Negative-pressure wound therapy for critically ill adults with open abdominal wounds: A systematic review

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BACKGROUND: Open abdominal management with negative-pressure wound therapy (NPWT) is increasingly used for critically ill trauma and surgery patients. We sought to determine the comparative efficacy and safety of NPWT versus alternate temporary abdominal closure (TAC) techniques in critically ill adults with open abdominal wounds.

METHODS: We conducted a systematic review of published and unpublished comparative studies. We searched MEDLINE, PubMed, EMBASE, Scopus, Web of Science, the Cochrane Database, the Center for Reviews and Dissemination, clinical trials registries, and bibliographies of included articles. Two authors independently abstracted data on study design, methodological quality, patient characteristics, and outcomes.

RESULTS: Among 2,715 citations identified, 2 randomized controlled trials and 9 cohort studies (3 prospective/6 retrospective) met inclusion criteria. Methodological quality of included prospective studies was moderate. One randomized controlled trial observed an improved fascial closure rate (relative risk [RR], 2.4; 95% confidence interval [CI], 1.0–5.3) and length of hospital stay after addition of retention sutured sequential fascial closure to the Kinetic Concepts Inc. (KCI) vacuum-assisted closure (VAC). Another reported a trend toward enhanced fascial closure using the KCI VAC versus Barker's vacuum pack (RR, 2.6; 95% CI, 0.95–7.1). A prospective cohort study observed improved mortality (RR, 0.48; 95% CI, 0.25–0.92) and fascial closure (RR, 1.5; 95% CI, 1.1–2.0) for patients who received the ABThera versus Barker's vacuum pack. Another noted a reduced arterial lactate, intra-abdominal pressure, and hospital stay for those fitted with the KCI VAC versus Bogotá bag. Most included retrospective studies exhibited low methodological quality and reported no mortality or fascial closure benefit for NPWT.

CONCLUSION: Limited prospective comparative data suggests that NPWT versus alternate TAC techniques may be linked with improved outcomes. However, the clinical heterogeneity and quality of available studies preclude definitive conclusions regarding the preferential use of NPWT over alternate TAC techniques. (*J Trauma Acute Care Surg*. 2012;73: 629–639. Copyright © 2012 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: Systematic review, level III.

KEY WORDS: Abdominal injuries; intra-abdominal sepsis; temporary abdominal closure; vacuum-assisted wound closure; wounds and injuries.

Open abdominal management with temporary abdominal closure (TAC) is increasingly used for patients with critically ill trauma, general, and vascular surgery patients.[1] Indications for leaving the abdomen open include damage control laparotomy, intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS), and planned relaparotomy, among others.[1–5] A number of TAC techniques have been used for these patient populations, including Bogotá bag, Wittmann patch (Starsurgical Inc., Burlington, WI), Barker's vacuum pack,[6,7] and commercial negative-pressure wound therapy (NPWT).[1,2,5]

NPWT is a particular TAC technique that may enhance fascial closure rates by preventing visceral adherence to the abdominal wall while maintaining medial fascial traction.[8,9] It also potentially more effectively removes proinflammatory cytokine-rich peritoneal fluid than do alternate TAC methods, which may reduce the systemic inflammatory response to injury or sepsis and associated organ dysfunction.[10,11] Unfortunately, this technique has also been linked with adverse events, including development of IAH/recurrent ACS and intestinal and enteroatmospheric fistulae.[12–15]

Although a previous systematic review afforded a weighted pooled outcomes analysis of NPWT-associated fascial closure rate and mortality, this investigation's findings were limited by its inclusion of largely uncontrolled case

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This study was presented in part at Trauma 2012: The Trauma Association of Canada Annual Scientific Meeting in Toronto, Ontario, Canada on April 12, 2012.
Drs. Roberts, Zygun, and Kirkpatrick had full access to all of the data in the study and take responsibility for the integrity of the data and accuracy of the data analysis.
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series only.[16] Since then, the results of several randomized controlled trials (RCTs) and cohort studies examining the differential efficacy of NPWT versus alternate TAC methods have been reported.[9,10,17–23] We therefore conducted a systematic review to determine the comparative efficacy of NPWT versus alternate TAC techniques on in-hospital mortality, length of hospital or intensive care unit (ICU) stay, fascial closure rate, and adverse events in critically ill adults with open abdominal wounds.

MATERIALS AND METHODS

Methods for inclusion and analysis of articles and reporting of their results were prespecified in a protocol (available at www.traumacanada.org/Default.aspx?pageId=829763) developed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses[24] and the Meta-analysis Of Observational Studies in Epidemiology proposal.[25]

