Open abdominal management after damage-control laparotomy for trauma: A prospective observational American Association for the Surgery of Trauma multicenter study

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BACKGROUND: We conducted a prospective observational multi-institutional study to examine the natural history of the open abdomen (OA) after trauma and identify risk factors for failure to achieve definitive primary fascial closure (DPC) after OA use in trauma.

METHODS: Adults requiring OA for trauma were enrolled during a 2-year period. Demographics, presentation, and management variables were used to compare primary fascial closure and non–primary fascial closure patients, with logistic regression used to identify independent risk factors for failure to achieve primary fascial closure.

RESULTS: A total of 572 patients from 14 American College of Surgeons–verified Level I trauma centers were enrolled. The majority were male (79%), mean (SD) age 39 (17) years. Injury Severity Score (ISS) was 15 or greater in 85% of patients and 84% had an abdominal Abbreviated Injury Scale (AIS) score of 3 or greater. Overall mortality was 23%. Initial primary fascial closure with unaltered native fascia was achieved in 379 patients (66%). Patients surviving at least 48 hours were grouped into those achieving DPC and those who did not achieve DPC after OA use. After logistic regression, independent risk factors for failure to achieve DPC included the number of reexplorations required (adjusted odds ratio [AOR], 1.3; 95% confidence interval (CI), 1.2–1.6; $p < 0.001$) the development of intra-abdominal abscess/sepsis (AOR, 2.4; 95% CI, 1.2–4.8; $p = 0.011$) bloodstream infection (AOR, 2.6; 95% CI, 1.2–5.7; $p = 0.017$), acute renal failure (AOR, 2.3; 95% CI, 1.2–5.7; $p = 0.007$), enteric fistula (AOR, 6.4; 95% CI, 1.2–32.8; $p = 0.010$) and ISS of greater than 15 (AOR, 2.5; 95% CI, 1.1–5.9; $p = 0.037$).

CONCLUSION: Our study identifies independent risk factors associated with failure to achieve primary fascial closure during initial hospitalization after OA use for trauma. Additional study is required to validate appropriate algorithms that optimize the opportunity to achieve primary fascial closure and outcomes in this population. (*J Trauma Acute Care Surg*. 2013;74: 113–122. Copyright © 2013 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: Prognostic study, level III.

KEY WORDS: Trauma; open abdomen; abdominal trauma.

Since the 1990s,[1] the use of open abdominal techniques has emerged as a common component of the management of severe abdominal trauma. Although the precise incidence of open abdomen (OA) use after injury has not been well defined, this operative approach is used for a variety of reasons potentially beneficial to severely injured patients. Commonly espoused benefits of OA use in this population include the mitigation of risk for abdominal compartment syndrome and the facilitation of abbreviated operation in physiologically depleted patients.

Appreciation for the potential complications of prolonged OA use, however, has continued to evolve. Accordingly, various surgical techniques and nonanatomic coverage alternatives for early restoration of abdominal domain after OA use

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have been proposed. The ideal outcome, however, remains the restoration of normal anatomic architecture of the abdominal wall through definitive primary fascial closure (DPC). Ideally, this DPC would be completed at the earliest safe interval following the resolution of the need for OA management.

The risks for failure to achieve DPC after OA use, to date, have not been well elucidated. The purposes of our present study were to document the natural history of OA use in a large population of trauma patients treated with this approach and to identify the independent risk factors associated with failure to achieve DPC in this population.

PATIENTS AND METHODS

Methods

This was a prospective observational multi-institutional study sponsored by the American Association for the Surgery of Trauma (AAST). The AAST Multi-Institutional Trials Committee approved the study protocol, and each participating center obtained approval from its institutional review board. Patients with OAs following damage-control laparotomy were prospectively enrolled during a 2-year period from 2010 through 2011. The primary aim of the study was to determine the independent predictors of failure to achieve primary closure of an OA during the initial hospitalization following trauma. Secondary aims were to (i) document the indications for the OA (ii) and determine the effectiveness of various surgical management approaches in achieving primary closure.

The inclusion criterion was nonclosure of fascia following the initial trauma laparotomy. Patients younger than 18 years and pregnant patients were excluded from the study. All patients included in the study had basic demographic data, admission laboratory values, intraoperative details, injury patterns, fluid use (both intraoperatively and postoperatively for the first 48 hours), ventilator settings, and OA management documented. Participating centers securely uploaded data through the AAST multicenter study portal. These data were subsequently collected at the end of the study period and analyzed by the principal investigators.

Patients who failed to survive at least 48 hours from admission underwent recording of their information but were not included in the present analysis. Among those that survived at least 48 hours, patients who achieved primary closure during initial hospitalization were compared with patients managed otherwise. Univariate analyses were performed to compare these two groups of patients. The Student's t test was used to compare continuous variables, and Pearson's χ^2 or Fisher's exact test was used to compare proportions. Two-tailed comparisons were used in all cases when available. Variables from the univariate analysis differing at $p < 0.2$ and clinically important variables were entered into a stepwise logistic regression model to identify independent risk factors for failure to achieve definitive primary closure of the OA. Patients who died within the first 48 hours were excluded from this analysis.

