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Intra-abdominal packing with laparotomy pads and QuikClot™ during damage control laparotomy: A safety analysis

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ABSTRACT

Background: Intra-abdominal packing with laparotomy pads (LP) is a common and rapid method for hemorrhage control in critically injured patients. Combat Gauze™ and Trauma Pads™ ([QC] Z-Medica QuikClot®) are kaolin impregnated hemostatic agents, that in addition to LP, may improve hemorrhage control. While QC packing has been effective in a swine liver injury model, QC remains unstudied for human intra-abdominal use. We hypothesized QC packing during damage control laparotomy (DCL) better controls hemorrhage than standard packing and is safe for intracorporeal use.

Methods: A retrospective review (2011–2014) at a Level-I Trauma Center reviewed all patients who underwent DCL with intentionally retained packing. Clinical characteristics, intraoperative and postoperative parameters, and outcomes were compared with respect to packing (LP vs. LP + QC). All complications occurring within the patients' hospital stays were reviewed. A $p \leq 0.05$ was considered significant.

Results: 68 patients underwent DCL with packing; (LP n = 40; LP + QC n = 28). No difference in age, BMI, injury mechanism, ISS, or GCS was detected (Table 1, all $p > 0.05$). LP + QC patients had a lower systolic blood pressure upon ED presentation and greater blood loss during index laparotomy than LP patients. LP + QC patients received more packed red blood cell and fresh frozen plasma resuscitation during index laparotomy (both $p < 0.05$). Despite greater physiologic derangement in the LP + QC group, there was no difference in total blood products required after index laparotomy until abdominal closure (LP vs LP + QC; $p > 0.05$). After a median of 2 days until abdominal closure in both groups, no difference in complications rates attributable to intra-abdominal packing (LP vs LP + QC) was detected.

Conclusion: While the addition of QC to LP packing did not confer additional benefit to standard packing, there was no additional morbidity identified with its use. The surgeons at our institution now select augmented packing with QC for sicker patients, as we believe this may have additional advantage over standard LP packing. A randomized controlled trial is warranted to further evaluate the intra-abdominal use of advanced hemostatic agents, like QC, for both hemostasis and associated morbidity.

Introduction

The leading cause of death in injured patients who reach the hospital is uncontrolled hemorrhage [1]. In patients with an abdominal source of bleeding, many die at the scene and up to 14% lose vital signs during transport to the hospital [2]. For the patients who present to the hospital alive, damage control laparotomy (DCL) is an effective method of identifying and controlling abdominal hemorrhage and contamination, often with the aid of intraperitoneal packing [3,4]. Currently, laparotomy pads (LP) are

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the most commonly utilized material for intraperitoneal packing. However, the use of hemostatic agents, in addition to LP, may offer better hemostasis without generating new complications.

Over the past ten years there has been a focus on the development of hemostatic agents to improve hemorrhagic control. Many of these efforts have been driven by the United States military to improve the hemostatic armamentarium of military combat care providers. Currently all deployed US army soldiers carry the hemostatic agent Combat Gauze™ (Z-Medica QuikClot®, Wallingford, CT) and are advised to use it by the Tactical Combat Casualty Care committee in the setting of external hemorrhage not amenable to tourniquet placement.5 In March of 2013, CG was approved by the US Food and Drug Administration (FDA) for external usage commercially in the civilian sector as well (510(K); #K120782) [5–7].

CG packing has been reported to decrease hemorrhage and mortality in both femoral artery and liver swine injury models [8–13], however the intra-corporeal use of CG or TP remains unstudied in humans. We hypothesized that the off-label addition of QC to standard LP packing during damage control laparotomy would improve hemostasis when compared to LP packing alone. We also sought to determine if QC packing would be associated with additional complications when used for intraabdominal packing.