Search Strategy

Two surgical investigators (D.J.R., A.W.K.) created a preliminary search strategy by selecting exploded Medical Subject Heading terms and keywords for IAH/ACS, NPWT and alternate TAC techniques, trauma or sepsis, and critical care. A medical librarian (H.L.R.) subsequently refined this strategy by conducting iterative database queries and incorporating novel terms when new relevant citations were found. Searches were conducted in the following databases from their inception to July 6, 2011, without restrictions: MEDLINE, PubMed, EMBASE, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, the National Institute for Health Research Economic Evaluation Database, the Health Technology Assessment Database, and the Turning Research into Practice database (Appendix 1 shows the refined MEDLINE search). To identify unpublished studies, we also investigated two clinical trials registries (ClinicalTrials.gov and Current Controlled Trials), questioned field experts, and wrote the manufacturer of a NPWT device (Kinetic Concepts Inc. [KCI], San Antonio, TX). Additional citations were located by using the PubMed "related articles" feature and hand-searching reference lists of included trials and relevant reviews[16,26,27] and guidelines.[1,2,5] We corresponded with several authors to clarify study procedures.[17,19–21]

Study Selection

Two reviewers (D.J.R., J.G.) independently screened titles and abstracts, reviewed potentially relevant citations in full, and decided on study inclusion. We used the following inclusion criteria: (1) design was a comparative study; (2) study participants were adult (≥16-year-olds) ICU patients requiring management of type II (exposed bowel or omentum) or III (presence of intra-abdominal sepsis) open abdominal wounds[28] caused by trauma, intra-abdominal sepsis, IAH/ACS, or vascular surgical emergencies; (3) intervention included NPWT, such as the KCI vacuum-assisted closure (VAC) or ABThera open abdomen NPT system (KCI, San Antonio, TX); (4) comparison was an alternate NPWT technique or TAC method; and (5) the study reported mortality or fascial closure rate as an outcome. In accordance with present recommendations on systematic reviews[29,30] and because NPWT trials are frequently terminated early and prone to publication bias,[26] we included detailed conference abstracts and unpublished studies. We used the definitions afforded by Boele van Hensbroek et al.[16] for TAC methods and excluded uncontrolled studies. Several non-English language abstracts and three trials (two in German[22,23] and one in French[31]) were translated by two coinvestigators (J.G., J.-F.O.). Eligibility disagreements were resolved by consensus.

Data Extraction and Risk of Bias Assessment

The same two reviewers independently extracted data on: (1) trial design; (2) study patient characteristics, including age, indication for TAC, wound classification,[28] initial systolic blood pressure (SBP) and illness severity (including Injury Severity Score [ISS] and/or Acute Physiology and Chronic Health Evaluation II[32] [APACHE-II]), presenting acid/base status (arterial pH, base deficit, and serum lactate), international normalized ratio (INR), and body temperature, and amount of fluid (blood product and crystalloid) resuscitation in the first 24-hours; (3) TAC technique, including the time interval from initial laparotomy to NPWT application and whether NPWT was the first TAC technique used; and (4) outcome measures (described below).

Two reviewers with methodological expertise (D.J.R., D.A.Z.) evaluated risk of bias.[24] RCTs were graded with the five-point Jadad score, which includes four questions on randomization and blinding and one on withdrawals and dropouts,[33] and the Cochrane Collaboration criteria, which include adequate sequence allocation, allocation concealment, blinding, incomplete outcome data addressed, selective reporting, and other bias.[34] Sources of other bias were defined a priori as inadequate study descriptions of presenting SBP, patient physiology (acid/base status, international normalized ratio, or body temperature), illness severity scores, or amount of fluid resuscitation.[35] Cohort studies were assessed using the Newcastle-Ottawa scale.[36] This scale evaluates selection and attrition bias, intergroup comparability, and ascertainment of exposure bias using a starring system. As we deemed one scale item irrelevant ("demonstration that outcome of interest was not present at start of study"), as has been done before,[37] the maximum score for cohort studies was eight rather than nine.

Outcomes and Analysis

The primary outcome was in-hospital mortality. Secondary outcomes were fascial closure rate, duration of hospital or ICU stay, effect on intra-abdominal pressure (IAP), ACS occurrence rate (defined as sustained IAP > 20 mm Hg associated with new organ dysfunction/failure[38]), and frequency of abdominal fistula formation or infectious complications (e.g., intra-abdominal abscesses or surgical site infection).

We compared dichotomous data using Fisher's exact test and means using Student's *t* test. We selected relative risks (RRs) with 95% confidence intervals (CIs) as the summary measure of association. Whenever possible, RRs were calculated using an intention-to-treat (ITT) method of analysis. Although outcome estimates were presented for included studies, planned

pooled analyses were not performed owing to significant methodological and clinical heterogeneity between studies.

RESULTS

Study Selection

Our database searches identified 2,715 citations (Fig. 1). After removing duplicates and screening titles and abstracts, we retrieved 53 articles for full-text review. Manual searches of reference lists from included articles, reviews, and guidelines yielded an additional three potentially relevant trials, two of which were written in German[22,23] and one in French.[31] We also obtained unpublished abstract data presented in the public forum from the recent ABTAC-50 (ABThera open abdomen NPT system versus Barker's vacuum pack technique) prospective cohort study.[39]

The French study was excluded after full translation and review revealed that it was uncontrolled.[31] One prospective cohort study was also excluded as the comparison group was composed of adults that received intraoperative primary fascial closure.[40] Inter-reviewer agreement on independent selection of 11 of the remaining 12 articles was complete. The 12th trial was excluded after the author clarified that the study population did not include critically ill adults with open abdominal wounds.[41] We therefore included 11 studies[9,10,17–23,39,42] in the systematic review.

