## RESEARCH



# Temporary abdominal closure in trauma surgery: a comparative cohort study between open abdomen techniques with negative pressure therapy

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#### **Abstract**

**Background** The use of negative pressure therapy (NPT) to maintain an open abdomen (OA) is a well-established practice in trauma surgery. The aim of this study was to compare two techniques for temporary closure of the OA using negative pressure therapy NPT with regard to the outcome of definitive closure of the abdominal wall, the incidence of complications and mortality.

**Methodology** Controlled retrospective cohort study with trauma patients submitted to NPT as a method of maintaining OA. The groups were divided into "Group B", referring to the use of NPT by Barker dressing, and "Group V", referring to the use of NPT by RENASYS<sup>TM</sup> AB abdominal dressing.

Results A total of 76 patients were analyzed (Group B, n=48; Group V, n=28), with mean age of 34 years, and 92% male. The groups were equivalent in their trauma severity scores. The overall rate of abdominal cavity closure was 38%, higher in Group V than in Group B (46%, n=13 vs. 33%, n=16, p=0.374). The peritoneostomy outcome was significantly higher in group B (48%, n=23 vs. 21%, n=6, p=0.028). Moderate negative correlation was observed between the duration of OA therapy and the rate of definitive closure of the abdominal cavity ( $\rho$  -0.637; p<0.0001). Damage control surgery (DCS) and shorter duration of OA were identified as predictors of closure.

**Conclusion** OA with NPT by industrial abdominal dressing decreases the rate of peritoniostomy as abdominal wall outcome compared to Barker dressing.

**Keywords** Open abdomen techniques · Negative pressure wound treatment · Surgical treatment of trauma · Multiple trauma

# Introduction

In seriously injured patients, physiological homeostasis is the priority and anatomical reconstruction is postponed until the patient regains hemodynamic stability. In this approach, the focus will be on controlling bleeding and contamination.

operative tactic, with a view to approaching the abdominal cavity at a scheduled time. In trauma surgery, this technique is applied not only in damage control surgery (DCS), but also in the treatment of patients with abdominal complications after definitive surgery [1, 2].

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<sup>3</sup> General and Trauma Surgery Department, Hospital de Pronto Socorro de Porto Alegre, Porto Alegre, Brazil There are three main indications for the use of OA: anatomical (due to inability to approach the edges of the surgical incision, loss of tissue or risk of compartment syndrome), physiological (due to clinical instability) or strategic (due to the need for scheduled re-interventions). All three indications are seen in trauma patients, possibly overlapping depending on the case [3]. Peritoneostomy and laparostomy are synonyms for open abdomen, corresponding to

Thus, the definitive closure of the laparotomy will not be performed and the open abdomen (OA) is indicated as an



the operative strategy in which abdominal closure by planes is considered impossible or undue, and the option is to keep the abdominal viscera under some form of containment [4]. However, depending on the scenario, a programmed ventral hernia is also a viable option. In situations where the abdomen is considered frozen, the option can be taken to reconstruct the abdominal wall later, up to a year after the traumatic event [5].

Choosing the OA strategy, however, implies risks of various complications, including gastrointestinal (such as enteroatmospheric fistulas and abdominal adhesions), hydroelectrolytic balance (loss of electrolytes and fluids), infectious (such as surgical wound infection or fungal contamination of the abdominal cavity due to prolonged tissue exposure), programmed incisional hernias and loss of abdominal dominance, as well as overall mortality. These complications can cause significant damage to the post-operative recovery and quality of life of trauma patients, including making it difficult for them to return to productive life after hospital discharge [6, 7].

A number of methods have been described for temporarily closing the abdominal cavity, with negative pressure therapy (NPT) being the most recent and currently recommended technique of choice. It is already well established in the literature that NPT has better results than other methods [8, 9].

Among the techniques for applying NPT are the Barker technique and industrial model dressings. Handmade dressings using the Barker technique use low-cost materials available in a hospital environment, such as sterile compresses, silicone suction tubes and adhesive plastic, and are connected to the hospital's central vacuum system. The industrial dressing, on the other hand, consists of a set of equipment manufactured to ensure that the vacuum is maintained at a constant pressure in a closed system, providing adequate drainage of inflammatory liquids from the splanchnic circulation, and performing more efficient traction of the edges of the aponeurotic incision to prevent loss of abdominal domain [7, 10, 11].