Methods

A retrospective review at an urban, ACS verified, Level-I Trauma Center from August 2011 through December 2014 of all patients who underwent damage control laparotomy (DCL) with intra-abdominal packing was undertaken. The Institutional Review Board at Cooper University Hospital approved this retrospective review. Study exclusion criteria included age less than 18. During the 3.5-year study period, 329 injured patients presented to the trauma admitting area and were found to have intra-abdominal injuries necessitating laparotomy (Fig. 1). DCL was required and performed on 68 of those patients; the other 261 patients had standard laparotomies with abdominal closure. The 68 patients with damage control laparotomies represent our final study population.

Demographics, clinical characteristics, intraoperative and postoperative parameters, and outcomes were compared with respect to packing type. The type of packing, laparotomy pads (LP) or laparotomy pads plus Combat Gauze™ or Trauma Pads™ (LP + QC), was reviewed for each DCL. In the present study, we refer to Combat Gauze™ and Trauma Pads™ collectively as QuikClot (QC). Demographic data evaluated included age, gender, and BMI. Clinical characteristics studied included injury mechanism, Glasgow Coma Scale, Injury Severity Score, and injury grade. Intra-operative findings recorded included packing site, the number of LP or LP + QC used, and the length of time LP or LP + QC were left in place. Hemodynamic parameters studied included systolic blood pressure nadir, heart rate, and temperature in the trauma admitting area, during DCL, and postoperatively. Resuscitation parameters evaluated included massive transfusion protocol activation, intraoperative estimated blood loss, and blood product transfusion. Complications, hospital length of stay, intensive care unit length of stay, duration of mechanical ventilation, and mortality were analyzed.

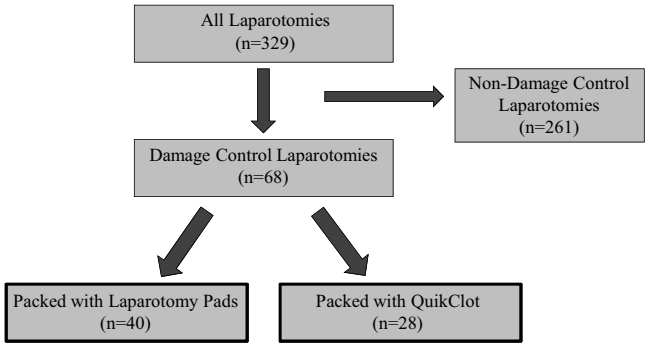

Fig. 1. The Final Study Population: Damage Control Laparotomy Patients with Intra-Abdominal Packing.

The primary study outcome we reviewed was hemostasis as measured by the volume of total blood product resuscitation (packed red blood cells, fresh frozen plasma, and platelets) required after packing placement. Complications were also analyzed. Measured complications included pneumonia, ventilator dependent respiratory failure, urinary tract infection, bacteremia, acute respiratory distress syndrome, deep vein thrombosis, pulmonary embolism, pancreatitis, ileus, acute kidney injury, enterocutaneous fistula, gastrointestinal bleed, wound infection, wound dehiscence, small bowel obstruction, pancreatic leak, cholecystitis, intra-abdominal abscess, and anastomotic leak. Organ/space infections were defined based on CDC criteria as any abdominal abscess located beyond the incision in an area that was manipulated during surgery [14].

Fisher's exact test, Student's *t*-test, Wilcoxon rank sum test, and multivariable analysis were used to compare categorical and continuous variables. A multivariable linear regression analyzed the total blood product resuscitation required by patients to evaluate our study endpoint, hemostasis. Group, age, BMI, injury mechanism, injury severity score, Glasgow Coma Scale, injury grade, massive transfusion protocol activation, systolic blood pressure on admission, intraoperative systolic blood pressure, intraoperative temperature, intraoperative, pH, and total number of packs placed were included in the multivariable model. A p-value < 0.05 was considered statistically significant.

