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THE EFFECT OF DAMAGE CONTROL LAPAROTOMY ON MAJOR ABDOMINAL COMPLICATIONS: A MATCHED ANALYSIS

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Introduction

Damage control laparotomy (DCL) has revolutionized care of severely injured trauma patients.^{1,2} However, the open abdomen necessitated by damage control has been associated with a multitude of complications including increased rates of fascial dehiscence, infection, incisional hernia, and enteric suture line failure.^{3,4}

A major limitation of studies evaluating complications associated with DCL is that patients receiving definitive laparotomy and those receiving a DCL are systematically different. Additionally, it is impossible to retrospectively evaluate the appropriateness of DCL in order to estimate the independent effect of DCL on these complications.

As one facet of a multifaceted quality improvement project aimed to decrease the utilization of DCL, all DCLs were adjudicated to have been either appropriate for DCL or potentially safe for definitive laparotomy (potential definitive laparotomy or pDEF).⁵ We hypothesize that patients who underwent DCL but may have safely been closed at the first operation (pDEF) will have increased major abdominal complications compared to those who underwent definitive laparotomy.

Methods

This study was approved by the UT Health McGovern Medical School Institutional Review board. Emergent laparotomy was defined as admission directly to the operating room from the emergency department (ED). Definitive laparotomy (DEF) was defined as in which the fascia was closed at the primary operation. DCL was defined as temporary closure of the abdomen with a dressing.

From November 1, 2013 through October 31, 2015, all emergent trauma laparotomies were prospectively followed as part of a prospective quality improvement project intended to decrease the rate of DCL at our institution. As part of that quality improvement project, trauma faculty adjudicated by majority vote all DCLs as patients who either a) were

appropriate for DCL or b) could have been safely closed at the first operation. Thus, a unique group of patients was identified – those who underwent DCL but could have safely undergone definitive laparotomy, the pDEF group.

Adjudication occurred at monthly trauma faculty meetings, with high rates of attendance. A PowerPoint presentation of each DCL was given, including: the anesthetic record of the operation, including vital signs, transfusions, and lab values from the beginning through the end of the case; the stated indication for DCL; ICU arrival vital signs and lab values; patient outcome and indication-specific outcomes (e.g. if indication was planned second look, did the second look identify any ongoing pathology). The meeting was then opened for discussion about the specific patient and the utility of the indication that was stated for DCL.

As one of the goals of the quality improvement project was to evaluate the indications for DCL utilized at our institution, no specific criteria were given to faculty as to whether a patient was appropriate for DCL or could have safely undergone definitive laparotomy. Those decisions were made individually after reviewing the patient data, indication for DCL, and outcome, fully utilizing “20/20” retrospective point of view. After the discussion was complete, the trauma faculty voted the DCL to be appropriate or that the patient may have been safely closed. pDEF was determined by majority vote.

This group of patients who were felt to have been safe for closure, the pDEF patients, were then matched to DEF patients collected from January 1, 2011 through October 31, 2015. Matching was performed in a 1:1 ratio using the following variables that were determined *a priori*: mechanism, abdominal Abbreviated Injury Scale, operating room red blood cell transfusions, and performance of a colectomy. Bowel anastomotic and abdominal closure methods were not standardized nor compared between groups.

The primary outcome of this study was major abdominal complications (MAC). MAC was a composite variable intended to increase the power of the study and consisted of the following complications: organ/space surgical site infection, fascial dehiscence, enteric suture line failure, reopening of laparotomy after fascial closure, or death, as it is a competing variable. Secondary outcomes included the individual components of MAC, other morbidity, and lengths of stay.

Continuous data are presented as medians with 25th to 75th interquartile range (IQR). Categorical data are presented as numbers with percentages. A frequentist analysis was performed using Wilcoxon rank sum, Chi Square, and Fisher’s Exact test for continuous, binary, and sparse binary variables, respectively.

A Bayesian analysis was also performed to complement the frequentist analysis.^{6,7} Bayesian analyses estimate the probability of treatment benefit based upon both prior known data and the collected data in a study and is especially advantageous in studies with limited sample size to detect treatment effects. This approach is also more intuitive for surgeons as it is easier to use probabilities in medical decision making as opposed to odds ratios.^{8,9,10} Bayesian statistics can not only calculate the probability of that a treatment effect exists at all (i.e. $RR < 1.0$) but also can calculate the probability of a specific treatment effect (i.e. $RR < 0.8$). As no existing treatment effects for this group of patients exists, we used a neutral

informative prior centered at a relative risk of 1.0 with a 95% prior interval of 0.5 – 2.0 (a prior that excludes large treatment effects).

All calculations were performed using STATA statistical software (version 14.2; Stata Corporation, College Station, TX).