According to trial registries and field experts, there are presently three ongoing comparative studies, including two RCTs and one prospective cohort study (Table 1). Two of these trials are recruiting patients, whereas the third has an unknown recruitment status.

Description of Included Studies

Characteristics of the 11 included investigations are summarized in Table 2. Of the 11, 1 included unpublished data,[39] 1 was available only as a conference abstract,[42] and the others were published in full. There were two RCTs,[17,18] three prospective cohort studies,[9,10,39] two of which used a historical control (Bogotá bag[10] or NPWT during technique development and before introduction of an institutional protocol[9]), and six retrospective cohort studies.[19–23,42] Four studies were performed in the United States,[17–19,39] whereas the remainder were conducted in five countries within Europe.

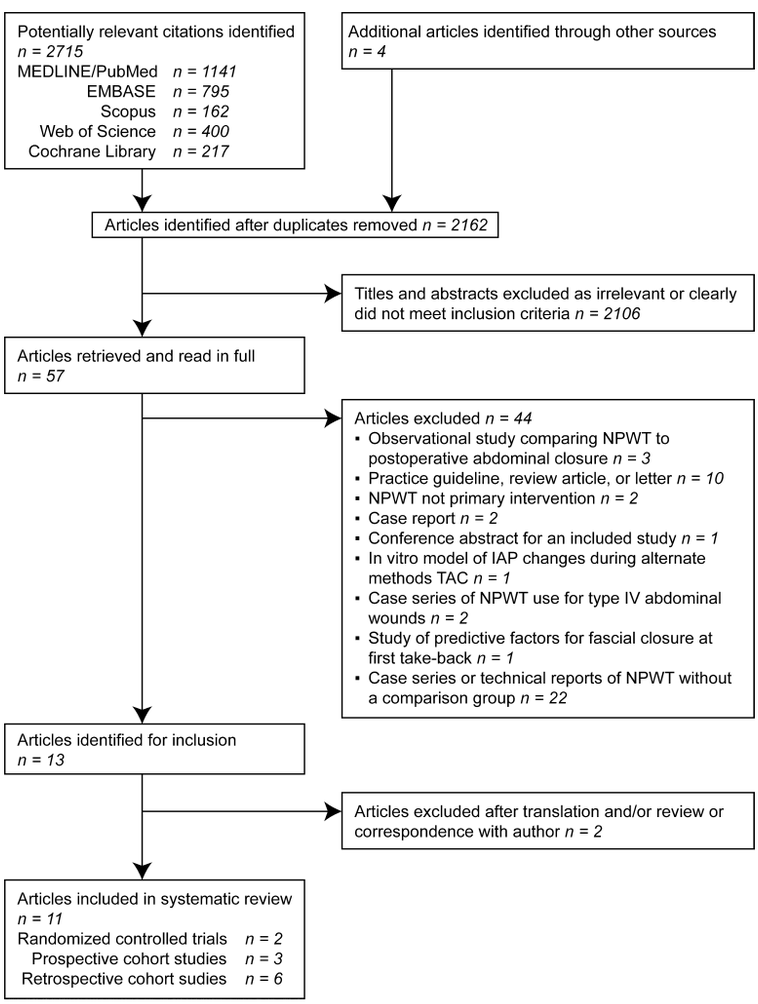

Figure 1. Flow chart of steps in systematic review.

TABLE 1. Characteristics of Registered Ongoing Comparative Studies*

Principal Investigator, Year of Study Initiation, Country	Planned Sample Size, n	Inclusion Criteria	Type of NPWT	Comparison TAC Method	Primary Outcome	Current Study Status
Randomized controlled trials						
A.W. Kirkpatrick et al., 2011, Canada	20	Critically ill or injured patient requiring ICU admission and open abdomen, age > 18 y, nonpregnant	ABThera open abdomen NPT system	Institution-specific vacuum pack technique entitled " Stampede VAC"	Systemic and peritoneal fluid inflammatory marker levels	Active, recruiting
S. Post et al., 2009, Germany	20	Open abdomen therapy felt indicated and technically possible by surgeon (target patient population not described)	KCI VAC	Vacuum pack	Combined outcome of failure of delayed fascial closure and/or in-hospital mortality	Unknown
Prospective cohort studies						
P. Chang et al., 2008, United States	30	Patients aged 18–70 y deemed not a candidate for primary fascial closure at second laparotomy after initial damage control procedure	KCI VAC with ABRA Abdominal Wall Closure System	KCI VAC	Time to abdominal wound closure	Active, recruiting

*Studies that did not appear to have a control group where patients received an alternate TAC method are not displayed.

The included studies examined a total of 1,018 adults with critical illness. One of the RCTs[18] and all three prospective cohort studies[9,10,39] enrolled trauma, general, or vascular surgery patients requiring damage control laparotomy/ACS decompression or who exhibited massive visceral edema or IAH at fascial closure. Another RCT included adults with necrotizing pancreatitis or intra-abdominal sepsis.[17] Four of the retrospective cohort studies enrolled general surgery patients with abdominopelvic sepsis,[21–23,42] whereas one included those with infected pancreatic necrosis,[20] and another enrolled a mixed trauma/surgical population,[19] many of which required planned relaparotomy only.