RESULTS

A total of 572 patients from the 14 Level 1 trauma centers participating in the study were included in this study. Five hundred seventeen survived at least 48 hours and were included in this analysis. The mean (SD) age of these patients enrolled was 39 (17) years, with 20% of this population 55 year or older. Most patients (79%) were male and were predominantly patients with blunt trauma (61%). Severe abdominal injury (Abbreviated Injury Scale [AIS] score ≥ 3) was a common pattern in this population (84%), which was associated with a severe global injury burden (Injury Severity Score [ISS] ≥ 15, 85%) (Table 1.).

Patients were divided into two subpopulations—those who achieved definitive primary fascial closure during their initial hospitalization without complications (DPC) and those that did not (nonprimary closure [NPC]). Figure 1 shows the strategies used in achieving abdominal coverage in this study. Among 572 patients enrolled overall, 55 died in the first 48 hours and were not able to have coverage attempted. Of the survivors for more than 48 hours, 379 (66%) had an attempted primary reapproximation/closure of native, unaltered fascia. Of these patients, 41 required exploration for a variety of reasons, including abdominal compartment syndrome, abdominal sepsis, dehiscence, and bleeding. The mortality in the reexploration subset was 22%. Of the patients, 138 (24%) underwent an alternative form of management, including split-thickness skin grafting over exposed viscera, synthetic mesh and biosynthetic/biologic mesh use, or separation of components to achieve visceral coverage. The overall mortality in this group was 30%. For the purpose of our study, patients with failed attempt at primary fascial closure owing to the need for reexploration were included with those who were managed with other nonprimary fascial closure modalities for analysis. This grouping provided the ability to compare those patients with successful primary fascial closure after open abdominal management for trauma with those that did not achieve DPC.

Patients with DPC were less likely to be male (76% vs. 84%, $p = 0.033$) and were less likely to have an ISS of 15 or greater (ISS ≥ 15, 83% vs. 90%; $p = 0.020$) than did patients who did not achieve DPC (NPC) (Table 1). There were no significant differences in the pattern of injury in this population. Patients in the DPC group also had higher admission pH and were less likely to have significant elevations in admission lactate (lactate ≥ 7.5 was 14% for DPC and 30% for NPC, $p < 0.001$)

Most patients overall (60%) had operative procedures within the first 2 hours following injury (Table 2). Time to initial operation did not differ between DPC and NPC groups. The most common indication for an OA overall was damage control (69%), followed by the need to facilitate early reexploration (26%). Perioperative antibiotics were used in 89% of cases with the estimated blood loss exceeding 5 L in 14% of the cases. Patients who did not achieve primary closure in the study were more likely to have encountered estimated intraoperative blood loss in excess of 5 L (11% vs. 20%). This was matched with a significant increase in the use of intraoperative blood products among NPC patients (Table 2). There was no significant difference in the use of intraoperative crystalloids. Acidosis was the most frequently encountered damage-control indicator overall and in both groups, with a nonstatistically significant trend of more acidosis among NPC patients (68% vs. 74%, $p = 0.139$).

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TABLE 1. Basic Demographics Clinical Characteristics and Laboratory Values in Patients With Open Abdomens After Trauma Surviving 48

	Total (N = 517)	DPC (n = 338)	NPC (n = 179)	*p*
Age, mean (SD), y	39.1 (17.3)	38.1 (17.2)	40.8 (17.4)	0.096
Age ≥ 55 y, n (%)	104/517 (20.1)	68/338 (20.1)	36/179 (20.1)	0.999
Male, sex, n (%)	409/517 (79.1)	258/338 (76.3)	151/179 (84.4)	**0.033**
Mechanism type, n (%)				
Penetrating	200/517 (38.7)	127/338 (37.6)	73/179 (40.8)	0.476
GSW	160/517 (30.9)	98/338 (29.0)	62/179 (34.6)	
Shot gun injury	4/517 (0.8)	4/338 (1.2)	0/179 (0)	
Stab wound	32/517 (6.2)	22/338 (6.5)	10/179 (5.6)	
Other Penetrating	4/517 (0.8)	3/338 (0.9)	1/179 (0.6)	
Blunt	317/517 (61.3)	211/338 (62.4)	106/179 (59.2)	0.476
MVC	180/517(34.8)	117/338 (34.6)	63/179 (35.2)	
MCC	36/517 (7.0)	25/338 (7.4)	11/179 (6.1)	
Fall	28/517 (5.4)	22/338 (6.5)	6/179 (3.4)	
Automobile vs. pedestrian	35/517 (6.8)	21/338 (6.2)	14/179 (7.8)	
Machinery	7/517 (1.4)	4/338 (1.2)	5/179 (1.7)	
Assault	6/517 (1.2)	5/338 (1.5)	1/179 (0.6)	
Other Blunt	25/517 (4.8)	17/338 (5.0)	8/179 (4.5)	
Injury severity indices, n (%)				
Head AIS ≥ 3	109/426 (25.6)	69/266 (25.9)	40/160 (25.0)	0.830
Chest AIS ≥ 3	272/465 (58.5)	184/301 (61.1)	88/164 (53.7)	0.118
Abdomen AIS ≥ 3	414/496 (83.5)	261/321 (81.3)	153/175 (87.4)	0.080
ISS, mean (SD)	28.2 (13.7)	27.5 (13.8)	29.6 (13.6)	0.094
ISS ≥ 15	431/505 (85.3)	272/329 (82.7)	159/176 (90.3	**0.020**
Hb, mean (SD)	11.6 (3.0)	11.7 (3.4)	11.5 (2.3)	0.293
Hb < 7.0, n (%)	21/515 (4.1)	15/336 (4.5)	6/179 (3.4)	
Hb, 7.0–7.9, n (%)	26/515 (5.0)	20/336 (6.0)	6/179 (3.4)	0.305
Hb, 8.0–9.9, n (%)	87/515 (16.9)	51/336 (15.2)	36/179 (20.1)	
Hb, ≥10.0, n (%)	381/515 (74.0)	250/336 (74.4)	131/179 (73.2)	
pH, mean (SD)	7.28 (1.33)	7.31 (0.65)	7.21 (0.13)	0.418
pH < 7.0, n (%)	30/504 (6.0)	20/330 (6.1)	10/174 (5.7)	
pH, 7.0–7.19, n (%)	152/504 (30.2)	86./330 (26.1)	66/174 (37.9)	**0.046**
pH, 7.2–7.39, n (%)	284/504 (56.3)	199/330 (60.3)	85/174 (48.9)	
pH ≥ 7.40, n (%)	38/504 (7.5)	25/330 (7.6)	13/174 (7.5)	
INR, mean (SD)	1.34 (0.59)	1.33 (0.46)	1.37 (0.78)	0.442
INR < 1.20, n (%)	225/505 (44.6)	147/330 (44.5)	78/175 (44.6)	
INR, 1.20–1.59, n (%)	203/505 (40.2)	132/330 (40.0)	71/175 (40.6)	0.998
INR, 1.60–1.99, n (%)	50.505 (9.9)	33/330 (10.0)	17/175 (9.7)	
INR ≥ 2.00, n (%)	37/505 (5.3)	18/330 (5.5)	9/175 (5.1)	
Lactate, mean (SD)	5.5 (6.5)	5.1 (7.0)	6.1 (5.3)	0.109
Lactate < 2.5, n (%)	94/449 (20.9)	69/296 (23.3)	25/153 (16.3)	
Lactate, 2.5–4.9, n (%)	187/449 (41.6)	137/296 (46.3)	50/153 (32.7)	<**0.001**
Lactate, 5.0–7.4, n (%)	80/449 (17.8)	48/296 (16.2)	32/153 (20.9)	
Lactate ≥ 7.5, n (%)	88/449 (19.6)	42/296 (14.2)	46/153 (30.1)	