Results

During this time period there were 1,029 emergent laparotomies. Of these, 665 (65%) were DEF and 321 (31%) were DCL, with 43 (4%) intraoperative deaths. During the two year quality improvement project, a total of 101 DCLs were adjudicated identifying 27 pDEFs. After 1:1 matching, 16 matched pairs were identified. The groups were well matched, with no significant differences in age, gender, mechanism, body mass index, pre-hospital vital signs, and pre-hospital resuscitation (Table 1). The pDEF and DEF groups also had no significant differences in any regional abbreviated injury scale (AIS) or ISS. As Abdominal AIS was used as a matching variable, it was not significantly different between the two groups.

Upon arrival to the emergency department, no significant differences in vital signs or resuscitation were seen (Table 2). No difference in coagulopathy by thromboelastography was seen. The pDEF did have a significantly lower arrival base excess (median -5 [-8 , -3] versus -3 [-5 , 0], $p=0.016$).

Upon arrival to the operating room, no difference in vital signs or degree of shock were seen (Table 3). Intra-operative resuscitation and end of laparotomy vital signs were also not significantly different. Additionally, there were no significant differences in the procedures performed in the operating room.

In the pDEF group, the indications for DCL were as follows: contamination (1 or 7%), to expedite post-operative imaging (3 or 19%), hemodynamic instability (2 or 13%), packing (1 or 7%), and planned second look (9 or 56%). Second look operations were planned to evaluate either bowel viability after severe mesenteric or pancreaticoduodenal injury. If a second look operation was negative, the DCL was considered to have potentially been safe for DEF. If expedited post-operative imaging was negative, for example in the case of suspected traumatic brain injury, the DCL was considered to have potentially been safe for DEF. Intestinal discontinuity was utilized in all 9 patients who had any enteric resection.

The pDEF group had a clinically, but not statistically, significant higher rate of MAC or death (56% versus 19%, $p=0.066$) (Table 5). The pDEF had higher rates of fascial dehiscence (38% versus 0%, $p=0.018$) and reopening of laparotomy after fascial closure (38% versus 0%, $p=0.018$). In the six reopening in the pDEF group, 5 were for sepsis and 1 for hemorrhage. There was no statistically significant difference in organ/space surgical site infection, enteric suture line failure, or death. The pDEF group also had higher rates of sepsis, acute renal failure, and superficial surgical site infections (Table 5).

The pDEF group had fewer ventilator- (29 (27, 30) vs 30 (29, 30), $p=0.001$), intensive care unit- (13 (2, 24) vs 29 (27,30), $p=0.001$), and hospital-free (1 (0, 7) vs 18(23,30), $p=0.001$)

days. Finally, disposition options included skilled nursing facility, long term assisted care, rehabilitation, transfer or home. Disposition home following hospitalization did not differ between the two groups (DEF 69% versus pDEF 50%, $p=0.776$).

Using the Bayesian model, there was a 92% probability that DEF was associated with lower MACs than pDEF and an 88% probability that the DEF was associated with an at least 10% reduction the relative risk of MAC compared to pDEF. Additional probabilities of different levels of treatment benefit are listed in Table 6.

Discussion

In this study of matched patients, a frequentist analysis of pDEF patients showed a clinically but not statistically significant increase in MAC or death compared to DEF patients. Using a Bayesian model, there was a high probability of increased MAC or death in patients who underwent pDEF compared to DEF.

While DCL certainly has improved survival for severely injured and physiologically deranged patients, it has probably been overused in trauma patients undergoing emergent laparotomy.^{4,11} Indeed, there is much variation in the use of DCL across the United States.¹² A major problem is that the indications for DCL supported by high quality data are lacking or poorly defined. Expert opinion studies have identified 1,099 indications for DCL, but only 87 of these have been evaluated in original research publications, all retrospective.¹³

This study supports the existing literature that overwhelmingly suggests an association between the open abdomen necessitated by DCL with post-operative abdominal complications, including incisional hernia, fascial dehiscence, enterocutaneous fistula, and organ/space surgical site infection.^{3,14,15,16,17,18} While the results of this study were not surprising, this analysis adds to the existing literature attempting to determine the treatment effect of DCL on post-operative morbidity by using novel methodology.

First, this analysis was unique in that we included prospectively identified patients who underwent damage control laparotomy but were felt to have been candidates for definitive laparotomy. This was performed by extensive review of the medical record and majority vote by trauma faculty. This creates a group of patients who are at risk for both definitive and damage control laparotomy during the emergent operation. Attempting to retrospectively determine by chart review if a patient undergoing damage control laparotomy could or should have undergone definitive laparotomy is not possible. This methodology decreases the inherent bias involved in such types of analyses by only including patients at risk for both damage control and definitive laparotomy.

