

Enteroatmospheric fistulas in open abdomen in trauma associated with abdominal reintervention and VAC[®] therapy

Fístulas enteroatmosféricas en abdomen abierto en trauma asociadas con la reintervención abdominal y la terapia VAC[®]

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Abstract

Background: Open abdomen is an alternative for the management of trauma patient, and negative pressure therapy of the wound using VAC[®] device is a genuine sort of treatment. Although the device poses technical advantages, risks are present and a critical complication is the enteroatmospheric fistula formation (EAF). **Objective:** To analyze the role of negative pressure therapy length and VAC[®] device number of changes on the EAF formation in trauma patients undergoing open abdomen. **Method:** Cut-off points were calculated using receiver operational characteristics curve. Values were compared with Student's t or Mann-Whitney U tests, considering statistically significant $p < 0.05$. **Results:** EAF were present in 39 cases (5.9%). A significant difference in the presence of EAF was present in patients with negative pressure therapy of the wound length ≥ 11.2 days (46.9 vs. 1.3%; relative risk [RR]: 3.67; 95% confidence interval [95%IC]: 2.4-6.68; $p = 0.017$) and when ≥ 2.6 VAC[®] device changes were performed (34.6 vs. 0.5%; RR: 6.92; 95%IC: 1.1-4.3; $p < 0.001$). **Conclusions:** At our institution, the practice of > 3 VAC[®] device changes and length of therapy > 11 days should be carefully considered leading to reduce the risk of EAF formation.

Keywords: Enteroatmospheric fistula. Negative pressure therapy of the wound. Open abdomen.

Resumen

Introducción: El abdomen abierto es una alternativa para manejar al paciente traumatizado, y una variante para instituirlo es la terapia de presión negativa de la herida con el dispositivo VAC[®]. Aunque tiene ventajas técnicas, no está exento de riesgos y una complicación crítica es la formación de fístulas enteroatmosféricas (FEA). **Objetivo:** Analizar el papel de la duración de la terapia de presión negativa y del número de cambios del dispositivo VAC[®] sobre la aparición de FEA en pacientes traumatizados manejados con abdomen abierto. **Método:** Se establecieron puntos de corte con curva de características operacionales del receptor. Los valores se compararon con la prueba t de Student o U de Mann-Whitney, considerando $p < 0.05$ como valor estadísticamente significativo. **Resultados:** La FEA se presentó en 39 casos (5.9%). Hubo una diferencia significativa en la aparición de FEA en pacientes con duración de la terapia de presión negativa de la herida ≥ 11.2 días (46.9 vs 1.3%; riesgo relativo [RR]: 3.67; intervalo de confianza del 95% [IC95%]: 2.4-6.68; $p = 0.017$) y cuando se practicaron ≥ 2.6 cambios del dispositivo VAC[®] (34.6 vs. 0.5%; RR: 6.92; IC95%: 1.1-4.3; $p < 0.001$). **Conclusiones:** En nuestra institución, la práctica de más de tres cambios del dispositivo VAC[®] y el mantenimiento de la terapia por más de 11 días debe ser cuidadosamente considerado para reducir el riesgo de formación de FEA.

Palabras clave: Fístula enteroatmosférica. Terapia de presión negativa. Abdomen abierto

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Introduction

Trauma is a global public health issue, and Mexico is no stranger to this problem. Globally, trauma is the leading cause of death among individuals aged 1 to 60, the primary cause of temporary and permanent work disability, and the main reason for school absenteeism among students. Additionally, it is the third most costly disease.¹ Many severely injured patients require management with the open abdomen technique. The implementation of this technique requires the creation, preservation, and care of an open abdominal wound, known as a "laparotomy," to repeatedly access the abdomen for the intended purposes.² At the beginning of the century, the company 3M[®], KCI[®] (St. Paul, MN, United States) developed a commercial negative pressure wound therapy (NPWT) device called VAC[®] (Vacuum Assisted Therapy), which has represented a tremendous advancement and contributed to the effective management of laparotomy.³ However, despite its significant advantages, VAC[®] is no stranger to morbidity directly associated with its use. Complications such as bleeding, visceral necrosis, suture line failures, abdominal sepsis, secondary or recurrent abdominal compartment syndrome, and intestinal fistulas have been reported.⁴ In this study, we will be focusing on investigating 2 likely causes of this specific variant of morbidity that are under the relative control of the surgeon: the number of changes performed to the VAC[®] NPWT and the duration of NPWT.