Of note, the Eastern Association for the Surgery of Trauma, provided research support to the Trauma Surgical Department at Cooper University Hospital through funding from Z-Medica. There are no other disclosures or conflicts of interests.

Results

Of 329 patients who underwent exploratory laparotomies for traumatic injuries, 261 had standard laparotomies with abdominal closure and 68 patients underwent damage control laparotomy (Fig. 1). The median age of these DCL patients (n = 68) was 31 years (25th–75th percentile range: 25–41 years) and 44% sustained penetrating injury. Physiologic compromise was present in DCL patients as the median systolic blood pressure nadir during the trauma resuscitation was 80 mmHg (57–103 mmHg) with a GCS of 14 (3–15) and massive transfusion protocol was initiated in 77% of patients. After a median of 2 laparotomies, hospital length of stay was prolonged at 24.5 days (7–43 days), and 72% survived their hospitalization.

Patients were compared with respect to packing type during DCL. Of the 68 patients who underwent DCL, 40 patients had LP packing alone and 28 patients had LP + QC packing. There was no difference among the two study populations with respect to age, BMI, mechanism of injury, ISS, or GCS (Table 1; all $p > 0.05$). Likewise, solid organ injury occurred in 55% of LP and 57% of LP + QC patients (both $p > 0.05$). Of those 28 LP + QC, Combat Gauze™ was used in 19 patients and Trauma Pads™ were used in 9 patients. There were 13 trauma surgeons that performed the 68 DCLs. The use of LP vs. LP + QC was evenly distributed among attendings; 11 of the 13 trauma surgeons utilized LP + QC intra-abdominal packing.

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Table 1
Clinical Characteristics Compared with Respect to QuikClot Packing™.

	Laparotomy Pads (LP) (n = 40)	Laparotomy Pads + QuikClot (LP + QC) (n = 28)	*p* Value
Age (years)	29.5 (24.0–43.0)[a]	34.5 (27.5–40.0)	0.782
BMI	26.6 (23.5–30.8)	25.7 (22.6–31.1)	0.765
Injury Mechanism			
Blunt	23 (58%)	15 (54%)	0.807
Penetrating	17 (43%)	13 (46%)	0.807
Injury Severity Score	22 (16–34)	25.5 (13.5–34)	0.892
Initial Glasgow Coma Score	12.5 (3–15)	14 (6–15)	0.340
Massive Transfusion Protocol	28 (70%)	24 (86%)	0.158
TAA Systolic Blood Pressure Nadir (mmHg)	84.5 (60–110)	70 (50–89)	0.079
Initial OR Systolic Blood Pressure Nadir (mmHg)	80 (60–96)	72 (60–98)	0.411
Initial OR Temperature Nadir (degrees Fahrenheit)	95.2 (94.1–96.4)	95.0 (93.7–96.6)	0.276
Initial OR pH Nadir	7.17 ± 0.1[b]	7.18 ± 0.1	0.581
Initial OR Estimated Blood Loss (mL)	1650 (500–2750)	2000 (1000–7000)	0.064
Initial OR IVF (mL)	3000 (2000–6250)	3000 (1350–4950)	0.609
Initial OR PRBC (units)	5 (1.5–12.5)	10 (5–19.5)	**0.040**
Initial OR FFP (units)	4 (0–10)	8 (3.5–20.5)	**0.025**
Initial OR Platelets (units)	0 (0–2)	1 (0–4)	0.070
Solid Organ Injury (Indication for Packing)	22 (55%)	16 (57%)	0.460
Mean Grade	3 (2–4)	3 (3–4)	0.190
Major Vascular Injury (Indication for Packing)	10 (25%)	10 (36%)	0460
Mean Grade	3 (1–3)	3 (3–4)	0.719
Total IVF, Initial Laparotomy to Closure (mL)	10,088 (5804–17,508)	11,088 (8700–18,299)	0.621
Total PRBC Initial Laparotomy to Closure (units)	1.5 (0–3)	2 (0–4.5)	0.147
Total FFP Initial Laparotomy to Closure (units)	2 (0–4.5)	2 (0.5–5.5)	0.265
Total Platelets Initial Laparotomy to Closure (units)	0 (0–1)	1 (0–2)	0.129
Total Blood Products, Initial Lap to Closure (units)	4 (0.5–10)	4.5 (2.5–13.5)	0.144
Total # of Laparotomies per Patient	2 (2–3)	2 (2–3)	0.239
Total # of Packs Placed (LP or LP + CG)	3 (1–8)	6 (4–9)	0.182
Duration of Abdominal Packing (days)	1.0 (0–2)	2.0 (1–2)	<0.001
Days until Abdominal Closure	2.0 (1–4)	2.0 (2–4)	0.405