p values in bold are statistically significant to $p < 0.05$.
GSW, gunshot wound; Hb, hemoglobin; INR, international normalized ratio.

Intraoperatively, packing was used in 70% of cases overall, with 38% of cases requiring some hepatic intervention (Table 3). The most common hepatic intervention used was packing (18%), followed by hepatorrhaphy (13%). Bowel resection was commonly required, with 21% of patients requiring small-bowel resection and 17% requiring large-bowel resection overall. The bowel was left in discontinuity at initial operation in 23% of patients overall. Patients in the DPC group had a lower rate of nonanastomosed bowel resections (20% vs. 30%, $p = 0.031$). Vascular repairs were also common, performed in 28% of cases. Splenectomy was required in 23.6% of patients overall at initial operation. There was no difference in the frequency of other operative interventions in either group (Table 3). Negative-pressure dressings were used in 94% of

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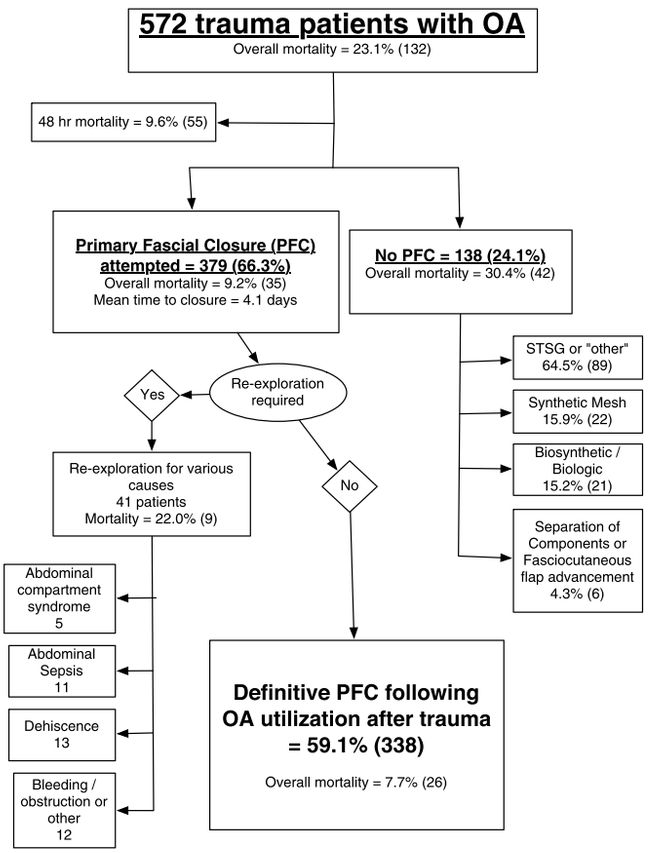

Figure 1. A total of 572 trauma patients with OA.

cases overall, with almost universal use of continuous negative pressure. There was no difference in the use, mode, and pressure setting used in either group. Most patients with negative-pressure dressings used a KCI product (61%), as opposed to an improvised negative-pressure wound device.