Repeated interventions are a cause of intestinal fistulization, not only in trauma patients but in any patient where they are necessary. A shortened, clean, and careful surgical technique, along with the prevention of tissue friction and the expedite resolution of the factor requiring reintervention have been proposed as the most viable and effective strategies to prevent this condition.⁴⁻⁸

The duration of NPWT has also been considered as a promoting factor for intestinal fistulization and, in the case of patients with an open abdomen, for enteroatmospheric fistula (EAF).⁸⁻¹⁴

In the Trauma Group of Hospital Central Militar, Mexico City, Mexico, we believe that understanding the limits of NPWT duration with the VAC[®] device and the number of abdominal reinterventions allowed in trauma patients treated with the open abdomen technique to reduce the possibility or avoid the appearance of EAF can contribute to modifying the center's existing management protocols. Little is known of high

consistency associated with the role of prolonged NPWT, the number of necessary reinterventions to pacify the abdomen, or the incidence of EAF formation. Since the aforementioned technical factors are conditions that remain under the relative control of the surgeon, we believe that information on the duration of NPWT with the VAC[®] device and the number of abdominal reinterventions to change the device have the potential to modify the technical-medical procedures to approach these types of patients and reduce the possibility of EAF occurrence.

Method

Patients who met the inclusion criteria and were not included in any condition considered in the exclusion or elimination criteria were selected from the Trauma Registry of Hospital Central Militar (Department of General Surgery, Hospital Central Militar, SEDENA) to consult their physical records in the MEDSyS or SDS system. According to the clinical study model proposed by Mintziras et al.,¹⁵ 4 groups were formed with mutually exclusive nominal levels: 1) based on the number of changes performed to the VAC[®] NPWT device ($<$ cutoff value and $\geq$ cutoff value) and 2) based on the duration of therapy with the VAC[®] NPWT device ($<$ cutoff value and $\geq$ cutoff value). Demographic and clinical variables were described with relative frequency of occurrence and measures of dispersion, while dependent quantitative variables (duration of NPWT and number of changes performed to the VAC[®] device) were statistically compared between both groups using the Student's t-test or the Mann-Whitney U test, depending on whether they met normality assumptions. The level of statistical significance was set at $p < .05$. The text capture program was Microsoft[®] Word[®] for Microsoft[®] 365 MSO (16.0.13231.20098), and the statistical programs used for calculations were Microsoft[®] Excel[®] for Microsoft[®] 365 MSO (16.0.13231.20098) and SPSS[®] version 21 for Windows.

To determine the number of safe reintervention procedures and the optimal duration of NPWT with the VAC[®] device, and to establish cutoff values, a ROC curve analysis (Receiver Operating Characteristic) was performed. The values of the area under the curve were set with the corresponding 95% confidence interval (CI95%), and the Youden index was used to determine the optimal cutoff value to discriminate between patients with and without EAF. IBM[®] SPSS[®] Statistics tool was used to develop the ROC curve and determine the area under the curve values.

Results

During the study period (168 months, from January 1, 2006 through December 31, 2019), a total of 665 patients with abdominal trauma treated at any time during their hospital stay with the open abdomen technique using the VAC® device were admitted to Hospital Central Militar for an average 3.95 patients/month. The VAC® device was used when indicated and available.