(TAA = Trauma Admitting Area).
[a] Median (25th–75th Percentile Range).
[b] Mean ± Standard Deviation.

Both study groups were hypotensive, hypothermic, and acidotic during the index DCL (all $p > 0.05$). The LP + QC patients had a trend towards lower systolic blood pressure on presentation during trauma resuscitation (70 (50–89) vs. 84.5 (60–110)mmHg; $p = 0.079$) and had greater median blood loss (2000 vs. 1650cc; $p = 0.064$). The LP + QC patients required more blood product resuscitation, specifically greater packed red blood cell units (10 vs. 5 units PRBC; $p = 0.040$) and fresh frozen plasma units (8 vs. 4 units FFP; $p = 0.025$), during index laparotomy than LP patients. There was no significant difference in the number of packs placed in the

Table 2
Post-Operative Complications.

	Laparotomy Pads (LP) (n = 40)	Laparotomy Pads + QuikClot (LP + QC) (n = 28)	*p* Value	Odds Ratio	95% Confidence Interval
Pneumonia	19 (48%)	12 (43%)	0.81	0.83	0.31–2.19
Ventilator Dependent Respiratory Failure	22 (55%)	15 (54%)	1.00	0.94	0.36–2.49
Urinary Tract Infection	4 (10%)	7 (25%)	0.18	3.00	0.78–11.47
Bacteremia	12 (30%)	10 (36%)	0.79	1.30	0.46–3.62
Acute Respiratory Distress Syndrome	1 (3%)	2 (7%)	0.56	3.00	0.26–34.8
Deep Vein Thrombosis	13 (33%)	10 (37%)	0.80	1.22	0.44–3.40
Pulmonary Embolism	3 (8%)	1 (4%)	0.64	0.46	0.05–4.63
Pancreatitis	1 (3%)	0	1.00	0.46	0.02–11.76
Ileus	12 (30%)	6 (21%)	0.58	0.64	0.21–1.97
Acute Kidney Injury	9 (23%)	16 (57%)	0.01	4.60	1.60–13.18
Enterocutaneous Fistula	0	0			
Gastrointestinal Bleed	3 (8%)	2 (7%)	1.00	0.95	0.15–6.08
Wound Infection	3 (8%)	4 (14%)	0.43	2.06	0.42–10.01
Dehiscence	5 (13%)	3 (11%)	1.00	0.84	0.18–3.84
Small Bowel Obstruction	1 (3%)	0	1.00	0.46	0.02–11.76
Cardiac Tamponade	1 (3%)	0	1.00	0.46	0.02–11.76
Pancreatic Leak	4 (10%)	0	0.14	0.14	0.01–2.75
Intra-abdominal Abscess	8 (20%)	4 (14%)	0.75	0.67	0.18–2.48
Packing Placed in Area of Abscess	1/8 (13%)	1/4 (25%)	1.00		
Anastomotic Leak	4 (10%)	0	0.14	0.14	0.01–2.75
Cholecystitis	0	3 (11%)	0.07	11.12	0.55–224.27
Total Complications	3.5 (0–5)	3.5 (1–6)	0.34	3.57	0.90–14.13
Ventilator Days	6.0 (2–12)[a]	7 (2–13)	0.42		
ICU Length of Stay (days)	11.0 (2–17)	11.5 (3–20.5)	0.83		
Hospital Length of Stay (days)	26.0 (11–34)	25.5 (7.5–50)	0.43		
Hospital Mortality	11 (28%)	8 (29%)	1.00		

[a] Median (25th–75th Percentile Range).