Although OA is a well-established strategy in terms of the overall survival of patients undergoing DCS or who develop post-operative complications, there is still no definitive literature on morbidity outcomes in trauma patients, especially when comparing different NPT techniques and the rate of definitive abdominal wall closure within 30 days of the trauma [12].

In this context, the aim of this study was to compare the rate of primary closure of the abdominal cavity in the acute period (within 30 days of the trauma) between two techniques for maintaining the OA with NPT (handmade dressing and industrial dressing) in a population of trauma victims, as well as to compare NPT techniques in relation to the incidence of complications.

## **Methods**

This is a historically-controlled cohort study that analyzed trauma patients treated at the Hospital de Pronto Socorro de Porto Alegre, a referral hospital for trauma care, from November 1, 2016 to July 31, 2022, in which the strategy of OA by NPT was employed in surgical management during their hospital stay. Patients were included if NPT was indicated both as a stage of DCS on admission and for the treatment of early complications (within 30 days of trauma). Patients with incomplete medical records, who had undergone any other OA maintenance technique other than NPT, who had died within 48 h of hospital admission, and those who had not completed their hospital stay by the end of the study period were excluded from the study. The study was approved by the Research Ethics Committee of the Municipal Health Department of Porto Alegre under opinion nº 4.743.882 of Plataforma Brasil, and with Certification of Submission for Ethical Appraisal registration no 44991720.1.000.5338.

The patients were divided into two groups ("Group B" and "Group V") based on the NPT technique used. "Group B" comprised patients who exclusively used NPT by handmade dressing using the Barker technique (Fig. 1), while 'Group V' comprised those who used NPT with RENASYS<sup>TM</sup> AB Abdominal Dressing (Smith&Nephew<sup>®</sup>, London, UK - fig. 2) as the main technique for maintaining the OA.

The indication for the OA and the technique used were defined by the attending surgeon, with no influence from the study. However, the hospital's General Surgery and Trauma service follows specific guidelines for choosing the technique, according to the availability of resources and institutional protocol. The recommendation is to use NPT for all trauma and OA patients, starting with handmade dressings using the Barker technique for the first intervention and moving on to industrial dressings from the second intervention onwards. This guideline was implemented in May 2019 and remained valid until the end of the study. During the period, the industrial dressing used was the "RENASYSTM AB with Soft Port", manufactured by Smith & Nephew® and acquired by public tender, without interference from the study in the choice of device.

The main outcome chosen was definitive closure of the OA within 30 days of the trauma. A sample size of 44 subjects (22 for each group) was calculated to test whether there was a difference between the percentages of closure of the OA between "Group B" and "Group V" (with the



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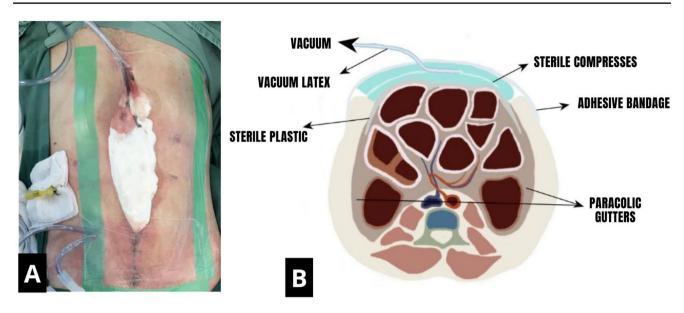


Fig. 1 A - Schematic representation of an axial cut at abdominal level of an open abdomen using handmade negative pressure therapy. **B** - Negative Pressure Therapy with Barker Dressing, handmade method (personal archive)

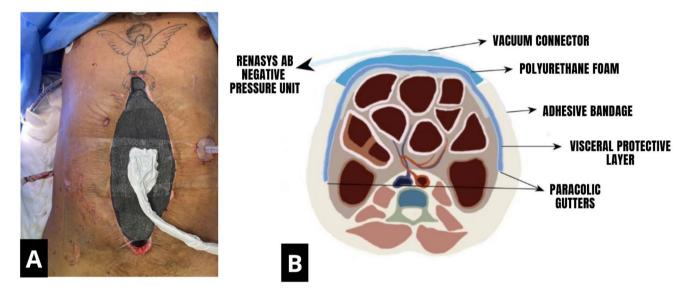


Fig. 2 A - Schematic representation of an axial cut at abdominal level of an open abdomen using industrial negative pressure therapy. B - Negative Pressure Therapy with RENASYS<sup>TM</sup> AB Abdominal Dressing with Soft Port (personal archive)

addition of 5% for possible losses and refusals, this number should be 48). The calculation considered a power of 80%, a significance level of 5%, percentages of 73% and 27%, respectively, according to an article published by Cheathan et al. [13, 14].