Second, the Bayesian model improves upon the existing literature aiming to understand the effect of damage control laparotomy on post-operative morbidities. The low number of patients decreases the power of the study to detect a treatment effect. We attempted to address this by using a composite primary outcome and including a Bayesian model. The Bayesian model aids in understanding the treatment effect of damage control laparotomy by providing probabilities. Probabilities are much easier for surgeons to understand compared to the p-values and odds ratios determined from logistic regression. Not only are they easier

to understand, probabilities are easier to incorporate into medical decision making compared to odds ratios.^{19,20}

The limitations of this study include a small sample size. We attempted to address this lack of power by using a composite outcome variable, MAC, and by complementing the frequentist analysis with a Bayesian model. Additionally, though the pDEF patients were collected prospectively, this study was not a randomized clinical trial and, as such, was still subject to the inherent biases of retrospective studies.

Conclusions

Performing a damage control laparotomy in patients who could have safely undergone definitive laparotomy was associated with an increased risk of major abdominal complications. Future study using a similar methodology and Bayesian analysis but with more patients is needed to better estimate the treatment effect of damage control laparotomy on post-operative morbidity.

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Table 1.

Demographics, Pre-Hospital Variables, and injury Severity

Variable	DEF (n=16)	pDEF (n=16)	p value
Demographics			
Age, years	29 (23, 41)	38 (27, 64)	0.193
Gender Female Male	6 (37%) 10 (63%)	4 (25%) 12 (75%)	0.704
Mechanism Blunt Penetrating	10 (63%) 6 (37%)	10 (63%) 6 (37%)	1.000
BMI, kg/m ²	27 (22, 32)	28 (27, 33)	0.187
Pre-Hospital Vitals and Resuscitation			
SBP, mmHg	114 (105, 130)	100 (90, 129)	0.437
Heart rate, bpm	119 (88, 110)	110 (100, 126)	0.189
Glasgow Coma Score	15 (15, 15)	15 (14, 15)	0.557
Crystalloid, mL	150 (0, 500)	0 (0, 740)	0.975
Red blood cells, units	0 (0, 0)	0 (0, 0)	0.380
Injury Severity			
Head AIS	0 (0, 2)	0 (0, 0)	0.828
Face AIS	0 (0, 0)	0 (0, 0)	0.576
Chest AIS	2 (0, 3)	3 (1, 3)	0.624
Abdomen AIS	3 (2, 4)	3 (2, 4)	1.000
Extremity AIS	2 (0, 3)	1 (0, 2)	0.572
External AIS	1 (0, 1)	1 (0, 1)	1.000
Injury Severity Score	18 (13, 40)	22 (13, 32)	0.895

Continuous variables presented as: median (IQR) DEF- definitive laparotomy; pDEF – potentially safe for definitive laparotomy; BMI – body mass index; SBP – systolic blood pressure; AIS – abbreviated injury scale

Table 2.**Emergency Department Vitals, Labs, and Resuscitation**

Emergency Department	DEF (n=16)	pDEF (n=16)	p value
Vitals			
Temperature, F	97.7 (96.5, 98.1)	97.7 (97.0, 98.0)	0.923
Systolic blood pressure, mmHg	105 (89, 125)	108 (85, 122)	0.940
Heart rate, bpm	114 (93, 121)	105 (94, 115)	0.497
Glasgow Coma Score	15 (15, 15)	15 (14,15)	0.053
Laboratory Values			
Lactic Acid	3.2 (1.9, 4.0)	3.9 (3.0, 4.5)	0.192
Base Excess	-3 (-5, -0)	-5 (-8, -3)	0.016
Hemoglobin	13.3 (12.3, 14.4)	12.4 (10.8, 14.8)	0.449
Platelet level	230 (196, 280)	207 (200, 265)	0.826
Activated clotting time, seconds	113 (105, 121)	113 (105, 113)	0.576
R-time, minutes	0.7 (0.6, 0.8)	0.7 (0.6, 0.7)	0.557
Alpha angle, degrees	75 (72, 76)	70 (69, 75)	0.155
Maximum amplitude, mm	65 (61, 68)	59 (56, 67)	0.063
LY30	0.6 (0.0, 1.5)	0.8 (0.0 2.0)	0.917
Resuscitation and Other			
Red blood cells, units	1 (0, 2)	1 (0, 2)	0.984
Fresh frozen plasma, units	1 (0, 1)	0 (0, 2)	0.984
Positive FAST, %	7 (44%)	12 (75%)	0.149
CT in ED, %	9 (56%)	5 (31%)	0.154