NPWT techniques used included the ABThera open abdomen NPT system,[39] the KCI VAC,[9,10,18,19] the KCI VAC with addition of retention sutured sequential fascial closure,[17] a modified vacuum sealing system stated to be similar to the KCI VAC,[20,21] an institution-specific "abdominal VAC,"[22,23] or an unclear NPWT technique.[42] Although a Barker's vacuum pack technique was used before NPWT in one study (until visceral edema had resolved, which was often at the second look laparotomy),[9] in 10 other studies, the timing of NPWT application was not described[19,22,23,39,42] or NPWT was likely applied during the initial laparotomy.[10,17,18,20,21] One RCT randomized only 16% of patients in the NPWT group to KCI VAC, whereas the remainder received vacuum pack.[18] Comparative methods of TAC used in control groups included Barker's vacuum pack,[39] KCI VAC,[17] polyglactin mesh,[18] Bogotá bag,[10] NPWT during technique development and before introduction of an institutional protocol,[9] skin closure or Bogotá bag/burr,[19] "classic VAC" or open packing,[22,23] adhesive impermeable foil with midline zip,[20,21] and an unclear TAC technique.[42] Descriptions of the TAC techniques used in included studies are shown in Table 2.

Assessment of Risk of Bias

Risk of bias among included RCTs and cohort studies is summarized in Tables 3 and 4, respectively. The methodological quality of RCTs was moderate, with Jadad scores of 2 and 3.[17,18] Although the randomization scheme appeared adequate in both RCTs, only one trial described allocation concealment.[18] All of the prospective and most of the retrospective cohort studies selected largely representative cohorts of critically ill trauma or surgery patients through hospital or surgical records. Aside from one retrospective study that reported standardized mortality ratios,[42] remaining cohort studies did not control for covariates that could influence reported outcomes. Nearly all cohort studies used record linkage to assess outcome and followed up patients until hospital discharge. Data from 27%[20] and 43%[21] of patients from the control group of two included studies were identical. Identified sources of "other bias" included inadequate or absent descriptions of initial SBP (all trials but one[18]), Injury Severity Score or Acute Physiology and Chronic Health Evaluation II (all trials but four[9,10,18,20]), presenting acid/base status (all trials but three[9,10,18]), and hypothermia (all trials). Moreover, although one RCT reported that the amount of blood product resuscitation between the NPWT and polyglactin mesh treatment groups were comparable at 24 hours,[18] no trial afforded data on the degree of crystalloid resuscitation.

Effect of NPWT Versus Alternate TAC Techniques on Outcomes

In-Hospital Mortality

Eight included articles (two RCTs,[17,18] three prospective cohort studies,[9,10,39] and three retrospective cohort studies[20,21,23]) reported in-hospital mortality (Table 5). Of the two RCTs, one

TABLE 2. Characteristics of Included Comparative Studies

Source, Year (N)	Country/Publication Status	ICU Patient Population and Indication for TAC (n)	Wound Class (I–IV)*	Type of NPWT (n)	Suction Amount, mm Hg	Comparison TAC Method(s) (n)
Randomized controlled trials						
Pliakos et al.,[17] 2010 (53)	Greece/full text	Patients with necrotizing pancreatitis or purulent/fecal peritonitis	III	KCI VAC (15)	50–150	KCI VAC with retention sutured sequential fascial closure (15)
Bee et al.,[18] 2008 (51)	United States/full text	Trauma (46) or general surgery (5) patients requiring DCL/relaparotomy or with massive visceral edema	II and III	KCI VAC (5) and Barker's vacuum pack technique (26)	Unknown	Polyglactin mesh (20)
Prospective cohort studies						
Cheatham et al.,[39] unpublished (168)	United States/unpublished data	Trauma (90) or general surgery (48) patients requiring DCL, IAH/ACS decompression, or laparotomy for sepsis	II or III	ABThera (94)	Unknown	Barker's vacuum pack technique (44)
Batacchi et al.,[10] 2009 (66)	Italy/full text	Trauma (22) or general surgery/ruptured AAA patients (44) with IAH at fascial closure	II and III	KCI VAC (35)	Unknown	Bogotá bag (31)
Miller et al.,[9] 2004 (82)	United States/full text	Trauma patients requiring DCL/ACS decompression (82)	II and III	Barker's vacuum pack technique followed by KCI VAC (43)	Unknown	Same method, but during development and before introduction of an institutional protocol (39)
Retrospective cohort studies						
Patel et al.,[19] 2011 (108)	United States/full text	Trauma (12), general (82), or vascular (14) surgery patients with ACS or inability to close without IAH (29) or requiring relaparotomy (79)	II and III	KCI VAC (15)	Unknown	Skin closure (34) or Bogotá bag/burr (49)
Hogg et al.,[42] 2010 (221)	Scotland/abstract only	General surgery patients with abdominopelvic sepsis (162)	III	Unclear ("VAC Abdominal Dressing System") (26)	Unknown	Unclear (open abdomen management pretopical negative-pressure therapy) (195)
Olejnik et al.,[20] 2008 (106)	Slovak and Czech Republics/full text	General surgery patients with infected pancreatic necrosis (106)	III	Modified vacuum sealing system (described as fine porous polyurethane sponge with centered Redon drain and temporary retention sutures covered by hermetic adhesive plastic foil) (39)	50–75	Adhesive impermeable foil with midline zip (67)
Olejnik et al.,[21] 2007 (80)	Slovak Republic/full text	General surgery patients with intra-abdominal sepsis (87)	III	Modified vacuum sealing system (described previously) (46)	50–75	Adhesive impermeable foil with midline zip (41)
Wild et al.,[22] 2006 (62)	Austria/full text	General surgery patients with secondary peritonitis (62)	III	"Abdominal" VAC (described as fenestrated polyvinyl plastic with integrated foam dressing that sits atop bowel) (19)	Unknown	"Classic" VAC (described as a polyurethane sponge that sits on a silicone net that is atop bowel) (16) or open packing (27)
Wild et al.,[23] 2004 (21)	Austria/full text	General surgery patients with secondary peritonitis (21)	III	"Abdominal" VAC (described previously) (8)	Unknown	"Classic" VAC (described previously) (8) or open packing (5)

