Comparison of a standardized negative pressure wound therapy protocol after midline celiotomy to primary skin closure and traditional open wound vacuum-assisted closure management

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ABSTRACT

A negative pressure wound therapy (NPWT) protocol using Hydrofera Blue[®] bacteriostatic foam wicks and silver-impregnated foam overlay to close midline skin incisions after emergency celiotomy was compared to primary skin closure only and traditional open wound vacuum-assisted closure management as part of a quality improvement initiative. This single-institution retrospective cohort study assessed all consecutive emergency celiotomies from July 2013 to June 2014 excluding clean wounds. Included variables were demographics, wound classification, NPWT days, and surgical site occurrences (SSOs). Primary outcome was days of NPWT. Secondary outcomes included SSOs (surgical site infections, fascial dehiscence, return to operating room). Analysis used exact chi-square between categorical variables, Kruskal-Wallis for analysis of variance for ordinal and categorical variables, and Wilcoxon rank sum for total days of NPWT. One hundred fifty-eight patients underwent emergency celiotomy with primary skin closure ($n = 51$), open NPWT ($n = 63$), or the NPWT protocol ($n = 44$). There was no difference in American Society of Anesthesiologists Physical Status score, body mass index, wound classification, or SSO between the three groups. Total NPWT days were reduced in protocol versus open NPWT (median 3 vs 20.5 days, range 3–51 vs 3–405 days, $P = 0.001$). Primary skin closure and NPWT protocol had fewer patients discharged with NPWT than open NPWT (0% and 14% vs 63.5%, $P < 0.0001$, odds ratio = 10.7, 95% confidence interval 3.7–35.1). Primary skin closure and NPWT protocol decrease NPWT usage days and maintain low SSOs in emergency midline celiotomy incisions.

KEYWORDS Midline celiotomy; negative pressure wound therapy; primary skin closure; surgical site infections; vacuum-assisted therapy; wound care

Surgical site infections (SSIs) are the most common complication following emergency general surgery operations.¹ Primary skin closure in trauma damage control laparotomies significantly increases the risk of superficial SSIs ninefold.² Negative pressure wound therapy (NPWT) was developed for open or infected wounds in the early 1990s^{3,4} and has become the standard of care in open wound management for general surgery and trauma. NPWT decreases wound edema and seroma formation, increases vascularity and nutrient delivery, and promotes positive mechanical wound remodeling.^{4–6} NPWT has been proposed to decrease the risk of SSI in patients with multiple comorbidities or emergency surgery.^{7–10} However, the current NPWT technique remains unchanged from its original design for large open infected wounds. Current NPWT recommendations require wound

vacuum-assisted closure (VAC) changes to occur every 2 to 3 days until closure, which has led to an explosion in outpatient NPWT use and cost. Due to this increase in cost and patient dissatisfaction, we developed a quality improvement initiative to standardize NPWT and facilitate primary surgical site skin closure prior to patient discharge from the hospital. We hypothesized that our new standardized NPWT protocol would decrease NPWT days, surgical site occurrences (SSOs), and outpatient wound VAC use compared to traditional “open” NPWT or primary skin closure.

METHODS

After approval by the institutional review board, a retrospective cohort chart review of consecutive patients undergoing emergent celiotomy from July 1, 2013, through June 30,

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2014, at our 640-bed, state-designated American College of Surgeons–verified level I trauma center and tertiary referral hospital in central Texas was performed. All patients undergoing emergent celiotomy or laparoscopic converted to open celiotomy with primary fascial closure were included. Exclusion criteria included patients less than 18 years of age and wounds that were classified as clean. Patient demographics, operative variables, and postoperative management were recorded. Primary outcomes evaluated were total days of NPWT usage and discharged home with outpatient wound VAC. The secondary outcome was the incidence of SSOs. SSO was defined as postoperative superficial surgical site infection (SSI), deep space SSI, organ space SSI, return to the operating room, and fascial dehiscence.

Prior to the quality improvement initiative, the skin incision was closed in one of two ways as determined by the staff operating surgeon. For patients in the primary skin closure group, the skin was closed with stainless steel staples. For patients in the open NPWT group, the skin was left open and a KCI Wound V.A.C.® (KCI, San Antonio, TX) was used to attain wound closure. This technique utilized black foam in the wound bed sealed with a nonadherent dressing attached to a KCI vacuum pump. The standard KCI V.A.C.–recommended setting of low continuous suction at -125 mm Hg¹¹ was used for all patient. The wound VAC was changed three times per week in both the inpatient and outpatient settings. Duration of wound care using NPWT was decided upon by the surgical and wound care teams.