The following variables were analyzed in the study: Gender, age, comorbidities, body mass index (BMI), physics of the trauma, vital signs on admission, transfusion and quantity of blood products in the first 24 h of hospitalization, abdominal organs affected, associated extraperitoneal injuries, indication for laparotomy (therapeutic or DCS), making an ostomy, time of starting OA (first surgery or at

reintervention), method of OA, indication for OA (physiological, strategic or anatomical), number of OA changes, days in OA, clinical and surgical complications, complications related to OA, reoperation after aponeurosis closure, number of unscheduled reinterventions, length of stay, days in the intensive care unit (ICU), outcome from the point of view of the aponeurosis and patient outcome (discharge, hospital transfer or death).

For the purposes of this study, trauma scores were calculated and verified based on information related to injuries, vital signs and physical examination/imaging findings contained in medical records. The RTS was calculated according



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to the formula RTS=0.9368 x GCS+0.7326 x SBP+0.2908 x RR, where GCS=Glasgow Coma Scale, SBP=systolic blood pressure, and RR=respiratory rate of the patient at hospital admission [15, 16]. The ATI was scored based on the severity classification of the anatomical injury attributed to each intra-abdominal organ during laparotomy [17]. The ISS was calculated as the sum of the squares of the highest Abbreviated Injury Scale (AIS, 2015) code in three most severely injured body regions [18]. The NISS uses the same calculation criteria as the ISS, but it scores the three most severe injuries regardless of the affected body region [19].

The probability of survival (Ps), estimated by TRISS was determined by the equation Ps=1/(1+e-b), where e=2.7183, and  $b=b0+(b1 \times RTS)+(b2 \times ISS)+(b3 \times age)$ , where b0 to b3 are coefficients with different weights for blunt or penetrating trauma, and the age index is 0 in patients < 55 years and 1 in  $\geq$ 55 years [20, 21]. NTRISS uses the same calculation criteria as the TRISS, replacing ISS for NISS as the anatomical index [22]. These trauma indices standardize the assessment of injury severity, guiding critical decisions and resource allocation in trauma care, and are essential for optimizing patient management and improving outcomes in trauma patients.

Initially, descriptive statistics were extracted. The qualitative variables were described using absolute numbers and percentages. Quantitative variables were described using the mean and standard deviation in cases where their distribution was normal, and using the median and interquartile range in asymmetric distributions. The interquartile range (IQR) measures data dispersion by calculating the difference between the first (Q1) and third (Q3) quartiles, representing the middle 50% of the data. It is less sensitive to outliers compared to the full range, making it a more robust measure of variation. Normality was assessed using the asymmetry and kurtosis coefficients, as well as the Shapiro-Wilk test.

To compare proportions, the chi-square test with Pearson's correlation was used, or Fisher's Exact Test for cases in which one or more expected values lower than five were present in the contingency table. The Student's t-test for independent samples (variables with a normal distribution) or the Mann-Whitney test (variables with an asymmetric distribution) were used to compare measures of central tendency.

The two study groups were defined using stratification based on dressing mode (Group B vs. Group V). Baseline and operative variables and outcomes were assessed using univariate statistics. The predictive accuracy of the severity scores in relation to the aponeurosis closure outcome was assessed using sensitivity and specificity analyses (ROC curves).

Variables with statistical significance in the univariate analysis or with clinical importance were modeled using binary logistic regression to identify independent predictive factors related to the abdominal wall closure outcome. To assess the quality and fit of the model, Nagelkerke's  $R^2$ , the Hosmer-Lemeshow test and the calculation of the model's predictive accuracy through sensitivity and specificity analysis were used. Associations were described by odds ratios and their respective 95% confidence intervals. Values of p < 0.05 were considered statistically significant. The statistical analysis was carried out using the Python programming language in the JupyterLab® tool, version 4.2.3.