Most patients received less than 5 L of crystalloid (94%) or colloids (58%) within the first 24 hours postoperatively. Patients who achieved DPC did have lower mean 24-hour total fluid intake than NPC counterparts (Table 3). There was also no difference between DPC and NPC patients with regard to the time between the initial operative procedure and subsequent reexploration, but patients in the DPC group had fewer surgeries (1.9 [3.2] vs. 4.0 [4.1], $p < 0.001$). DPC patients also had significantly lower peak airway pressures (28.1 [9.1] mm Hg vs. 30.8 [10.6] mm Hg, $p < 0.002$) (Table 3).

Complications were not infrequent among patients undergoing OA use, as outlined in Table 4. Overall rates of intra-abdominal abscess/sepsis and enteric fistula were 20% and 5%, respectively. Both of these complications were significantly more likely to occur for patients failing to achieve DPC (33% abscess/sepsis, 13% fistula). Among other complications, NPC patients were also significantly more likely to manifest acute renal failure, sepsis, acute lung injury/acute respiratory distress, bloodstream infections (BSI) and catheter-related urinary tract infections (Table 4).

Compared with DPC patients, NPC counterparts had longer intensive care unit stay (22 [20] vs. 14 [12], $p < 0.001$) and hospital length of stay (37 [34] vs. 23 [16], $p < 0.001$). They also had greater ventilator day requirements (15 [16] vs. 10 [11], $p < 0.001$). Among patients surviving 48 hours, the overall mortality was significantly higher among NPC patients at 29% versus 7.7% for DPC counterparts ($p < 0.001$).

Overall closure rate for patients surviving 48 hours was 59.1% (Fig. 1). Across participating centers, the rate of closure in this study population varied from 33.4% to 72.2%. Variables differing between DPC and NPC counterparts at $p < 0.2$ in the univariate analyses were entered in a forward LR model to identify independent risk factors for failure to achieve definitive primary closure during initial hospitalization. Independent predictors identified (Table 5) included the number of explorations required, the occurrence of intra-abdominal abscess/sepsis, BSIs, acute renal failure, enteric fistula, and ISS greater than 15.

DISCUSSION

While the use of the OA has emerged as a common tool in the management of severe abdominal trauma in a variety of settings,[2] the potential for adverse events associated with OA use has not been well elucidated. Early DPC, however, remains the optimal outcome following OA use because it facilitates the restoration of normal abdominal domain and mitigates the risk represented by prolonged exposure of the viscera. Our present study is the largest examination of OA use after trauma and identifies several independent risk factors of failure to achieve DPC.

Our present data suggest that assessment of potential risk for failure to achieve DPC may begin with consideration of the initial injury magnitude. In our analysis, higher ISS proved an independent risk factors for failure to achieve DPC. The emergence of this variable in our logistic regression model suggests that the severity of initial injury plays a significant role in the subsequent course of OA patients, including the ability to achieve DPC. Non-DPC patients were also more likely to require a greater number of subsequent explorations, suggesting that the complexity of injuries and the visceral edema occurring in response to injury and resuscitation may prove significant challenges to the ability to achieve early restoration of abdominal domain. The finding that non-DPC patients had higher abdominal AIS, higher admission lactate level, greater blood loss, and higher operative blood product requirements than DPC counterparts on univariate analysis may also support the linkage between overall injury severity, resuscitative need, and subsequent inability to achieve DPC.

The choice of surgical approach for the management of OA may also prove influential in determining the subsequent success of DPC attempts. Surgical techniques, with the goal of either achieving DPC or restoring abdominal domain by other means, are diverse and sophisticated.[3,4] A variety of techniques have been described, including negative-pressure wound therapy,[5,6] Wittman patch use,[7,8] serial closure,[9] separation of components,[10] biosynthetic/synthetic mesh use,[11] or combinations of various approaches.[12]

Each of these approaches has advocates. Burlew et al.[9] at Denver Health Medical Center have recently reported their

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TABLE 2. Intraoperative Considerations in Patients With Open Abdomens After Trauma Who Survived 48 Hours

	Total (N = 517)	DPC (n = 338)	NPC (n = 179)	*p*
Time from injury to OR, n (%)				
<1 h	178/510 (34.9)	114/335 (34.0)	64/175 (36.6)	
1–2 h	127/510 (24.9)	82/335 (24.5)	45/175 (25.7)	
2–3 h	64/510 (12.5)	38/335 (11.3)	26/175 (14.9)	0.458
3–6 h	82/510 (16.1)	59/335 (17.6)	23/175 (13.1)	
>6 h	59/510 (11.6)	42/335 (12.5)	17/175 (9.7)	
Indication for open abdomen, n (%)				
Damage control	351/508 (69.1)	229/334 (68.6)	122/174 (70.1)	
To facilitate early reexploration	134/508 (26.4)	88/334 (26.3)	46/174 (26.4)	0.792
Decompression of abdomen/ICP	2/508 (0.4)	1/334 (0.3)	1/174 (0.6)	
Other	21/508 (4.1)	16/334 (4.8)	5/174 (2.9)	
Intraoperative conditions, n (%)				
Perioperative antibiotics	459/517 (88.8)	300/338 (88.8)	159/179 (88.8)	0.981
Estimated blood loss ≥ 5 L	72/510 (14.1)	36/332 (10.8)	36/178 (20.2)	**0.004**
Intraoperative crystalloids, n (%)				
<5 L	382/508 (75.2)	251/331 (75.8)	131/177 (74.0)	
5–10 L	104/508 (20.5)	69/331 (20.8)	35/177 (19.8)	0.310
>10 L	22/508 (4.3)	11/331 (3.3)	11/177 (6.2)	
Intraoperative blood products, n (%)				
<5 L	379/513 (73.9)	257/335 (76.7)	122/178 (68.5)	
5–10 L	84/513 (16.4)	55/335 (16.4)	29/178 (16.3)	**0.010**
>10 L	50/513 (9.7)	23/335 (6.9)	27/178 (15.2)	
OR fluid balance, n (%)				
<5 L	269/505 (53.3)	181/331 (54.7)	88/174 (50.6)	
5–10 L	163/505 (32.3	111/331 (33.5)	52/174 (29.9)	0.061
>10 L	73/505 (14.5)	39/331 (11.8)	34/174 (19.5)	
Damage-control indicators, n (%)				
Acidosis	363/517 (70.2)	230/338 (68.0)	133/179 (74.3)	0.139
Hypothermia (<35.0°C)	159/517 (30.8)	109/338 (32.2)	50/179 (27.9)	0.312
Clinical coagulopathy	219/517 (42.4)	141/338 (41.7)	78/179 (43.6)	0.684