*This four-point scale describes type II and III wounds as exposed bowel or omentum and intra-abdominal sepsis, respectively.[28]
AAA, abdominal aortic aneurysm; DCL, damage control laparotomy.

largely allocated patients to Barker's vacuum pack technique and observed no in-hospital mortality difference when compared with polyglactin mesh.[18] The other similarly reported no mortality difference when retention sutured sequential fascial closure was used with the KCI VAC.[17] One of the three prospective cohort studies observed a large in-hospital mortality

TABLE 3. Risk of Bias Assessment for Randomized Controlled Trials

Source, Year	Jadad Score (0–5)[33]	Cochrane Collaboration Criteria[34]					
		Adequate Sequence Allocation*	Allocation Concealment	Blinding	Incomplete Outcome Data	Free of Selective Reporting	Free of Other Bias†
Pliakos et al.,[17] 2010	3	Yes	Unlikely	No	Yes	Unlikely	Unlikely
Bee et al.,[18] 2008	2	Probably	Yes	No	Yes	No	Yes

*The randomization scheme was confirmed by the author to be performed with a random sequence generator.

†Defined as differences in presenting SBP, illness severity scores, patient physiology (acid/base status, coagulation, or body temperature), and amount of fluid (blood product and crystalloid) resuscitation.

difference between patients who received the ABThera open abdomen NPT system versus Barker's vacuum pack technique (RR, 0.48; 95% CI, 0.25–0.92 according to the ITT principle).[39] In the two remaining prospective cohort studies, no in-hospital mortality difference was observed when the KCI VAC was compared with Bogotá bag[10] or the KCI VAC during technique development and before introduction of an institutional protocol.[9] Although in-hospital mortality was reduced among patients who received NPWT versus a midline zip in one of the six retrospective cohort studies (RR, 0.26; 95% CI, 0.13–0.54),[20] mortality was unchanged after the use of NPWT versus alternate TAC methods in the remaining five studies.

Fascial Closure

Six included studies (two RCTs,[17,18] three prospective[9,10,39] studies, and one retrospective cohort study[19]) examined fascial closure rates (Table 5). One RCT reported an increased fascial closure rate with addition of retention sutured sequential fascial closure to the KCI VAC (RR, 2.4; 95% CI, 1.1–5.3 according to the ITT principle).[17] In the second RCT, an equivalent fascial closure rate was observed among patients allocated to the combination of Barker's vacuum pack and KCI VAC versus polyglactin mesh.[18] In this trial, however, use of the KCI VAC was linked with a trend toward a higher fascial closure rate than Barker's vacuum pack (RR, 2.6; 95% CI, 0.95–7.1 according to the ITT principle).[18] Of the three included prospective cohort studies, one observed an increased fascial closure rate after the use of the ABThera open abdomen NPT system versus Barker's vacuum pack technique (RR, 1.5; 95% CI, 1.1–2.0).[39] A second reported an increased fascial closure rate using the KCI VAC after technique development and introduction of an institutional protocol (RR, 1.3; 95% CI, 1.0–1.6).[9] However, no difference in fascial closure rate was reported for patients who received NPWT versus alternate TAC methods in the third prospective cohort study[10] or any of the included retrospective cohort studies.[19–23,42]

Duration of Hospital and ICU Stay

The effect of NPWT versus alternate TAC methods on hospital or ICU stay was reported by one RCT,[17] one prospective cohort study,[10] and four retrospective cohort studies (Table 5).[19,21,22,42] Addition of retention sutured sequential fascial closure to the KCI VAC decreased hospital stay by 5.6 days in one RCT.[17] Trauma or general/vascular surgery patients similarly had a 6.4 day shorter hospital stay after use of the KCI VAC versus Bogotá bag in one prospective cohort study.[10] Hospital length of stay was also reduced among patients who received NPWT versus midline zip in one retrospective cohort study[21] but increased for patients who