# Results

In the period analyzed, 110 trauma patients underwent OA at the study institution. After excluding 34 patients due to the established criteria, 76 patients were selected for analysis, with 48 patients allocated to "Group B" and 28 patients to "Group V" (Fig. 3).

The study sample was predominantly male (n=70; 92%), with an average age of 34 years. The most common physical trauma was penetrating (n=60; 79%), most of which was caused by a firearm projectile (n=50; 65%). DCS was indicated on admission for 29 patients (38%). There was no difference between the groups in terms of baseline characteristics, trauma mechanism, associated injuries, indication for DSC and indication for OA (Table 1). Group V showed greater severity in the anatomical injury scores (ISS and NISS), but no difference in the physiological and mixed scores.

Table 2 summarizes the postoperative evolution, complications related to the OA and the abdominal wall outcomes found in the study. There was a higher proportion of patients with OA-related complications in group B (19%; n=9 vs. 7%; n=2, p=0.198), mostly enteroatmospheric fistulas, although this was not statistically significant. There was also no statistically significant difference between the groups in terms of mortality, length of ICU stay and length of hospital stay.

As for the analysis of abdominal wall reconstruction within 30 days, there was no statistically significant difference between the groups in terms of definitive closure (33%; n=16 vs. 46%; n=13, p=0.374); however, the outcome peritoniostomy was more frequent in group B (48%; n=23 vs. 21%; n=6, p=0.028), so group V had a higher proportion of definitive closures and programmed hernias. Only one patient with complications related to OA had definitive closure.

Patients undergoing DCS had a higher rate of abdominal wall closure compared to patients undergoing OA for other indications (62%, n=18 vs. 40%, n=11, p=0.001). In fact, patients with an early indication for OA had a higher rate



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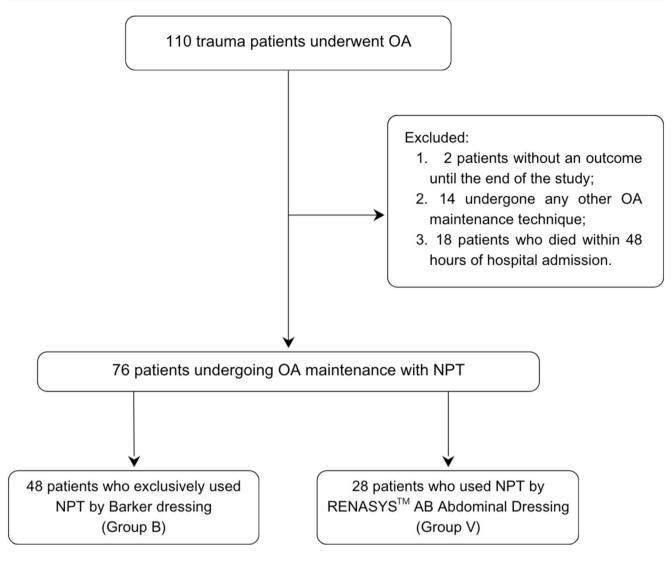


Fig. 3 Sampling flowchart

of primary closure compared to those with a late indication (53% vs. 26%; p=0.017). Of the indications for OA, the strategic one had the lowest closure rate (13.8%, p=0.003). Based on the univariate model, the logistic regression analysis defined the indication for OA by DCS and the duration of OA as independent predictors of abdominal wall closure (Table 3).

A moderate negative correlation was observed between the duration of OA therapy and the rate of definitive closure of the abdominal cavity (Spearman's Coefficient: -0.637; p<0.0001), i.e. the shorter the duration of OA, the greater the chance of total closure of the aponeurosis. The median number of days of OA use was 4 days (IQR 4) for patients who achieved abdominal closure, compared to a median of 17 days (IQR 17) of OA for those whose outcome was programmed ventral hernia, regardless of the study group. Thus, for each additional day of OA use, the chance of definitive

closure of the abdominal cavity decreased by around 42.4% (95% CI 0.396–0.837).

None of the trauma scores evaluated showed good predictive performance for the outcome of aponeurosis closure (Fig. 4). The NISS showed the best predictive accuracy among the scores evaluated, although only 55%.