p values in bold are statistically significant to $p < 0.05$.
ICP, intracranial pressure; OR, operating room.

experience with 100 consecutive patients undergoing damage-control laparotomy during a 5-year study period. Among 29 patients who did not achieve DPC at the second laparotomy and were subjected to a protocolized approach at serial closure, they reported a 100% DPC rate during the initial hospitalization. In another study conducted by Acosta et al.,[12] they found that a methodological approach using vacuum and mesh-mediated fascial traction facilitated a DPC rate of 89%. Tieu et al.[7] have reported a similar DPC rate of 82% among patients treated using a Wittman patch to facilitate closure in severely injured trauma patients and emergency surgery patients with critical illness.

To date, however, there is no substantial prospective randomized data comparing various closure approaches in a trauma OA population. In addition, the long-term outcomes following the use of various techniques is lacking. Our present examination of OA practices at several large trauma centers is illustrative of the diverse practices used in contemporary practice. In our analysis of the various approaches used, none proved superior in facilitating DPC. While the management of this challenging patient population is likely to require individualization and a familiarity with several possible surgical options, additional study is required to determine the optimal algorithm for attaining DPC after OA use.

Consistent achievement of DPC after OA use likely requires a comprehensive strategy that incorporates meticulous optimization of both surgical and perioperative management factors.[4,5,13–18] Although our present examination did not discern any difference between DPC and non-DPC patients in this regard, overresuscitation in the perioperative period may increase bowel edema and contribute to loss of abdominal domain. Prolonged intestinal discontinuity may also exacerbate this process and should likely be avoided.[19] In our present study, the perioperative management elements that emerged as independent predictors of failure to achieve DPC after OA were the occurrence of fistula development, intra-abdominal sepsis/abscess, acute renal BSIs, and the number of reexplorations. The latter finding reinforces the hypothesis that the restoration of abdominal domain at the earliest safe juncture may improve outcomes following OA use for trauma.

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TABLE 3. Operative Intervention in Patients With Open Abdomens After Trauma Surviving 48 Hours