As part of the quality improvement initiative, our wound care and acute care surgical teams employed an NPWT protocol aimed to reduce SSOs and total wound VAC days as follows. Once primary fascial closure was attained, the midline wound was partially closed with staples. The staples were spaced 0.5 cm apart for 3 cm and followed by a 1-cm gap. Hydrofera Blue bacteriostatic foam (Hollister, Libertyville, IL) was cut into 1-cm strips to fit the depth of the wound for each 1-cm gap (*Figure 1*). Next, a silver-impregnated foam dressing (Mepilex AG® Foam Dressing; Molnlycke Health Care, Norcross, GA) was placed over the incision and a negative-pressure vacuum pump from KCI V.A.C. was attached to the wound. The postoperative protocol required removal of the NPWT protocol dressing on postoperative day 3 for assessment. If the surgical and wound care teams determined that the wound was granulating appropriately and without significant drainage, the wound underwent delayed primary closure with Steri-strips. If there was persistent drainage or the wound was determined to need continued NPWT, another NPWT protocol dressing was applied at the bedside. The dressing was changed every other day until it could be closed secondarily with Steri-strips (Appendix).

The patients were divided into three groups according to their wound management: primary skin closure, traditional open wound VAC, and NPWT protocol. Data were analyzed using SAS statistical software, version 9.4 (SAS Institute, Cary, NC). Exact chi-square tests were used to

Figure 1. Model of negative pressure wound therapy protocol. The wound is closed with surgical staples. The staples are spaced 5 mm apart for 3 cm. A 1-cm gap is left to place the Hydrofera Blue bacteriostatic foam wicks. Once complete, the entire wound is covered with silver-impregnated foam overlay and connected to suction.

assess the association between categorical variables, and exact Monte Carlo Kruskal-Wallis tests were used to compare the association of ordinal vs categorical variables. Analysis of variance was used to compare the means of normally distributed variables, and Kruskal-Wallis tests were used as the nonparametric alternative of analysis of variance for nonnormal variables. A significant difference was accepted for variables at $P < 0.05$.

RESULTS

Between July 1, 2013, and June 30, 2014, 212 patients underwent emergent celiotomy. After excluding clean wounds ($n = 54$), the remaining patients were divided into groups for primary skin closure ($n = 51$) and traditional open wound VAC ($n = 64$) versus our new NPWT protocol ($n = 44$). The patient demographics, surgical etiologies, and operative variables are depicted in *Table 1*. There were no significant demographic differences between the patient groups. We achieved 100% follow-up for all patients through 3 months of care.

The average total days of NPWT were reduced in the NPWT protocol group versus traditional NPWT group ($P < 0.003$; *Table 1*). The average total days of NPWT in the protocol group was 8.4 days, with a median of 3 days and range of 3 to 51 days. The average total days of NPWT in the traditional NPWT group was 33.8 days, with a median of 20 days and a range of 3 to 405 days. Patients undergoing traditional NPWT were more likely to be discharged while still requiring the use of a wound VAC (odds ratio [OR] = 10.7, 95% confidence interval [CI], 3.7–35.1, $P < 0.0001$).

SSOs included all incidences of superficial SSI, deep space SSI, organ space infection, return to the operating room, and fascial dehiscence (*Table 1*). The rates of SSOs

Table 1. Baseline demographics, characteristics, and etiologies for patient groups

Variable	Primary closure (<i>n</i> = 51)	Traditional NPWT (<i>n</i> = 64)	NPWT protocol (<i>n</i> = 44)	<i>P</i> value
Male	26 (51%)	22 (35%)	23 (52%)	0.1772
Female	25 (49%)	41 (65%)	21 (48%)	
Age (years) ^a	64.2 (18.6)	61.9 (16.4)	61.6 (14.4)	0.3054
ASA PS ^b				0.1413
I and II	9 (18%)	10 (16%)	11 (25%)	
III	29 (57%)	26 (41%)	23 (52%)	
IV and V	13 (25%)	27 (43%)	10 (23%)	
BMI (kg/m ²) ^c				0.4477
<30	34 (68%)	38 (60%)	25 (57%)	
30–34.99	11 (22%)	12 (19%)	11 (25%)	
35–39.99	2 (6%)	8 (13%)	5 (11%)	
40+	3 (6%)	5 (8%)	3 (7%)	
Current smoking ^b	9/51 (18%)	17/63 (27%)	9/44 (20%)	0.312
Diabetes mellitus ^b	9/51 (18%)	15/63 (24%)	7/44 (16%)	0.3932
Immunosuppressant ^b	4/51 (8%)	7/63 (11%)	4/44 (9%)	0.9414
Admission albumin (g/dL) ^a	3.1 (0.8)	3.1 (0.8)	2.9 (0.8)	0.3039
Wound class ^b				0.0964
Clean–contaminated	21 (42%)	16 (25%)	14 (32%)	
Contaminated	14 (29%)	18 (29%)	12 (28%)	
Infected	14 (29%)	29 (46%)	17 (40%)	
Surgical site outcomes ^b	6/51 (12%)	14/63 (22%)	5/44 (11%)	0.2295
Total days of NPWT ^d		20.5 (3–405)	3 (3–51)	<0.0001
Discharge to home ^b		40/63 (64%)	6/43 (14%)	<0.0001