TABLE 4. Risk of Bias Assessment for Cohort Studies

Source, Year	Newcastle Ottawa Scale Categories[36]			Cochrane Collaboration Criterion[34]
	Selection (None to***)	Comparability (None to **)	Outcome (None to ***)	Free of Other Bias†
		Prospective cohort studies		
Cheatham et al.,[39] unpublished	**	None	**	Yes
Batacchi et al.,[10] 2009	***	None	***	Yes
Miller et al.,[9] 2004	***	None	**	Yes
		Retrospective cohort studies		
Patel et al.,[19] 2011	*	None	***	Unlikely
Hogg et al.,[42] 2010	***	*	***	Probably
Olejnik et al.,[20] 2008	**	None	***	Unlikely
Olejnik et al.,[21] 2007	**	None	**	Unlikely
Wild et al.,[22] 2006	*	None	**	Unlikely
Wild et al.,[23] 2004	*	None	None	Unlikely

Presented stars refer to the Newcastle Ottawa ordinal rating scale, which ranges from none to *** for selection and attrition bias, none to *** for inter-group comparability, and none to *** for ascertainment of exposure (where more stars indicate a lower risk of bias).

†Differences in presenting SBP, illness severity scores, patient physiology (acid/base status, coagulation, or body temperature), and amount of fluid (blood product and crystalloid) resuscitation.

TABLE 5. Summary of Effect of Negative-Pressure Wound Therapy Versus Alternate Temporary Abdominal Closure Techniques on Outcomes

		1° Outcome, n (%)	2° Outcomes, Mean (SD) or n (%)		
Source, Year	**Therapy (n)**	**Hospital Mortality**	**Length of Hospital Stay, d**	**Fascial Closure**	**ACS Rate or Effect on IAP, mm Hg**
Randomized controlled trials					
Pliakos et al.,[17] 2010	KCI VAC + RSSFC (26)	5 (19)	11.9 (2.1)	14 (54)	IAP was 12 vs. 16 for VAC after the first dressing change ($p < 0.001$)
	KCI VAC (27)	6 (22)	17.5 (4.6)	6 (22)	
		($p = 1.0$)*	($p < 0.001$)	($p = 0.02$)*	
Bee et al.,[18] 2008†	KCI VAC (5)	NA	NA	3 (60)	NA
	Barker's vacuum pack (26)	NA		6 (23)	
	NPWT (KCI VAC/vacuum pack) (31)	8 (26)		15 (31)	
	Polyglactin mesh (20)	5 (25)		5 (26)	
		($p = 1.0$)		(KCI VAC vs. vacuum pack, $p = 0.13$)* (NPWT vs. mesh, $p = 0.14$)*	
Prospective cohort studies					
Cheatham et al.,[39] unpublished	ABThera (111)	14 (13)	NA	72 (65)	NA
	Barker's vacuum pack (57)	15 (26)		25 (39)	
		($p = 0.03$)*		($p = 0.01$)*	
Batacchi et al.,[10] 2009	KCI VAC (35)	8 (23)	28.5 (4.7)	9 (26)	IAP lower for VAC between 8th and 24th h after laparotomy ($p < 0.01$ for all)
	Bogotá bag (31)	11 (35)	34.9 (8.8)	4 (13)	
		($p = 0.29$)	($p = 0.02$)	($p = 0.23$)	
Miller et al.,[9] 2004	KCI VAC (43)	3 (7)	NA	38 (88)	NA
	KCI VAC during technique development (39)	4 (10)		27 (69)	
		($p = 0.70$)		($p = 0.05$)	
Retrospective cohort studies					
Patel et al.,[19] 2011	KCI VAC (15)	NA	29 (5–109)	12 (79)	NA
	Skin closure (34)		16 (5–85)	33 (97)	
	Bogotá bag/burr (49)		23 (5–81)	45 (91)	
			($p = 0.01$)	($p = 0.13$)	
Hogg et al.,[42] 2010	VAC (26)	4 (15)	11.3	NA	NA
	Pre-TNP management (195)	53 (27)	5.8		
		($p = 0.24$)	(no statistics)		
Olejnik et al.,[20] 2008	Modified vacuum sealing system (39)	7 (18)	NA	NA	NA
	Midline zip (25)	17 (25)			
		($p < 0.001$)			
Olejnik et al.,[21] 2007	Modified vacuum sealing system (46)	11 (24)	14.5	NA	NA
	Midline zip (41)	15 (37)	19.4		
		($p = 0.24$)			
Wild et al.,[22] 2006	"Abdominal" VAC (19)		38.9 (27.2)	NA	NA
	"Classic" VAC (16)		34.6 (30.2)		
	Open packing (27)		26.6 (23.0)‡		
			(no statistics)		
Wild et al.,[23] 2004	"Abdominal" VAC (8)	0	NA	NA	NA
	"Classic" VAC (8)	1 (13)			
	Open packing (5)	3 (60)			
		($p = 0.22$)			