	Total (N = 517)	DPC (n = 338)	NPC (n = 179)	*p*
Abdominal packing, n (%)	363/517 (70.2)	240/338 (71.0)	123/179 (68.7)	0.843
No. packs, mean (SD)	3.9 (5.2)	3.7 (4.5)	4.5 (6.2)	0.161
Gastric injury repair, n (%)	62/517 (12.0)	39/338 (11.5)	23/179 (12.8)	0.663
Diaphragm injury repair, n (%)	68/517 (13.2)	42/338 (12.4)	26/179 (14.5)	0.502
Bowel resection, n (%)	196/517 (37.9)	118/338 (34.9)	78/179 (43.6)	0.053
No. resections, mean (SD)	1.5 (0.1)	1.4 (0.8)	1.6 (0.9)	0.109
Small bowel resections, n (%)	109/517 (21.1)	68/338 (20.1)	41/179 (22.9)	0.120
Large bowel resections, n (%)	87/517 (16.8)	50/338 (14.8)	37/179 (20.7)	0.123
Bowel left in discontinuity, n (%)	120/517 (23.2)	67/338 (19.8)	53/179 (29.6)	**0.031**
Hepatic intervention, n (%)	196/517 (37.9)	131/338 (38.8)	65/179 (36.3)	0.586
Packing	91/517 (17.6)	63/338 (18.6)	28/179 (15.6)	
Hepatorrhapy	67/517 (13.0)	46/338 (13.6)	21/179 (11.7)	
Resection	18/517 (3.5)	11/338 (3.3)	7/179 (3.9)	0.713
Other	20/517 (3.9)	11/338 (3.3)	9/179 (5.0)	
Splenectomy, n (%)	122/517 (23.6)	78/338 (23.1)	44/179 (24.6)	0.702
Nephrectomy, n (%)	35/517 (6.8)	26/338 (7.7)	9/179 (5.0)	0.251
Vascular injury repair, n (%)	144/517 (27.9)	93/338 (27.5)	51/179 (28.5)	0.814
Thoracotomy, n (%)				
EDT	10/517 (1.9)	5/338 (1.5)	5/179 (2.8)	0.326
Posterolateral thoracotomy	6/517 (1.2)	4/338 (1.2)	2/179 (1.1)	1.000
Anterolateral thoracotomy	28/517 (5.4)	18/338 (5.3)	10/179 (5.6)	0.901
Other operative intervention	304/517 (58.8)	199/338 (58.9)	105/179 (58.7)	0.962
Negative-pressure dressing, n (%)				
Continuous NPWT	488/517 (94.4)	318/338 (94.1)	170/179 (95.0)	0.273
Type of device, n (%)				
Noncommercial apparatus	196/517 (37.9)	122/338 (36.1)	74/179 (41.3)	0.317
KCI device	314/517 (60.7)	211/338 (62.4)	103/179 (57.5)	0.070
Postoperative fluids				
24-h crystalloids, mean (SD)	6,584 (8,410)	6,043 (8,755)	7,592 (7,648)	**0.047**
<5 L, n (%)	428/457 (93.7)	279/299 (93.3)	149/158 (94.3)	
5–10 L, n (%)	12/457 (2.6)	9/299 (3.0)	3/158 (1.9)	0.827
>10 L, n (%)	17/457 (3.7)	11/299 (3.7)	6/158 (3.8)	
24-h colloids, mean (SD)	1,655 (3,843)	1,575 (4,044)	1,802 (3,444)	0.527
<5 L, n (%)	265/456 (58.1)	182/299 (60.9)	83/157 (52.9)	
5–10 L, n (%)	97/456 (21.3)	65/299 (21.7)	32/157 (20.4)	0.061
>10 L, n (%)	94/456 (20.6)	52/299 (17.4)	42/157 (26.8)	
Total fluid intake 24 h, mean (SD)	8,239 (9,694)	7,619 (10,012)	9,395 (8,986)	**0.049**
Total fluid intake 48 h, mean (SD)	8,531 (9,470)	7,831 (8,467)	9,329 (11,076)	0.118
Time to reexploration, mean (SD), h	40.6 (24.7)	35.9 (21.2)	36.3 (26.6)	0.833
No. reexplorations, mean (SD)	2.2 (1.8)	1.9 (3.2)	4.0 (4.1)	**<0.001**
Postoperative antibiotics, n (%)	291/517 (56.3)	198/338 (58.6)	93/179 (52.0)	0.149
Peak airway pressure, mean (SD)	29.1 (9.7)	28.1 (9.1)	30.8 (10.6)	**0.002**

p values in bold are statistically significant to $p < 0.05$.
EDT, emergency department thoracotomy; NPWT, negative-pressure wound therapy.

The development of enteric fistula (alternatively termed *enteroatmospheric fistula* [EAF] in the setting of the OA) remains a dreaded potential complication of OA use. In the setting of the OA, the inability to safely resect a fistulous enteric segment and restore intestinal integrity owing to the dense adhesions of a "frozen abdomen" may significantly complicate care. While several techniques for the management enterocutaneous fistula (ECF)/EAF in this setting have been described,[20–22] the presence of an active ECF/EAF is likely to preclude the achievement of safe DPC. Unfortunately, our study design did not adequately capture the temporal relationship between ECF/EAF development and failure to achieve DPC. Accordingly, we were unable to discern if the occurrence of this complication was the "chicken or the egg"—that is, a result of failure to achieve DPC or actually a determining factor in the need for prolonged OA use. The findings of Burlew et al.[18] of the Western Trauma Association multi-institutional study group have suggested that the temporal nature of this relationship may be important. These investigators found that ECF/EAF rates increased with fascial closure attempts beyond Day 5 in

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TABLE 4. Complications and Outcomes in Open Abdomen Patients Surviving 48 Hours

	Total (N = 517)	DPC (n = 338)	NPC (n = 179)	*p*
Intra-abdominal complications, n (%)				
Intra-abdominal abscess/sepsis	102/517 (19.7)	43/338 (12.7)	59/179 (33.0)	**<0.001**
Enteric fistula	27.517 (5.2)	4/338 (1.2)	23/179 (12.8)	**<0.001**
Extra-abdominal complications, n (%)				
Acute renal failure	93/517 (18.0)	42/338 (12.4)	51/179 (28.5)	<0.001
VAP	82/517 (15.9)	47/338 (13.9)	35/179 (19.6)	0.094
Sepsis	79/517 (15.3)	41/338 (12.1)	38/179 (21.2)	**0.006**
ALI/ARDS	74/517 (14.3)	34/338 (10.1)	40/179 (22.3)	**<0.001**
DVT/PE	63/517 (12.2)	36/338 (10.7)	27/179 (15.1)	0.143
BSI	55/517 (10.6)	22/338 (6.5)	33/179 (18.4)	**<0.001**
Catheter-associated UTI	55/517 (10.6)	29/338 (8.6)	26/179 (14.5)	**0.037**
Hospital-acquired pneumonia	32/517 (6.2)	20/338 (5.9)	12/179 (6.7)	0.724
Outcomes				
ICU LOS (SD)	17.1 (16.0)	14.4 (12.3)	22.2 (20.3)	**<0.001**
Ventilator days (SD)	12.0 (13.1)	10.2 (11.0)	15.4 (15.9)	**<0.001**
Hospital LOS (SD)	28.1 (24.9)	23.3 (16.2)	37.2 (34.2)	**<0.001**
Mortality (survivors > 48 h), n (%)	77/517 (14.9)	26/338 (7.7)	51/179 (28.5)	**<0.001**

p values in bold are statistically significant to $p < 0.05$.
ALI, acute lung injury; ARDS, adult respiratory distress syndrome; DVT, deep venous thrombosis; LOS, length of stay; PE, pulmonary embolism; UTI, urinary tract infection.

their study of 204 patients undergoing OA management for trauma. Other factors, including the type and number of anastomoses, may also be of significant import in the development of this problematic complication.[23] The risk factors for ECF/EAF occurrence in OA use requires additional study, as does the optimal management of this significant complication.