The discharge home and the total days of NPWT do not apply to the primary closure group. Numerical variables are reported as mean (standard deviation) for age and median (range) for total days of NPWT. NPWT indicates negative pressure wound therapy; ASA PS, American Society of Anesthesiologists Physical Status score; BMI, body mass index.

^aAnalysis of variance.

^bChi-square test.

^cKruskal-Wallis.

^dMedian days, range of days, Wilcoxon rank sum.

were similar for all three groups (*Table 1*; *P* = 0.2295). Patients in the primary closure group had a larger portion of clean–contaminated wounds (43%) compared to patients in the traditional and protocol NPWT groups. There was no difference in wound classification for the traditional and protocol NPWT cohorts.

Of the five SSOs in the NPWT protocol group, none required operative re-intervention. Three of the five SSOs were superficial SSIs requiring conversion to open NPWT. One patient had a small fascial dehiscence that was managed nonoperatively. One patient developed an enterocutaneous fistula. Of the 14 SSOs in the standard NPWT group, 9 required a second operative or procedural intervention. One patient developed an enterocutaneous fistula. The remaining SSOs were superficial SSIs requiring drainage and further open NPWT. The six SSOs in the primary skin closure patients were SSIs that were managed with open packing in the outpatient setting.

DISCUSSION

The majority of NPWT data since its invention in the early 1990s comes from its use in orthopedics, podiatry, burns, plastic surgery, and diabetic foot wounds.^{3,4} These studies have been used to justify the use of NPWT for emergency midline celiotomy wounds^{3,4} despite a paucity of published literature supporting improved outcomes in this patient population. With the increased focus on surgical outcomes, specifically SSI as a possible “never” event,¹² many surgeons are defaulting to open wound management in high-risk wounds to decrease SSI rates. Our group of acute care surgeons (prior to this study) was divided between primary skin closure and open wound management with wound VAC for emergency midline laparotomy wounds. In order to drive our SSI rates to zero, we considered converting all emergency laparotomies to open management with wound VAC. However, this change would force an increase in postoperative care and cost to the patient.

Therefore, as part of a quality improvement initiative, we developed our current protocol as a hybrid of the two techniques. The Hydrofera Blue bacteriostatic strips act as a high effluent wick and were chosen over the black KCI V.A.C. sponge to minimize bacterial overgrowth in the wound and decrease the risk of leaving behind a foreign object. The Hydrofera Blue sponge is nonadherent and requires great force to tear. The Mepilex AG® Foam Dressing serves as the bactericidal medium for the application of negative pressure therapy. The goal was to facilitate drainage of postoperative exudate while still attaining early primary skin closure at discharge from the hospital. Our wound care team helped develop this protocol and was the primary engine in its application. The wound care team examined and discussed each NPWT protocol wound with the surgical team to determine timing of closure. As the process evolved, the wound care team became proficient in predicting which patients were ready for delayed primary skin closure versus continued NPWT management. The lead surgeon met with the wound care team on a weekly basis to evaluate outcomes and modify the protocol in real time.

It is not surprising that our data supports the consideration of primary skin closure or NPWT with Hydrofera Blue bacteriostatic strips over the traditional open NPWT to decrease total wound VAC days ($P = 0.001$) and patients discharged home requiring a wound VAC (14% vs 64%, OR = 10.7, 95% CI, 3.7–35.1, $P < 0.0001$). It is significant that closed wound management did not increase the incidence of SSOs in this high-risk surgical population. The groups were fairly balanced for the risk factors of age, body mass index, smoking, diabetes, immunosuppression, and preoperative albumin (Table 1). The traditional open NPWT group did include a higher percentage of patients with American Society of Anesthesiologists Physical Status (ASA PS) class IV and V and infected wounds; however, this was not statistically significant. Based on this study, all patients requiring emergent celiotomy with ASA PS class I–III and wound class of clean–contaminated or contaminated should be eligible for primary skin closure or our NPWT protocol once the fascia is closed. Further studies are needed to determine the safety in patients with infected wounds or ASA PS class IV or V.