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LP vs. LP + QC groups (3 vs. 6 packs; $p = 0.182$), however the LP + QC group had a longer duration of intra-abdominal packing (2 vs. 1 days; $p < 0.001$). The indication for packing was solid organ injury in 55% of LP and 57% of LP + QC patients and major abdominal vascular injury in 25% of LP and 36% of LP + QC patients; the remaining patients had pelvic packing placed. No difference was detected between the number of laparotomies performed in either group; a median of two laparotomies was performed in both the LP and LP + QC groups ($p = 0.239$). Despite a greater injury and physiologic burden in the LP + QC group, there was no difference in total blood product resuscitation required in either group *after* intra-abdominal packing during index laparotomy until abdominal closure (LP 4 vs. LP + QC 4.5 units of product; $p = 0.144$).

Of the 68 patients who underwent damage control laparotomies, 13 different surgeons (maximum 8 cases, minimum 1 case) performed the index laparotomies. Nine of the 13 surgeons used both treatments (LP vs. LP + QC) for different patients. Each surgeon in turn was compared to the remaining 12 based on the primary outcome, volume of total blood products. None of the surgeons were significantly different when compared to the remaining group. Comparing the total packs used, twelve of the surgeons were not significantly different when compared to the remaining group.

Outcomes were assessed between packing study groups. Despite a longer duration of intra-abdominal packing in the LP + QC group, there was no difference in the median total number of complications between LP and LP + QC patients (3.5 vs. 3.5; $p = 0.336$). Table 2 describes post-damage control laparotomy complications among patients with either LP or LP + QC intra-abdominal packing. There was no difference between the two groups when comparing pneumonia, ventilator dependent respiratory failure, urinary tract infection, bacteremia, acute respiratory distress syndrome, pancreatitis, ileus, gastrointestinal bleed, wound infection, dehiscence, small bowel obstruction, cardiac tamponade, pancreatic leak, anastomotic leak, enterocutaneous fistulas, or cholecystitis (all $p > 0.05$). More patients with LP + QC packing were found to have an acute kidney injury complication.

Organ/space infections were also measured. Eight LP patients and 4 LP + QC patients had intra-abdominal abscesses ($p = 0.748$). Of the 8 intra-abdominal abscesses in the LP group and 4 intra-abdominal abscesses in the LP + QC group, only one abscess in each group was in the same region where packing had been placed (Table 2; $p = 1.000$). In the 12 patients who developed abscesses, 4 patients had peri-hepatic packing, 1 splenic bed packing, 2 vascular anastomosis packing, and 5 pelvic packing. Ten of these resulting abscesses were not in the same quadrants as the packing placed. However one LP patient developed a pelvic abscess after pelvic LP packing; this patient also had contamination after a GSW requiring ileocolectomy. One LP + QC patient developed a peri-hepatic abscess after GSW and peri-hepatic packing with LP + QC, hepatorrhaphy, pancreatic injury repair, and diaphragm repair. Thirteen trauma surgeons performed the DCLs, 8 of those surgeons were responsible for the 12 abscess complications indicating equal distribution.

There was no difference among survival between the two populations (Table 1; $p = 1.000$). There were 16 patients in total who underwent DCL and died within 48 h, Table 3 reveals their cause of death. Four died secondary to TBI, 9 died secondary to hemorrhagic shock from intra-abdominal injuries, 2 died secondary to hemorrhagic shock from cardiac injuries, and one died secondary to a thoracic crush injury and pulmonary contusions. There were 3 additional deaths that occurred from long-term sequelae at 12, 17, and 31 days of hospitalization. To our knowledge, no patient died secondary to a pulmonary embolism.