Our present study also identified the development of BSIs and intra-abdominal abscess/sepsis as independent predictors of failure to achieve DPC. The occurrence of these infectious complications has previously been reported to complicate attempts at primary abdominal closure by Vogel et al.[16] at Vanderbilt University. These investigators found that, among 344 patients requiring open abdominal management, BSI was associated with the inability to achieve primary closure after OA use for both trauma and decompression for compartment syndrome. Our present reported study did not identify any benefit for specific management elements, including the use of postoperative antibiotics, which may help mitigate this risk. There was, however, considerable variation in the type and duration of antibiotic use that precluded additional meaningful investigation into this specific element of care. The role of postoperative antibiotics, particularly their role in mitigating infectious complications in OA patients, requires additional examination.

Although our study is prospective in design and represents the largest examination of OA use in a trauma population to date, it does have several important limitations that must be acknowledged. While a large number of variables were collected, the variance in practices at each of the participating centers must be considered and could not be comprehensively captured. In particular, there was no standardized protocol across participating centers to define when damage control was to be used, the method that should be used to attempt subsequent definitive primary closure, or when to start abdominal closure attempts. We have also not included a site analysis in our present examination. The timing of complications in the

TABLE 5. Predictors of Failure to Achieve Native Fascial Closure of the Open Abdomen During Initial Hospitalization for Trauma

Method, Forward LR		AOR (95% CI)	*p*	Cumulative R^2
1	No. reexplorations	1.34 (1.15–1.57)	<0.001	0.142
2	Intra-abdominal abscess/sepsis	2.43 (1.22–4.83)	0.011	0.186
3	BSIs	2.60 (1.18–5.70)	0.017	0.214
4	Acute renal failure	2.31 (1.19–4.46)	0.013	0.236
5	Enteric fistula	6.38 (1.23–32.86)	0.027	0.258
6	ISS > 15	2.48 (1.06–5.85)	0.037	0.276

Model $R^2 = 0.276$; c statistic = 0.76 (0.71–0.81). Other variables in model: age, sex, chest AIS, pH, lactate, estimated blood intraoperative blood loss, acidosis, intraoperative blood products, operating room fluid balance, number of packs used, small-bowel resection, large-bowel resection, bowel left in di.
AOR, adjusted odds, ratio; BSI, blood stream infection; CI, confidence interval; ISS, Injury Severity Score.

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OA course, particularly the previously mentioned absence of precise timing of ECF/EAF development, also represents an important limitation. In addition, our present study lacks the follow-up needed to define the impact of failure to achieve DPC or the impact on quality of life for these patients.[19,24,25] All of these limitations represent concerns that should temper any conclusions reached from our analysis or extrapolation of these data to specific individual patients.

CONCLUSION

Open abdominal management has emerged as an important advancement in the care of severely injured trauma patients. Although optimal selection for OA has not been well elucidated, maturing management paradigms continue to strive to achieve the restoration of normal abdominal domain after OA use. Our study demonstrates that the variables affecting the inability to achieve DPC after OA use span considerations that include initial injury parameters and comprehensive perioperative care. Additional study is required in the ongoing effort to define the optimal role of OA use after trauma.

AUTHORSHIP

All of the listed authors were actively engaged in the study design, analysis, and interpretation of data and the construction and editing of the final article report for this work.

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DISCLOSURE

The authors declare no conflicts of interest.

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DISCUSSION

Dr. Preston R. Miller (Winston-Salem, North Carolina): I think this paper gives a very interesting snapshot about something that we all sort of think about and do commonly in the care of our trauma patients. I think that this gives us sort

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of a state of the union. There are some questions we cannot answer with these data, but there is a lot that we can.

A couple of brief comments. I think it is interesting that it looks like in the wild type here, approximately 60% of these people end up getting primary closure during their initial hospital stay. Also very interesting, I think, given the controversy over different types of abdominal closures, is that greater than 90% of these people were managed with some sort of negative-pressure–type closure device or closure system.

I have a few questions. It is sort of generally accepted that there are two different categories or groups of patients that are managed with open abdomens.

The first are those who are closed pretty easily. They are closed on the first or second return to the operating room. Those people tend to be less sick. They tend to be less severely injured. They tend to pose a little bit less of a therapeutic challenge ongoing. Then there is the sickest of the sick, the people who have open abdomens and have multiple other problems. Do you have a feel for what your data might look like if you had eliminated or performed a subset analysis, taking out these people who are generally easy to close, generally less sick, and injured on the front end?