## **Discussion**

This study implements a comparative cohort analysis with a trauma victim-only population undergoing OA therapy with different NPT techniques, a topic that has hitherto been scarce in the literature. Despite the small sample size compared to other studies already published on NPT, this study investigates a specific patient profile, with particularities of the trauma disease, treated with limited resources in the context of public health.



Table 1 Demographic data of the sample studied

Variables	Group B	Group V	p
	(n=48)	(n=28)	
Age, mean ± SD (years)	$33,3 \pm 12,8$	$36,1 \pm 15,0$	0,386
<b>Sex</b> , <b>male</b> - no. (%)	44 (91,7)	26 (92,9)	1,000
<b>BMI</b> , mean $(kg/m)^2$	$25,5 \pm 3,6$	$26,2 \pm 5,0$	0,489
Comorbidities - no. (%)	5 (10,4)	8 (28,6)	0,059
Trauma mechanism - no. (%)	38 (79,2)	22 (78,6)	0,951
Penetrating	32 (66,7)	18 (64,3)	
- FBI	6 (12,5)	4 (14,3)	
- BWI	10 (20,8)	6 (21,4)	
Blunt			
Associated injury - no. (%)	29 (60,4)	22 (78,6)	0,104
RTS, median (IQR)	8,0 (1)	8,0 (2)	0,595
ATI, mean±SD	$21,0 \pm 12,4$	$23,7 \pm 14,9$	0,390
ISS, mean ± SD	$22,1 \pm 10,4$	$30,8 \pm 11,3$	0,001
NISS, mean ± SD	$31,7 \pm 12,9$	$41,2\pm17,6$	0,017
TRISS, median (IQR), %	97,4 (5,4)	94,4 (16,1)	0,170
NTRISS, median (IQR), %	95,4 (10,9)	87,3 (23,0)	0,163
Shock Index, mean±SD	$1,19 \pm 0,49$	$1,14 \pm 0,44$	0,694
<b>Blood transfusion</b>	37 (77,1)	22 (78,6)	0,881
Damage control surgery - no.(%)	16 (33,3)	13 (46,4)	0,329
Late onset OA	28 (58,3)	14 (50,0)	0,481
Indication of OA - no. (%)			
Strategic	21 (43,8)	5 (17,9)	0,072
Anatomical	7 (16,7)	15 (25,0)	
Physiological	19 (39,6)	16 (57,1)	

SD: standard deviation; BMI: Body Mass Index; FPI: Firearm Projectile *Injury*; BWI: Blunt Weapon Injury; RTS: *Revised Trauma Score*; ATI: *Abdominal Trauma Index*; ISS: *Injury Severity Score*; NISS: *New Injury Severity Score*; TRISS: *Trauma Score and Injury System*; NTRISS: New Trauma Score and Injury *System*; OA: Open Abdomen

Table 2 Sample outcomes

Variables	Group B	Group V	p	
	(n=48)	(n=28)		
Dressing changes, median (IQR), number	3 (5)	3 (3)	0,947	
Aponeurosis reoperation - no. (%)	33 (67)	22 (79)	0,356	
<b>Ostomy</b> - no. (%)	15 (31)	15 (54)	0,055	
Surgical complications - no.(%)	41 (85)	27 (96)	0,245	
Enteroatmospheric fistula	24 (50)	15 (54)	0,815	
Intra-abdominal abscess	22 (46)	9 (32)	0,334	
Ischemia of the viscera	4 (8)	5 (18)	0,276	
Abdominal compartment syndrome	3 (6)	1 (4)	0,614	
Evisceration	6 (12,5)	4 (14)	0,824	
Intra-abdominal bleeding	0	1 (4)	0,133	
Complication related to OA - no.(%)	9 (19)	2 (7)	0,198	
Enteroatmospheric fistula	9 (19)	1 (4)		
Bleeding	0	1 (4)		
Definitive closure of the abdominal wall - no. (%)	16 (33)	13 (46)	0,374	
Programmed partial or total hernia - no.(%)	9 (19)	9 (32)	0,263	
Peritoneostomy - no.(%)	23 (48)	6 (21)	0,028	
Length of ICU stay, median (IQR), days	20 (39)	30,5 (24)	0,490	
Time until definitive closure, median (IQR), days	11 (20)	11 (11)	0,981	
Length of stay, median (IQR), days*	46 (42)	43,5 (28)	0,748	
<b>Death</b> - no. (%)	12 (25)	9 (32)	0,597	