A multivariable linear regression analyzed the total blood product resuscitation required by patients to evaluate our study endpoint, hemostasis (Table 4). While we did use a number of variables in the initial multivariable linear regression model, ultimately we used backwards statistical selection to determine the usage of two variables, initial systolic blood pressure nadir and injury grade, in the final model. This demonstrated that while the type or quantity of packs placed was not associated with blood product resuscitation or hemostasis, both injury grade and initial systolic blood pressure nadir were statistically significant predictors of blood product resuscitation.

Discussion

While we initially hypothesized the use of QC during damage control laparotomy would improve hemostasis, we did not find a difference in either blood product transfusion or crystalloid administration between study groups. Furthermore, we did not find that the addition of Combat Gauze™ or Trauma Pad™ packing to standard laparotomy pad intra-abdominal packing was associated with additional complications after damage control laparotomy.

Prior to Combat Gauze and Trauma Pads, first and second-generation QuikClot products used the mineral zeolite, in powder and bead form, to concentrate blood and non-selectively activate the clotting cascade. While zeolite QuikClot products were reported to improve hemorrhage and mortality in hemorrhagic swine models [15–18], exothermic reactions in several swine and human patients resulted in pain, tissue damage, and burns [18–20]. The third-generation QuikClot products, Combat Gauze™ and Trauma Pads™, utilize kaolin, not zeolite, and therefore those exothermic reactions have been eliminated [5]. The patients in our study were only exposed to kaolin-impregnated QuikClot products, not to zeolite containing products, appropriately there were no exothermic reactions or tissue changes identified among our study population.

During the first 2.5 years of this study, our institution only had access to the QuikClot product, Combat Gauze™. In the last year of the study our institution began supplying our trauma department with Trauma Pads™ as well. The patients who had LP + QC packing

Table 3
Cause of Death in Patients Who Underwent Damage Control Laparotomy and died within 48 h of Presentation.

Cause of Death	Laparotomy Pads (LP) (n = 40)	Laparotomy Pads + QuikClot (LP + QC) (n = 28)
Traumatic Brain Injury	3	1
Hemorrhagic Shock from Intra-abdominal Blood Loss	7	2
Hemorrhagic Shock from Cardiac Blood Loss	0	2
Hypoxia secondary to Pulmonary Contusions	0	1
Pulmonary Embolism	0	0
Total Mortality	10	6

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Table 4
Multivariable Model for Resuscitation Endpoint: Total Blood Products Required. (PRBC, FFP, and Platelets).

Variable	Regression Coefficients	95% Confidence Interval	*p* Value
Group	3.32	−2.09 8.74	0.219
Age	0.01	−0.20 0.23	0.893
BMI	0.33	−0.22 0.89	0.233
Injury Severity Score	−0.03	−0.25 0.18	0.756
Initial Glasgow Coma Score	−0.24	−0.82 0.33	0.395
Injury Grade	2.07	0.07 4.08	0.042
Massive Transfusion Protocol	−1.20	−7.64 5.23	0.705
TAA Systolic Blood Pressure Nadir	−0.02	−0.09 0.05	0.559
Initial OR Systolic Blood Pressure Nadir	−0.04	−0.15 0.07	0.454
Initial OR Temperature Nadir	0.19	−1.36 1.75	0.800
Initial OR pH Nadir	−11.43	−36.35 13.48	0.356
Total # of Packs Placed (LP or LP + CG)	0.26	−0.35 0.89	0.384

Multivariable Model with Statistical Selection for Resuscitation Endpoint: Total Blood Products Required (PRBC, FFP, and Platelets)