*Outcome statistics may differ from that reported in the original article as they were recalculated using the ITT principle.
†Patients were randomized to either NPWT or mesh closure with those in the NPWT arm receiving both KCI VAC or Barker's vacuum pack.
‡ICU length of stay among survivors.
NA, not analyzed, available, or reported; Pre-TNP, open abdomen management pretopical negative-pressure therapy; RSSFC, retention sutured sequential fascial closure.

received NPWT versus other TAC techniques in three other retrospective cohort studies.[19,22,42]

Abdominal Fistula Formation and Infectious Complications

Aside from one RCT that randomized patients largely to Barker's vacuum pack,[18] the rate of abdominal fistula formation or development after NPWT was not reported by included studies. In this RCT, although no difference in intra-abdominal abscess formation was observed, there was a trend toward an increased rate of small bowel fistulae for those randomized to the combination of vacuum pack and KCI VAC versus polyglactin mesh (RR, 3.9; 95% CI, 0.50–29.8).[18] However, each of the included open abdomen patients in this trial received gastric or jejunal feedings tubes, and all of the fistulae occurred among those fitted with Barker's vacuum pack.

Effect on IAP and Other Surrogate Outcomes

The effect of NPWT versus alternate TAC methods on IAP or other surrogate measures were examined by two investigations (Table 5).[10,17] In one RCT, IAP was 4 mm Hg higher after retention sutured sequential fascial closure was added to the KCI VAC.[17] In another prospective cohort study, IAP and arterial lactate were approximately 2.5 mm Hg and 1 mmol/L to 2 mmol/L lower for KCI VAC versus Bogotá bag between the 8th and 24th hour after laparotomy, respectively.[10]

DISCUSSION

This systematic review provides the most current and comprehensive estimate of the effect of NPWT versus alternate TAC methods on in-hospital mortality, fascial closure rate, and hospital and ICU length of stay. Although current evidence remains insufficient, data from a limited number of prospective comparative studies suggest that NPWT may be associated with improved patient-centered outcomes versus selected alternate TAC techniques. Moreover, no comparative evidence exists to support a greater risk of development of abdominal fistulae or IAH/recurrent ACS among patients receiving NPWT despite reported concerns.[12–15]

Data from an included and presently unpublished prospective cohort study suggest that use of the ABThera open abdomen NPT system versus Barker's vacuum pack technique may substantially improve in-hospital mortality and fascial closure rate.[39] However, in another prospective cohort study comparing the KCI VAC and Bogotá bag, no difference in mortality was observed despite a decreased hospital stay, arterial lactate, and IAP among patients who received NPWT.[10] A third prospective cohort study indicates that surgeon experience and introduction of an institutional NPWT protocol for patients with open abdominal wounds may enhance fascial closure rates.[9] Finally, randomized evidence supports that the use of retention sutured sequential fascial closure with the KCI VAC may increase fascial closure rate and reduce hospital stay without influencing mortality among those surviving to abdominal closure.[17]

NPWT may alter patient physiology and the mechanical properties of open abdominal wounds through several potential mechanisms.[8,9,11,43,44] Septic and hemorrhagic shock are common indications for open abdominal management and can lead to intestinal injury, increased vascular permeability, and an accumulation of inflammatory mediators in mesenteric lymph and peritoneal ascites.[11,45,46] As NPWT may more effectively remove proinflammatory cytokine-rich ascites than alternate TAC methods,[2,10] a recent preclinical investigation reported that it may improve organ dysfunction by reducing the systemic inflammatory response.[11] Abdominal fascial closure may be improved by NPWT by preventing visceral adherence to the anterior abdominal wall while maintaining medial fascial traction and abdominal domain.[8,9] NPWT also stretches and deforms the abdominal wound, which increases its surface area and induces cell proliferation and angiogenesis through several mechanisms.[2]

Unfortunately, NPWT may also increase the rigidity of the abdominal wall and reduce abdominal volume reserve capacity,[43,44] which has been reported by our institution to result in recurrent ACS after damage control laparotomy.[12] However, we found no comparative evidence to support a greater risk of development of IAH/ACS among patients receiving NPWT. Moreover, one included study observed that NPWT reduced IAP (mean, 2.5 mm Hg) among trauma and surgical patients with IAH at fascial closure.[10] Because the reduction in IAP with NPWT in this study likely resulted from aspiration of peritoneal ascites (mean at 24 hour, 820 mL),[10] it remains possible that IAH/ACS may occur in some open abdomen patients when NPWT is applied, the abdominal wall becomes more rigid, and limited intra-abdominal fluid is available for removal (e.g., predominantly visceral edema without significant ascites, retroperitoneal hemorrhage, or pelvic packing).[43]