IQR: Interquartile Range; OA: Open abdomen; ICU: Intensive Care Unit



Table 3 Multivariate analysis of factors predictive of abdominal wall closure

Explanatory Variables	В	p	Odds Ratio	CI 95% - Odds Ratio	
				Lower	Higher
DCS	5,482	,035	240,208	1,452	39731,551
Days OA	-0,552	0,004	0,576	0,396	0,837
Strategic OA		0,378			
Anatomical OA	0,823	0,592	2,276	0,112	46,113
Physiological	-1,763	0,389	0,172	0,003	9,491
OA					
Late OA	0,636	0,626	1,890	0,146	24,501
OA	33,095	,999	2,360E+14	0,000	
Complication					
Aponeurosis	0,899	0,480	2,456	0,202	29,816
reoperation					
Abscess	-0,694	0,676	0,500	0,019	12,954
Fistula	-50,100	0,999	0,000	0,000	
Group V	1,189	0,299	3,285	0,348	31,006
Constant	0,978	0,490	2,660		

OA plays an important role in DCS and in the initial control of infectious focus, shortening surgical time, allowing re-access to the abdominal cavity and preventing compartment syndrome, without damaging the aponeurotic fascia

[2, 5, 6]. However, the technique is not without risks and complications [23–25]. The definitive closure of the abdominal cavity should therefore be prioritized and considered in all interventions to which the patient is subjected, taking into account a multidisciplinary approach and, eventually, the combined use of closure techniques [26–28].

The health technologies involved in the management of OA have progressed in recent years, making this patient a challenge for intensivists and surgeons [29]. The use of direct peritoneal resuscitation as an ally to shock management, as well as the use of polypropylene mesh for dynamic traction of the aponeurotic fascia and maintenance of abdominal dominance have improved the care of critically ill patients undergoing OA [30, 31]. These techniques were not used in the population of this study, whose design focused exclusively on comparing the main modalities of NPT and their impact on patients, considering their clinical characteristics and the severity of the trauma.

The overall mortality rate of 27.6% found in the study population is compatible with that reported in the literature for patients with an indication for OA. A recent systematic review showed a mortality rate of 33.8% (ranging from 10 to 45%) in patients undergoing abdominal NPT [6, 13].

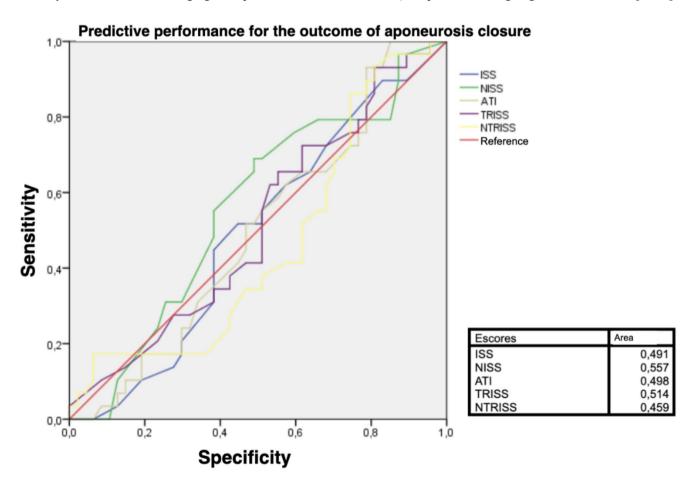


Fig. 4 ROC curve of trauma scores as predictive model for definitive aponeurosis closure



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Another series, exclusively involving the elderly, reported by Proaño-Zamudio, found a 50.6% 30-day mortality rate [32]. However, it should be emphasized that OA and the use of NPT are indicated for critically ill patients, and that mortality is mostly due to the pathophysiology of the underlying disease.

This study did not confirm the superiority of the industrial NPT device for definitive closure of the abdominal cavity when compared to the Barker dressing (33% vs. 46%, p=0.374). Cheatham et al. reported a rate of 69% vs. 51% (p=0.03) when comparing the two methods, but the study considered all indications for OA and not just trauma patients [13].

