC therapy. Despite the improvement in outcomes with recent advances in resuscitation, antibiotics, and anesthesia, combined with adequate surgical debridement, the mortality rates from Fournier's gangrene are still high, with reported rates of up to 75% (9, 10). But, in recent years, mortality rates decreased according to developing of surgical techniques and treatment options such as VAC therapy. Mortality rate was 15.7% in our study. Five years. general survival was 82.5% (std error: 0.025) and disease specific 5yrs. survival was 85.7% (std error: 0.021). In patients who received VAC therapy, mortality rate was 8.1%, but in patients who did not receive VAC therapy, it was 19.8% and there was statistically significance between groups ($p=0.006$).

Multiple predisposing factors for FG including diabetes mellitus, arterial hypertension, chronic renal failure, systemic disorders, malignant neoplasms, chronic alcoholism, immunosuppression, and local trauma were reported (11). We observed that most common etiological factor in our study was development of Fournier Gangrene after infections that affected genital region. However, we could not show a relationship between etiological factors and mortality.

Diabetes mellitus is the most common predisposing factor, but does not affect the prognosis and clinical outcome (12, 13). We observed diabetes mellitus in 89 (28.4%) patients and all of them developed Fournier Gangrene due to diabetes mellitus. However, we could not find relationship between mortality and diabetes mellitus; we consider that diabetes may facilitate the progression of the infection and delay wound healing. Hence, hospitalization time and recovering time may extend. We consider that

VAC therapy may also decrease wound healing time, as a result decreases hospitalization time. We showed that hospitalization time is shorter in patients submitted to VAC therapy than patients with non-VAC therapy.

Negative-pressure wound therapy (NPWT) or vacuum-assisted closure (VAC) therapy have been little studied in the postoperative management of FG. VAC therapy works by exposing a wound to sub-atmospheric pressure for an extended period to promote debridement and healing (14). The negative pressure in NPWT leads to an increased blood supply and thus encourages migration of inflammatory cells into the wound region. Also, it promotes and accelerates the formation of granulation tissue by removing bacterial contamination, end products, exudates and debris compared with traditional dressing (15). Czymek and colleagues prospectively collected data on 35 patients diagnosed with FG to assess the effectiveness of VAC therapy versus daily antiseptic (polyhexadine) dressings. Patients treated with VAC therapy had significantly longer hospitalization and lower mortality (16). Conversely, we observed that patients who performed VAC therapy have lower hospitalization time and reconstructive surgery requirement than patients who did not performed VAC therapy for Fournier Gangrene. VAC therapy could prevent repeated debridement of patients. As a result, VAC therapy may increase granulation formation and decreases requirement of reconstructive surgery.

Most authors advocate that intestinal diversion should be used in cases of colorectal perforation or anal sphincter involvement, or simply to prevent fecal contamination of the wound (17, 18). Yan-Dong Li and colleagues reported the clinical data of 51 patients (49 men and 2 women) with Fournier gangrene. They divided patients into two groups according the surgical technique performed: enterostomy combined with debridement (the enterostomy group, $n=28$) or debridement alone (the control group, $n=23$). In this study, average length of hospital stay (14.3 ± 7.8 d vs. 20.1 ± 8.9 d, $P<0.05$) was shorter in the enterostomy group. The case fatality rate was lower in the enterostomy group

than that in the control group (3.6% vs. 21.7%, $p < 0.05$) (19). We observed that 6 (24.3%) required colostomy, and colostomy requirement was related with mortality. We consider that patients who required colostomy generally applies to the hospital late, so these patients need wide debridement of necrotizing area and generally they are septic during the apply. And also, we observed that patients submitted to VAC therapy need less colostomy application than patients without VAC therapy.

Assensa and colleagues reported that in their study with 6 patients who were submitted to VAC therapy, showed less hospitalization duration and requirement of reconstructive surgery than those who did not performed VAC therapy (20). We found the same results of the study of Assensa and colleagues. In our study, we revealed that patients submitted to VAC therapy needed less reconstructive surgery and hospitalization time than patients who did not performed

VAC therapy for Fournier Gangrene debridement (Figure-1). Also, mortality rate was lower than patients who did not performed VAC therapy. We consider that VAC therapy increases the vascularization of debridement area, so that regional immunity increases and infection of necrotic area decreases. These results decrease the sepsis risk and related deaths. Also, VAC devices provide closed wound care and continuous wound irrigation with solution including antibiotics to prevent wound contamination. These applications may provide increased granulation formation and wound healing, and result in lower hospitalization.

Limitation of our study was the retrospective design of study. We could not randomize and standardize the patients submitted to VAC therapy. We consider that necrotized area is the most effective cause to decide the choice of VAC therapy after the surgical debridement. Size of necrotizing area may affect the results of both

Figure 1 - A) Image after debridement. B) and C) VAC therapy. D) Image after reconstructive surgery.



VAC therapy and non-VAC therapy. Further studies that standardize the size of necrotized area are needed to understand the effectiveness of VAC therapy.

CONCLUSIONS

Although Fournier's gangrene is a rare condition, it is nevertheless a fatal illness, namely in patients with comorbidities like diabetes, and as such it should remain a subject of study so that its treatment is optimized. The cornerstone of treatment remains early recognition, prompt surgical debridement, broad-spectrum antibiotherapy and aggressive supportive care. With the developing technologies, VAC therapy may play a key role in the treatment of FG. Early implementation of VAC therapy can decrease mortality rate, reconstructive surgery requirement and hospitalization time of patients with FG and increase the recovery time.

CONFLICT OF INTEREST

None declared.

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