Out of all the patients treated, 524 were men (78.8%), and 141 were women (21.2%). The mean age of the study group was 51.18 ± 15.34 years (range, 20-79). Blunt trauma was the most frequent mechanism of injury ($n = 452$; 67.9%), while penetrating trauma was present in one-third of the cases ($n = 213$; 32.1%). The most common variant of blunt trauma was motor vehicle events (371/452; 82.07%), and the most common specific variant of penetrating trauma was gunshot wounds (106/213; 49.8%) (Fig. 1). A total of 3923 specific organ injuries were recorded, for a mean 5.9 injuries per patient, including 2254 abdominal injuries (57.4%) and 1669 extra-abdominal injuries (42.6%). The most widely reported abdominal injuries were hepatic ($n = 349$; 15.5%) and colorectal injuries ($n = 340$; 15.1%), while the most common extra-abdominal traumas were skin and appendage injuries ($n = 684$; 40.9%) and thoracic skeleton injuries ($n = 517$; 31%) (Figs. 2 and 3). To determine the optimal duration of the therapy with the VAC® NPWT device, a ROC curve analysis was performed, computing the area under the curve with a 95% confidence interval (95%CI) and calculating the Youden index to define the discriminatory cutoff value between patients with and without EAF. The values obtained under which patients were categorized into 4 groups, were: 1) duration of therapy with the VAC® device < 11.2 days or ≥ 11.2 days, and 2) number of changes performed to the VAC® device (< 2.6 or ≥ 2.6) (Fig. 4). EAF occurred in 39 cases (5.9%). There was a statistically significant difference in the occurrence of EAF in patients with therapy regimens ≥ 11.2 days vs those with shorter courses of therapy (46.9 vs 1.3%; relative risk [RR], 3.67; 95%CI, 2.4-6.68; $p = .017$), and those who underwent ≥ 2.6 device changes (34.6 vs 0.5%; RR, 6.92; 95%CI, 1.1-4.3; $p < .001$) vs those with fewer changes performed (Table 1).

Discussion

The management of open abdominal wounds in critically trauma patients has evolved over the years. The way the VAC® NPWT device works is based on

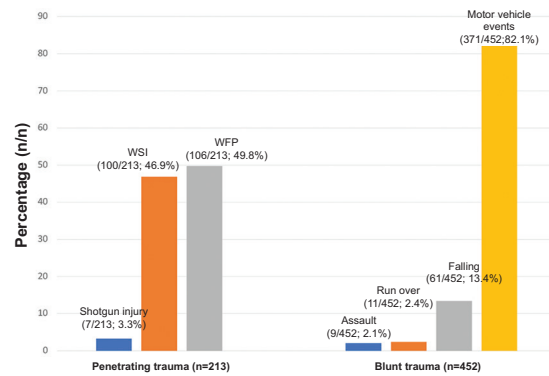


Figure 1. Distribution of injury mechanisms and their variants. WFP, wound by firearm projectile; WSI, wound by sharp instrument.