The study by Willms et al. described the use of a dynamic traction technique, the use of any type of NPT and the use of a visceral protective layer as the main predictors of definitive closure of the aponeurosis in OA [33]. However, the population studied by the author also includes different underlying diseases for the indication of OA, which makes it impossible to assess the outcome in trauma victims.

OA time was identified as an independent predictor of definitive closure of the cavity with a negative correlation, i.e. fewer days of OA was associated with a greater likelihood of closure. The median number of days of OA in the closure group was 4 days, compared to 14 days in patients who underwent programmed ventral hernia or peritoneostomy. Beale et al., in a study of trauma victims undergoing OA, also reported 4 days as the median time for successful abdominal wall closure [34]. Morais et al. reported that a greater number of interventions and prolonged ICU stay are associated with failure to close the abdominal cavity [35].

Despite the study's findings regarding total closure of the abdominal cavity, it should be noted that the outcome of partial or total hernia at the time of discharge is acceptable. Zosa et al. showed that patients who were discharged with total closure of the abdominal cavity or with a programmed ventral hernia had similar outcomes within 14 months, in terms of returning to daily activities and quality of life, as long as there was a plan to reconstruct the abdominal cavity within 9 months for the second group [5].

Nevertheless, this study identified a trend towards greater morbidity associated with the use of artisanal NPT compared to industrial NPT, with an incidence of enteroatmospheric fistula in 19% (n=9) of group B and 4% (n=1) of group V, but without statistical significance (p=0.198). Previous literature reports a prevalence of 8 to 10% of enteric fistula in OA, without differentiating the method of NPT [24, 36]. In a previous study, Vengail et al. analyzed risk factors for the development of abdominal fistula and sepsis in a similar population, but there was no correlation between the outcome and data on volume resuscitation and coagulopathy in the study sample [36]. This complication has a direct impact

on the quality of life and rehabilitation of trauma victims and should be prevented.

Previous studies suggest that the use of NPT with industrial dressing reduces ICU time and length of stay for patients undergoing OA [37, 38]. However, this sample showed no statistically significant difference between the groups in terms of these parameters. It is possible that trauma patients have more demands on their recovery and rehabilitation, requiring ICU beds and prolonged hospitalization, such as associated head trauma or spinal cord trauma, as well as severe injuries to the pelvis and extremities, with or without loss of substance.

In this context, Baele et al. reported that penetrating trauma and worse trauma scores on admission are independent factors for the failure rate of definitive closure of the abdominal cavity [34]. In the present study, severity scores did not show good predictive accuracy for this outcome. Among the independent predictive factors for successful closure identified in the logistic regression, the only one considered exclusive to the trauma population was the indication of OA by DCS on admission. This suggests that late indications for OA, for strategic or anatomical reasons, are related to complications that make it difficult to close the abdomen definitively, such as abscesses or fistulas.

The study has limitations as it is a single-center, retrospective analysis based on a review of medical records, with a limited number of patients included in the period. In addition, dynamic aponeurosis traction techniques were not applied to patients undergoing NPT, as recommended by some authors. However, the study reflects the routine use of NPT in OA in a reference trauma center.

# **Conclusion**

Choosing to maintain OA with NPT by industrial abdominal dressing decreases the rate of peritoniostomy as an abdominal wall outcome compared to Barker dressing. In addition, the shorter duration of OA therapy is associated with a greater likelihood of total abdominal wall closure. However, the use of industrial abdominal dressings was not superior to Barker dressings in terms of mortality, ICU time or length of stay for the trauma population studied. The patient's clinical status and severity of trauma on admission did not seem to influence the outcome studied. More studies, preferably multicenter, with an exclusively trauma population, are needed to obtain definitive evidence on the subject.

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Data availability No datasets were generated or analysed during the current study.

## **Declarations**

Ethics approval and patient consent to participate The study protocol is in accordance with the ethical standards of the institution at which the project was conducted and the 1964 Helsinki Declaration and its later amendments. Approval was granted from the Municipal Ethics and Research Committee (CEP-SMS) with a waiver of informed consent, under the registration number CAAE 44991720.1.0000.5338.

Competing interests The authors declare no competing interests.

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