As many included retrospective studies exhibited low methodologic quality and enrolled small sample sizes, and included prospective studies were linked with at least a moderate risk of bias, our findings should be regarded with caution. Although randomization appeared to be adequately performed in both included RCTs, one trial did not describe allocation concealment,[17] and inadequate masking of allocation can significantly inflate treatment efficacy.[47] Moreover, despite present recommendations that unpublished and abstract evidence be included in systematic reviews,[29,30] we were unable to conduct a complete quality assessment of one unpublished trial[39] and another abstract publication.[42] Most trials also inadequately described covariates known to influence mortality and fascial closure, including presenting SBP, illness or injury severity, acid/base status, and hypothermia.[2] Furthermore, although large amounts of intravenously administered crystalloids can contribute to ascites, visceral edema, and likely difficult abdominal fascial closure, no study afforded data on the amount of crystalloid resuscitation between TAC comparison groups.[46,48]

Despite these limitations, our findings are supported by their consistency with those reported by numerous existing uncontrolled case series. In a recent systematic review of mostly noncomparative case series of open abdomen patients who reported a weighted pooled outcomes analysis of NPWT-associated mortality and fascial closure rate, NPWT use was linked with a lower weighted mortality (18%; 95% CI, 13%–22%) and a higher weighted fascial closure rate (60%; 95% CI, 54%–66%) when compared with Barker's vacuum pack technique (mortality, 27% [95% CI, 24%–29%]; fascial

closure, 52% (95% CI, 49%–54]), dynamic retention sutures, mesh, loose packing, skin approximation, and a midline zipper.[16] Although these investigators also found that the Wittmann patch had comparable effects on mortality (17%; 95% CI, 12%–23%) and fascial closure (90%; 95% CI, 86%–95%), comparative trials with NPWT are unfortunately not yet available.

In conclusion, this systematic review found that among critically ill adults with open abdominal wounds, limited prospective comparative data suggest that NPWT versus selected alternate TAC methods may be associated with improved surrogate and clinical outcomes. However, because the studies supporting these improved outcomes are clinically heterogeneous and linked with at least a moderate risk of bias, our findings are preliminary, and no definitive conclusions regarding the preferential use of NPWT over alternate TAC techniques can be afforded. Adequately powered and internally valid RCTs comparing the ABThera or KCI VAC with other TAC methods, particularly Barker's vacuum pack technique and the Wittmann patch, are required before NPWT can be advocated as a superior surgical intervention.

Appendix 1. Refined Ovid MEDLINE Search (1950 to July 6, 2011)

1. abdominal pressure.mp.
2. intra-abdominal pressure*.mp.
3. intraabdominal pressure*.mp.
4. intra-abdominal hypertension.mp.
5. intraabdominal hypertension.mp.
6. intra-vesicular pressure*.mp.
7. intravesicular pressure*.mp.
8. bladder pressure*.mp.
9. abdominal compartment syndrome*.mp.
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. exp Sepsis/
12. intra-abdominal sepsis.mp.
13. intraabdominal sepsis.mp.
14. exp Peritonitis/
15. exp Abdominal Injuries/
16. 11 or 12 or 13 or 14 or 15
17. exp Abdominal Cavity/su [Surgery]
18. exp Abdominal Wall/su [Surgery]
19. exp Laparotomy/
20. exp Decompression, Surgical/
21. decompressive laparotomy.mp.
22. decompressive celiotomy.mp.
23. laparostomy.mp.
24. laparostomies.mp.
25. exp Negative Pressure Wound Therapy/
26. exp Vacuum/
27. vacuum assisted closure*.mp.
28. topical negative pressure therapy.mp.
29. vac.mp.
30. vacuum pack*.mp.
31. bogota bag*.mp.
32. towel clip*.mp.
33. temporary silo*.mp.
34. Wittmann patch.mp.
35. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36. exp Critical Care/
37. exp Intensive Care/
38. exp Intensive Care Units/
39. exp Critical Illness/
40. exp Postoperative Care/
41. 36 or 37 or 38 or 39 or 40
42. 10 or 16
43. 42 and 35 and 41

AUTHORSHIP

D.J.R., P.A.Z., and A.W.K. participated in the conception and design of this study. D.J.R., P.A.Z., C.G.B., H.L.R., J.-F.O., and A.W.K. created the initial study protocol. D.J.R. and H.L.R. performed the literature search. D.J.R. and J.G. acquired the data, which D.J.R., P.A.Z., J.G., C.G.B., M.L.C., and A.W.K. analyzed and interpreted. D.J.R. and P.A.Z. conducted methodological assessment. D.J.R. and P.A.Z. performed statistical analyses. D.J.R. and A.W.K. wrote the manuscript, which all authors critically revised. D.J.R., P.A.Z., and A.W.K. provided administrative, technical, and material support of the project. A.W.K. supervised this study.

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DISCLOSURE

Dr. Kirkpatrick has an investigator-initiated trial agreement with KCI USA and the Governors of the University of Calgary for funding of a randomized comparison of baseline wall suction and the ABThera open abdomen NPT system for adults with critical illness and open abdominal wounds (KCI contract number: KCI Clinical/UniversityCalgaryAlbertaHealth/082611-000/7). Dr. Cheatham has received compensation from KCI USA as a lecturer and is an investigator on the included ABTAC-50 study. The remaining authors have no conflicts of interest to declare. Dr. Roberts is supported by funding from the Clinician Investigator and Surgeon Scientist Programs at the University of Calgary. These institutions had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the article.

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