Continuous variables presented as: median (IQR) DEF- definitive laparotomy; pDEF – potentially safe for definitive laparotomy; LY30 – estimated lysis at 30 minutes; FAST – focused abdominal sonography for trauma; CT – computed tomography; ED – emergency department

Table 3.**Operating Room Vital Signs, Labs, and Resuscitation**

Operating Room	DEF (n=16)	pDEF (n=16)	p value
First Operating Room Vitals and Labs			
Temperature, F	97.3 (96.1, 97.7)	96.8 (96.5, 98.2)	0.720
Systolic blood pressure, mmHg	110 (93, 128)	120 (93, 141)	0.396
Heart rate, bpm	106 (91, 116)	97 (81, 109)	0.157
Lactic acid	2.6 (2.2, 3.1)	3.4 (2.1, 4.0)	0.243
Base excess	-5 (-6, -2)	-6 (-7, -4)	0.629
Intra-Operative Resuscitation			
Crystalloid	1050 (750, 1950)	1100 (750, 1500)	0.691
Colloid	500 (0, 1000)	500 (0, 1000)	0.857
Red blood cells, units	2 (1, 4)	2 (1, 4)	1.000
Fresh frozen plasma, units	2 (0, 4)	2 (0, 4)	0.828
Platelets, units	0 (0, 6)	0 (0, 0)	0.246
Tranexamic acid	0 (0%)	2 (13%)	0.484
Estimated blood loss, mL	500 (250, 1250)	700 (400, 1900)	0.330
Last Operating Room Vitals and Labs			
Temperature, F	96.7 (95.5, 97.3)	96.9 (95.4, 97.6)	0.720
Systolic blood pressure, mmHg	125 (115, 143)	120 (104, 135)	0.355
Heart rate, bpm	83 (67, 103)	91 (79, 104)	0.417
Lactic acid	3.0 (1.2, 3.9)	3.3 (2.1, 5.1)	0.279
Base excess	-4 (-4, 0)	-4 (-6, -2)	0.272
Duration of surgery, minutes	166 (129, 220)	126 (68, 132)	0.009

Continuous variables presented as: median (IQR) DEF- definitive laparotomy; pDEF – potentially safe for definitive laparotomy

Table 4.

Procedures Performed during Primary Laparotomy

Procedures During Primary Laparotomy	DEF (n=16)	pDEF (n=16)	p value
Hepatorrhaphy	1 (6%)	6 (38%)	0.083
Gastrorrhaphy	0 (0%)	1 (7%)	1.000
Enterorrhaphy	0 (0%)	2 (13%)	0.484
Colorrhaphy	1 (6%)	0 (0%)	1.000
Enterectomy	5 (31%)	8 (50%)	0.280
Colectomy	7 (44%)	7 (44%)	1.000
Any enteric resection	8 (50%)	11 (69%)	0.283
Stoma	3 (0%)	0 (0%)	0.058
Nephrectomy	0 (0%)	0 (0%)	-
Splenectomy	5 (31%)	4 (25%)	1.000
Distal pancreatectomy	2 (13%)	2 (13%)	1.000
Whipple	0 (0%)	0 (0%)	-
Vascular repair/ligation	0 (0%)	0 (0%)	-
Thoracotomy/sternotomy	1 (7%)	0 (0%)	1.000

Table 5.**Morbidity**

Morbidity	DEF (n=16)	pDEF (n=16)	p value
Abdominal Complications			
Major abdominal			
complication or death	3 (19%)	Times New Roman	0.066
Enteric suture line	1/6 (17%)	4/9 (44%)	0.580
failure	0 (0%)	6 (38%)	0.018
Fascial dehiscence	3 (19%)	9 (56%)	0.066
Organ/space SSI	0 (0%)	6 (38%)	6 (38%)
Reopened	0 (0%)	0 (0%)	–
Death			
Superficial SSI	0/15 (0%)	4/8 (50%)	0.008
Ileus	7 (44%)	7 (44%)	1.000
GI bleed	0 (0%)	2 (13%)	0.484
Non-Abdominal Complications			
Pulmonary embolus	0 (0%)	3 (19%)	0.226
Deep vein thrombosis	0 (0%)	2 (13%)	0.484
Pneumonia	2 (13%)	6 (38%)	0.102
Urinary tract infection	3 (19%)	3 (19%)	1.000
Sepsis	3 (19%)	10 (63%)	0.029
Acute renal failure	1 (6%)	7 (44%)	0.037

DEF- definitive laparotomy; pDEF – potentially safe for definitive laparotomy; SSI – surgical site infection; GI – gastrointestinal

Table 6.

Bayesian Analysis with % Reduction in MAC in DEF

% Reduction in MAC	Probability
Any	92%
>10%	88%
>20%	81%
>30%	70%
>40%	55%
>50%	38%

MAC – Major Abdominal Complications