Variable	Regression Coefficients	95% Confidence Interval	*p* Value
TAA Systolic Blood Pressure Nadir	−0.05	−0.10 −0.01	0.041
Injury Grade	2.25	0.56 3.95	0.010

during the first 2.5 years had Combat Gauze™ and the LP + QC patients during the 3rd year of the study had Trauma Pad™ packing. Both products are made by Z-Medica QuikClot® and are kaolin-impregnated hemostatic agents, however Combat Gauze™ comes in a form consistent with a long piece of gauze whereas Trauma Pads™ are impregnated 12 × 12 inch laparotomy pads. While Combat Gauze™ was still available during the 3rd year, our group found the Trauma Pads™ to be more consistent with regular laparotomy pads making for better hemostatic packing agents. Additionally, intraoperatively we found Trauma Pads™ to be less adherent to intra-abdominal structures than Combat Gauze™, making it easier to remove on return laparotomy. Therefore our practice trended toward the use of Trauma Pads™ instead of Combat Gauze™ when used intra-abdominally. Anecdotally we did not find that Trauma Pads™ were more or less adherent than plain laparotomy pads.

The development of local hemostatic agents to improve hemorrhagic control has been studied for several years. A human case series by Arul et al. indicated hemostatic pelvic packing with the agent, Celox Gauze™, proved to be a useful adjunct to plain laparotomy pad packing [21]. This study along with other clinical experiences led to further research developments involving intracorporeal hemostatic packing. Swine injury models using CG packing has successfully been shown to significantly decrease hemorrhage and mortality in external femoral swine injury models [8–11]. In 2009, Kheirabadi et al. created a femoral artery swine injury model and found CG was the most effective hemostatic agent tested in controlling arterial hemorrhage when compared to HemCon (HemCon Inc, Portland, OR), Celox (SAM Medical, Portland, OR), TraumaStat (Ore-Medix, LLC Company, Labanon, OR), and placebo plain gauze. Furthermore while CG did not significantly reduce bleeding, they revealed CG did improve the length of survival when compared to plain gauze [11]. In 2012, Causey et al. compared CG to plain gauze in an acidotic, coagulopathic swine model with a supraceliac aortic ischemic reperfusion injury and femoral artery injury and determined that CG maintained its efficacy in acidotic and coagulopathic conditions but did not significantly improve hemorrhage or survival [22]. Several studies have now used CG as a control for comparison to newer hemostatic products [23–25]. In our study, acidotic and coagulopathic bleeding patients underwent DCL for intra-abdominal injuries and had LP + QC or LP alone used to obtain hemostasis. While the addition of QC to standard LP packing intra-abdominally was not associated with a decrease in either blood product or crystalloid resuscitation, LP + QC packing was comparable to LP alone in an acidic environment.

The use of QC has been recognized and established for external use, but its internal use may improve intra-abdominal hemorrhage control as well. In 2013, Sena et al. created a left medial liver lobe injury with a wire saw in swine after exsanguination through a branch of the superficial femoral artery. The swine packed with CG had significantly less blood loss than swine packed with laparotomy pads but no difference in mortality. Post-operative tissue histology did not reveal any inflammation, necrosis, or residual material [12]. In 2012, Inaba et al. created a grade V liver injury in a swine exsanguination model; swine were packed with CG, Celox (SAM Medical, Portland, OR), Celox Gauze (SAM Medical, Portland, OR), or standard gauze. Blood loss was significantly less in the CG and Celox Gauze swine after DCL and survival was greater in CG swine after 14 days. Post-operative vascular tissue analysis did not reveal any embolic events in multiple organ systems.13 In our study, longer-term hospital course data revealed LP + QC did not result in more packing-related complications when compared to LP alone. There were 3 patients in the LP group and only 1 patient in the LP + QC group who developed pulmonary emboli ($p = 0.638$). There were no deaths secondary to pulmonary emboli in this study. We do not attribute the embolic complications that did occur to QuikClot packing because there was not a significant difference in pulmonary emboli between the two populations and all 4 of the patients with pulmonary emboli had deep vein thromboses as well. This data, along with findings from prior studies, suggests both Combat Gauze™ and Trauma Pads™ may be safely utilized for temporary intra-abdominal packing during DCL.