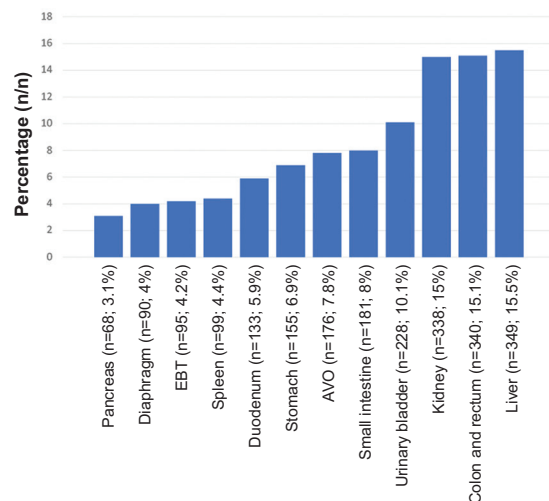


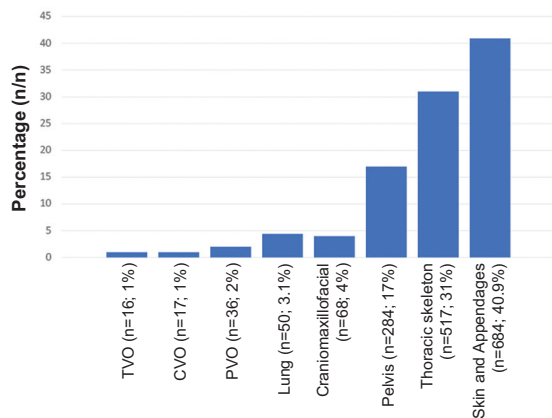
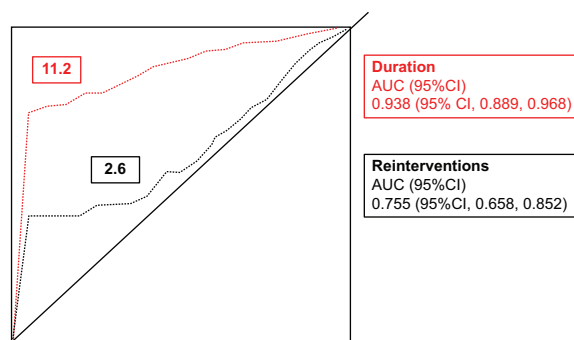
Figure 2. Distribution of specific abdominal injuries ($n = 2254$). AVO, abdominal vascular organ; EBT, extrahepatic biliary tree.

physical principles and cytomolecular mechanisms, resulting in a granulated, non-edematous (or minimally edematous), immunocompetent open abdominal wound in most cases, free from infection and ready for healing.^{15,16}

Despite having several advantages, management of open abdominal wounds comes with certain risks and complications. Various specific complications directly associated with its use have been described, including chronic pain, post-incisional ventral hernia, bleeding, visceral necrosis, suture line rupture (vascular, gastrointestinal, etc.), secondary or recurrent abdominal compartment syndrome, and EAF.¹⁷⁻²² The VAC® is not solely a NPWT device that works by evacuating fluids from the cavities where it is used. Currently, the cytomolecular mechanisms of its action and tissue

Table 1. Bivariate analysis of the duration and number of changes of the negative pressure wound therapy (NPWT) VAC® device in patients with and without enterocutaneous fistula.

Group	Total (n = 665)	Enteroatmospheric fistula (n; %)		p	RR
		Yes	No		
Duration of therapy with the NPWT VAC® device (days)					
< 11.2	599	8 (1.3)	31 (5.17)	0.017	3.67
> 11.2	66	31 (46.9)	8 (12)		
Number of changes of the NPWT VAC® device					
< 2.6	561	3 (0.5)	36 (6.41)	< 0.001	6.92
> 2.6	104	36 (34.6)	3 (2.8)		

**Figure 3.** Distribution of specific extra-abdominal injuries (n = 1669). CVO, cervical vascular organ; PVO, peripheral vascular organ; TVO, thoracic vascular organ.**Figure 4.** Discriminatory cutoff values with and without enteroatmospheric fistula for the duration of negative pressure wound therapy with the VAC® device and number of device changes estimated using the ROC curve.

the basal membrane of epithelial beds, generating bursts of gene signals for cellular replication and the synthesis of immune cell chemoattractants, such as macrophages and lymphocytes. Similarly, this traction promotes closure of endothelial gaps through electrical stimulation and mechanical apposition, reducing the interstitial space between the cellular beds and capillary vessels, thereby promoting capillary drainage. Under this concept, the ultimate result of this process is an immunocompetent open abdominal wound ready for healing.^{23,24} In several clinical series, the rates of abdominal infection and primary or definitive closure of laparotomy wounds in trauma patients treated with the VAC® NPWT device significantly improved vs wounds treated with other resources available to the scientific community.²⁵⁻²⁷ The management of open abdominal wounds in critically trauma patients takes too many resources for their care, the prolonged hospital stays associated with it, and the significant morbidity and mortality rates of patients in whom it occurs. Open abdominal wounds are pathological conditions of great current interest for the trauma team of Hospital Central Militar, which is why this clinical trial was designed, analyzing the role played by the duration of NPWT and the number of changes performed to the VAC® device on the rate of EAF occurrence in trauma patients treated with the open abdomen technique at the center.

In our study, most affected patients were young men (n = 524; 78.8%), in their working years (mean age of the entire group, 51.2 ± 15.3 years; range, 20-79), and blunt trauma was the most common mechanism of injury, present in 67.9% of the cases (n = 452).