This study has several limitations. First, the study was a retrospective chart review and was subject to selection bias. Prior to the quality initiative, patient placement into the primary skin closure group versus traditional NPWT group was based on surgeon decision. After intervention, placement into the new protocol NPWT group was not consistent. Attending preference still placed some patients into the traditional open NPWT group. This attending preference likely accounts for the traditional open NPWT having a slightly higher percentage of ASA PS class IV and V patients. Second, the study was not appropriately powered to detect a difference in SSOs between the groups. To obtain an 80% power detecting a difference in SSOs, we would have needed to enroll 670 subjects. Finally, our study could not determine whether primary skin closure or the NPWT protocol is better; however, both performed better than traditional

NPWT. We currently are prospectively evaluating primary skin closure with the KCI Prevena™ (KCI, San Antonio, TX) versus traditional open NPWT. In addition, there are currently two clinical trials in progress to help determine the efficacy of NPWT in midline abdominal incisions.^{13,14}

Our experience suggests that primary skin closure or NPWT with Hydrofera Blue bacteriostatic foam wicks can facilitate early wound closure with no increase in SSOs. Both of these methods decrease wound VAC days and discharge without a wound VAC.

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APPENDIX: GUIDELINES FOR MANAGEMENT OF AT-RISK SURGICAL INCISIONS

This guideline is meant to facilitate a regimented protocol for the management of abdominal surgical incisions in patients at high risk for surgical site infections—specifically, once the abdominal fascia is closed—among adult surgical patients admitted to the intensive care unit or general ward floor at Scott & White Medical Center. The individual patient's condition may necessitate deviation from this protocol on occasion. The guideline will be reviewed on a yearly basis or more often as advances in patient and wound care dictates.

Abdominal incision wound VAC protocol may *apply* to patients for whom the following apply:

1. Only surgical incisions with underlying fascia closed via suture or mesh.
2. Clean wounds with high surgical site infection risk factors, including but not inclusive of obesity, diabetes, current tobacco abuse, immunosuppression, and malnutrition.
3. Clean-contaminated wounds.
4. Open abdomen patients.
5. Contaminated or infected intra-abdominal contents but no evidence of soft tissue infection.
6. Partially closed ostomy sites.

Abdominal incision wound VAC protocol does *not* apply to patients for whom the following apply:

1. Grossly infected abdominal incisions.
2. Abdominal incisions draining enteric or pancreatic succus suggestive of an enterocutaneous fistula.
3. Reopening or reoperating incisions for necrotizing infections or soft tissue infections.

New abdominal incision wound VAC protocol (intraoperative application):

1. In the operating theater, once a patient satisfies the above criteria, the surgical team will ask the circulating nurse for the following:
 - a. A wound VAC unit with canister.
 - b. A single suction port.
 - c. Hydrofera Blue Wound Dressing (either the package of tubes or a 4 × 4-inch sheet).
 - d. Mepilex AG 4 × 8-inch surgical site dressing.
 - e. Tegaderm dressing (long).

2. The Hydrofera Blue wound dressing will need to be pre-soaked in sterile water prior to placement. The strips should be cut to 1 cm in diameter and long enough to extend at least 1 cm beyond the edge of the wound. (Dictate number of strips used and length of strips in operative report.)
3. The incision will be closed with staples in 3-cm sections with a 1-cm gap for insertion of the Hydrofera Blue dressing. Deeper wounds may require 2-cm spacing instead of 3-cm spacing to adequately drain the subcutaneous tissue (see below).
4. Once the Hydrofera Blue strips are placed with at least 1-cm extension outside the skin, the Mepilex AG will be applied. The Mepilex AG can be used to bridge skin incisions if connecting ostomy sites or more than one incision. The Mepilex AG is noncaustic to the skin and transmits the negative suction pressure of the wound VAC.
5. Next, apply the Tegaderm to occlude the Mepilex AG from the air.
6. Finally incise an "X" area through the Tegaderm onto the Mepilex AG to apply the Smith & Wesson suction port.
7. Set the wound VAC to 125 mm Hg of continuous suction.

New abdominal incision wound VAC protocol (postoperative management):

1. The abdominal wound VAC should remain in place as placed in the operating room for the first 3 days, unless wound or patient circumstances indicates earlier removal.
2. At day 3, the wound VAC and Hydrofera Blue wound dressings should be removed and the number of Hydrofera Blue strips should be verified by referencing the operative note in the chart or the dictated operative report in the computer. These may then be disposed of.
3. If the wound still shows a significant drainage, a new wound VAC protocol should be used for another 3 days.
4. The skin incision should then be prepped or cleansed with Chloraprep, and Steri-strips should be applied to completely close the wound. If a large gap remains or the patient's incision/body habitus requires, the skin gaps can be closed sterilely with skin staples or suture.
5. The patient will need postoperative assessment within 5 days of wound VAC packing removal, if discharged immediately.