Prior literature has identified post-operative complications secondary to intra-abdominal packing with laparotomy pads during damage control laparotomy. Abdominal organ/space infection rates as high as 18–33% have been reported as well as dehiscence and enteric fistulae [26–29]. Adams et al. collected fluid samples from laparotomy pads removed after damage control laparotomies, which revealed suppression of polymorphonuclear neutrophil responses and dysfunction contributing to systemic inflammatory response syndrome [30]. Abikhaled et al. found that patients with laparotomy pad packing left in place for greater than 72 h had significantly more abscesses and increased mortality [31]. Our practice is to remove packing well before 72 h and our abscess rate was 14.3% in patients packed with QC in addition to laparotomy pads. This organ/space infection rate compares favorably with prior studies from this institution utilizing plain

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LP packing for DCL that reported a 17–33% rate of organ/space infections [28,19]. This suggests that temporary intra-abdominal QC packing does not lead to increased rates of known packing-related complications.

At our institution, damage control laparotomy is performed in patients with intra-abdominal injuries who are hemodynamically unstable, coagulopathic, acidotic, and/or hypothermic. Hemostasis is achieved during index laparotomy via repair of vascular injuries and/or packing solid organ injuries while contamination is contained. Second look operations examine injuries for hemostasis and complete any anastomoses for concomitant hollow viscus injuries. At our institution, take-back laparotomy after index damage control laparotomy is performed within 48 h and packing is either removed or exchanged for new packing. In patients requiring prolonged abdominal packing, LP or LP + QC are exchanged every 48 h until final removal and attempted abdominal closure within 7 days. While type of anastomosis (stapled versus hand-sewn) and timing of anastomosis were based on the surgeon's discretion and not an institution specific guideline, no difference between study groups was appreciated. Over the course of this study, August 2011 through December 2014, we did not have any changes in the care or protocols used to treat patients who underwent damage control laparotomies. For example massive transfusion protocol remained the same.

While our institution follows guidelines regarding DCL and intra-abdominal packing, the decision to use kaolin-impregnated QuikClot® products for intra-abdominal hemostatic packing was based on surgeon discretion. Over the 3.5-year study period we saw an increasing trend in the use of QC intra-abdominally during DCL. In this study, the patients who were packed with QC had lower systolic blood pressure on presentation and higher estimated blood loss requiring greater resuscitation with blood product during the index laparotomy. While we don't have a protocol dictating when to use QC products, this indicates our surgeons tend to use QC products in patients who are sicker.

We recognize our study limitations. This was a retrospective study from a single institution with potential shortcomings inherent in this design. While study definitions were rigorously applied, documentation within the medical record was required for analysis of each study variable. This study would have benefited from a greater sample size to improve study power, especially when comparing complications since the frequency of complications was rare in both groups. Additionally, we acknowledge the possibility of a selection bias in our study, as patients were not randomized to receive LP + QC or LP alone, the decision to pack with QC was based on the discretion of the operating surgeon. Several additional or unrecognized factors likely contribute to both bleeding and complications in these critically injured patients. A larger randomized, prospective study that controls for the type of operation and surgeon, would better determine the effect of QC on hemorrhage and complications.

Conclusion

While the addition of QC to LP packing did not confer additional benefit to standard packing, there was no additional morbidity identified with its use. The surgeons at our institution now select augmented packing with QC for sicker patients, as we believe this may have additional advantage over standard LP packing. A randomized controlled trial is warranted to further evaluate the intra-abdominal use of advanced hemostatic agents, like QC, for both hemostasis and associated morbidity.

Conflict of interest

To the best of our knowledge, no personal conflict of interest exists.

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