To categorize the study, cutoff values for the duration of NPWT and the number of changes performed to the VAC® device were defined using the ROC curve to determine the area under the curve that would correspond to the estimation of the 95%CI. Therefore,

edema resolution are well known. Negative pressure and traction exerted on the beds where it is placed deform both the cellular cytoskeleton and proteins of

patients were stratified into study groups: based on the duration of therapy with the VAC® device (< 11.2 and ≥ 11.2 days) and on the number of changes performed to the VAC® device (< 2.6 and ≥ 2.6 changes).

The risk of EAF formation in trauma patients with an open abdomen varies widely in the scientific medical literature currently available, with figures ranging from 5% up to 54% (mean, 26% to 37%). Factors associated with EAF formation are diverse, including injuries with a high anatomical severity index, the duration of NPWT, the number of abdominal reinterventions, the interval between reinterventions, the systemic proinflammatory state, and ongoing sepsis.²⁸ In our series, the incidence of EAF was 5.9% ($n = 39$), which is low vs reliable sources of information. Our hospital's trauma team has a 14-year experience on the management of the VAC® device, always fully aware of the patient's clinical characteristics, type of intervention implemented in the abdomen, and need to abbreviate the number of device changes performed and the duration of NPWT in the abdomen. The present comparison of patients with and without EAF formation revealed that ≥ 2.6 changes performed to the VAC® device were significantly associated with EAF occurrence (34.6% vs 0.5%; RR, 6.92; 95%CI, 1.1-4.3; $P < .0001$), as previously described by Schmelzle.²⁹ Additionally, a duration of NPWT with the VAC® device ≥ 11.2 days was also significantly associated with the development of fistulization (46.9% vs 1.3%; RR, 3.67; 95%CI, 2.4-6.68; $P = .017$). More device changes performed weaken, dehydrate, and erode tissues, favoring the loss of continuity of the intestinal wall, while a longer duration of NPWT exposes visceral content to the destructive effects of the environment, leading to the deterioration of the anatomical conditions of the intestinal wall, mucosal exposure, and more chances of fistulization.^{30,31} Therefore, performing > 3 changes of the VAC® device and maintaining therapy for over 11 days should be carefully considered to reduce the risk of EAF formation. As far as we know, this is the first national series ever conducted to validate the duration of therapy with the VAC® NPWT device and the number of device changes performed as factors related to EAF development in trauma patients treated with the open abdomen technique. We followed the descriptive and comparative statistical model developed in the study conducted by Mintziras et al.²¹ to build this series.

We acknowledge that this study has certain limitations due to its retrospective and single-center design, and limited number of patients included. Additionally,

the correlation between the number of VAC® device changes performed and the duration of NPWT with EAF formation follows conclusions obtained from basic statistical tools, which were the only ones applicable to the small sample analyzed and are, thus, only descriptive and lack causality proof. However, the series includes a group of trauma patients (with a common condition) who, although with injuries of different nature, were subjected to standardized institutional therapy, which gives a more realistic picture of prognostic indices than studies showing combined results of trauma and non-trauma patients. Nevertheless, we are aware that the conclusions drawn should await validation that only a multicenter, prospective, and randomized study can provide to the scientific community interested in the topic.

Conclusions

In Hospital Central Militar, the rate of EAF formation in trauma patients undergoing the open abdomen technique with the VAC® NPWT device is 5.9%, which is lower than reported in specialized medical literature.

NPWT duration with the VAC® device ≥ 11.2 days in trauma patients undergoing the open abdomen technique significantly increases the possibility of developing an EAF (46.9% vs 1.3%; RR, 3.67; 95%CI, 2.4-6.68; $P = .017$). Performing ≥ 2.6 changes of the VAC® NPWT device in trauma patients undergoing the open abdomen technique significantly increases the possibility of developing an EAF (34.6% vs 0.5%; RR, 6.92; 95%CI, 1.1-4.3; $P < .0001$).

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Conflicts of interest

None declared.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee

for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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