Second, I think it is very interesting that 94% of these people were managed with some sort of negative-pressure device. As far as negative-pressure devices go, there is a lot of research out there that talks about ways in which the open abdomen can be managed and closed, and there are no data that suggest that one is particularly better than the other or no good data, but I do think it is very interesting to say that while there may not be data, there certainly seems to be consensus among trauma centers, and that is, way more than 90% of people are using negative-pressure devices. What about the other 6% in your study? What was used in the patients who did not have a negative-pressure management system used? Did that seem to affect their outcome in any way?

Third, one of the research questions that people have looked at over and over and over again is what device, management method, or technique of taking care of these patients facilitates closure of the abdomen? There are data out there that look at negative-pressure devices, other traction devices, the Whitman Patch, and other devices, and they all tend to show when people look at this closely, and they have a protocol somewhere between 80% or even 100% closure, successful closure in similarly injured, severely ill patients. There is only 60% in this study. Can you comment on why you think that might be?

Finally, these data tell us what is happening now, and they give us a unique insight into what some of the factors are, which may prevent abdominal closure. Based on these data, what is next? Where should we go next?

Dr. Juan Duchesne (New Orleans, Louisiana): Joe, congratulations. Very nicely done. My question is related to damage-control resuscitation, a topic that you are very familiar with. Based on your multi-institutional intraoperative results, how can you explain that our trauma centers are still giving so much nonoxygen-carrying fluid intraoperatively in patients with severe hemorrhage?

Second, there is a lot of new data that you will actually be seeing very soon today regarding 100% abdominal closure in patients managed with DCR and DCS when hypertonic resuscitation is used in the intensive care unit; I believe it is time to think out of the box and swing the pendulum toward the use of alternative effective low-volume resuscitation in this group of patients. Please comment. Thank you.

Dr. Jose Diaz (Baltimore, Maryland): Dr. Dubose, this is a very nice study. I think the one piece that is missing from this prospective study is the time noted to increased complications for the patient with an open abdomen.

A lot of the information you have presented has been confirmed or at least elucidated in multiple previous retrospective studies. This, I think, is a landmark in terms of defining it in a prospective manner.

Dr. Demetrios Demetriades (Los Angeles, California): Joe, congratulations for this beautiful study. A recent prospective, multicenter study found that the type of negative-pressure therapy used for temporary closure was an independent factor determining successful primary fascia closure. Did you take this into account when you performed your analysis? Thank you.

Dr. Juan Asensio (Valhalla, New York): Dr. DuBose, congratulations. A simple question. I would like to hear if you have standardized criteria for when to institute damage-control laparotomy.

In your presentation, you had a very low number of resuscitative thoracotomies. How would this have affected the results of your study? Do you have data on the estimated blood loss and intravascular blood volume replacement? This would also significantly impact the findings of your study.

Dr. Joseph DuBose (Baltimore, Maryland): Thank you, Dr. Miller, and the other discussants for their excellent questions. Dr. Miller, I think your first question spoke very well of the optimal selection for open abdomen usewhich I think remains something that we continue to refine with time. Specifically, how many of these patients really need to have their abdomens open. I do not think we have come at a concrete consensus on that issue, but I think we are continuing to move in the right direction.

Our population was very severely injured. More than 86% had an Injury Severity Score of greater than 15. There are, however, certainly elements with the creation of this registry that we can look at and try to identify and separate those patients, learn more about those patients whose abdomen were closed early and those that were not.

Your point about the use of negative-pressure therapy is also well taken. It has certainly emerged as, based on our data, a very common practice—using both commercial and noncommercial devices. There was a wide variability in the types of products and approaches that were used, often called many different names, but there is certainly more to be examined and looked at there.

Your point about several previous very well-designed studies from very respected centers illustrating very high closure rates is also important.

I think we benefit in our study, one, from the relative anonymity of a multicenter trial. I wonder, aloud, also, if we are hitting a different portion of the pendulum in the use of open abdominal use.

As we swung far to the left and we were using it more aggressively, were there more patients that were amenable to

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early closure? Maybe, some of these patients did not need an open abdomen. As we continue to refine our use, are we looking now at sicker patient populations relative to those initial other reports?

Briefly, Dr. Duchesne, you asked why are we giving so much fluid? That is an excellent question. I do think I look very much forward to the next talk as well to learn a little bit more about the potential impact of hypertonic saline use, which I am a big proponent of, but I think that there are a lot of things that we could potentially do with fluid resuscitation in the future to help achieve higher rates of definitive primary closure.

Dr. Diaz, thank you for your question about the timing of complications. We do have that data and intend to use it in the next phase of investigation as one of our a priori secondary outcomes.

We hope to report on that in the near future.

Dr. Demetriades, you commented on the types of temporary closures and the impact that their use may potentially have on achieving definitive primary closure. That is certainly something that we have the ability to look at. The difficulty with our present data set in this registry is the sheer disparity across the board regarding the different types of techniques used.

Dr. Miller also asked about the other types that were used in addition to negative pressure. There was considerable variability in the types of negative-pressure dressings used—as well as those that were nonpressure. Among those who did not have negative-pressure therapy, there were skin closures only, Bogota bags, Ioband dressings only—so considerable variability in practice.

Finally, Dr. Asensio, this was a purely observational study, so we did not have standardized criteria. I think as we move forward and we maybe go to the next phase, we will try to develop some consensus on this issue. Achieving this consensus, however, may be very difficult because we continue to learn and refine techniques not only for indications but also for ultimate closure for open abdomen. Thank you.

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