Trauma Surgery & Acute Care Open

Damage control laparotomy in trauma: a pilot randomized controlled trial. The DCL trial

John A Harvin ,[1,2,3] Sasha D Adams,[1,3] Shah-Jahan M Dodwad,[1,3] Kayla D Isbell,[1,3] Claudia Pedroza,[2] Charles Green,[2] Jon E Tyson,[2] Ethan A Taub,[1,3] David E Meyer,[1,3] Laura J Moore,[1,3] Rondel Albarado,[1,3] Michelle K McNutt,[1,3] Lillian S Kao,[1,2,3] Charles E Wade,[1,3] John B Holcomb[4]

[1]Department of Surgery, The University of Texas Health Science Center at Houston, Houston, Texas, USA
[2]Center for Clinical Research and Evidence-Based Medicine, The University of Texas Health Science Center at Houston, Houston, Texas, USA
[3]Center for Translational Injury Research, The University of Texas Health Science Center at Houston, Houston, Texas, USA
[4]Center for Injury Science, The University of Alabama at Birmingham School of Medicine, Birmingham, Alabama, USA

Correspondence to
Dr John A Harvin; John.Harvin@uth.tmc.edu

Received 25 May 2021
Accepted 5 July 2021

To cite: Harvin JA, Adams SD, Dodwad S-JM, *et al*. *Trauma Surg Acute Care Open* 2021;**6**:e000777.

ABSTRACT

Background Although widely used in treating severe abdominal trauma, damage control laparotomy (DCL) has not been assessed in any randomized controlled trial. We conducted a pilot trial among patients for whom our surgeons had equipoise and hypothesized that definitive laparotomy (DEF) would reduce major abdominal complications (MAC) or death within 30 days compared with DCL.

Methods Eligible patients undergoing emergency laparotomy were randomized during surgery to DCL or DEF from July 2016 to May 2019. The primary outcome was MAC or death within 30 days. Prespecified frequentist and Bayesian analyses were performed.

Results Of 489 eligible patients, 39 patients were randomized (DCL 18, DEF 21) and included. Groups were similar in demographics and mechanism of injury. The DEF group had a higher Injury Severity Score (DEF median 34 (IQR 20, 43) vs DCL 29 (IQR 22, 41)) and received more prerandomization blood products (DEF median red blood cells 8 units (IQR 6, 11) vs DCL 6 units (IQR 2, 11)). In unadjusted analyses, the DEF group had more MAC or death within 30 days (1.71, 95% CI 0.81 to 3.63, p=0.159) due to more deaths within 30 days (DEF 33% vs DCL 0%, p=0.010). Adjustment for Injury Severity Score and prerandomization blood products reduced the risk ratio for MAC or death within 30 days to 1.54 (95% CI 0.71 to 3.32, p=0.274). The Bayesian probability that DEF increased MAC or death within 30 days was 85% in unadjusted analyses and 66% in adjusted analyses.

Conclusion The findings of our single center pilot trial were inconclusive. Outcomes were not worse with DCL and, in fact, may have been better. A randomized clinical trial of DCL is feasible and a larger, multicenter trial is needed to compare DCL and DEF for patients with severe abdominal trauma.

Level of evidence Level II.

INTRODUCTION

Damage control laparotomy (DCL) is commonly performed and may be life-saving for patients with severe abdominal trauma. DCL was originally described for very narrow and limited indications.[1 2] As comfort with the open abdomen has increased, indications for DCL have gradually broadened and its use has reached upward of 40% of all trauma laparotomies at some centers.[3 4] However, when used liberally, DCL may result in more risks than benefits, as several studies from trauma centers across the country have reported increased complications associated with the open abdomen resulting from DCL.[5–7]

However, both the initial studies supporting the benefits of DCL and the subsequent studies suggesting harm have been limited by different inclusion and exclusion criteria and selection bias inherent to observational studies. Current indications for DCL are driven by expert opinion as opposed to high quality evidence.[8–10] Barriers to performing a randomized controlled trial (RCT) of DCL include a lack of equipoise about the indications and effectiveness of DCL, and the need for exception from informed consent (EFIC) to randomize patients during emergency surgery.[4 11]

The current pilot RCT had two aims: (1) to determine the feasibility of randomizing patients with severe abdominal trauma for whom surgeons had equipoise for DCL or definitive laparotomy (DEF) during emergency laparotomy and (2) to estimate the effect of DEF relative to DCL on the composite outcome of major abdominal complications (MAC) or death that might inform a larger definitive multicenter trial. We hypothesized that randomization during an emergency trauma laparotomy would be feasible and that DEF in our center would be associated with fewer MAC or death within 30 days.

METHODS

An EFIC was obtained from the Institutional Review Board to randomize patients into the trial during emergency trauma laparotomy.[12] Patients were only included if they or their legally authorized representative consented to further participation. Patients were enrolled at the Red Duke Trauma Institute at Memorial Hermann Hospital-Texas Medical Center, which admits >6000 adult trauma patients per year and is one of two American College of Surgeons verified level 1 trauma centers in Houston, Texas, USA.

The study began on June 7, 2016 and ended on May 31, 2019. The trial was paused from July 9, 2018 through December 9, 2018 for safety evaluation by the Data Safety and Monitoring Board and Institutional Review Board. All trauma patients ≥16 years of age who underwent emergency laparotomy were screened. Emergency laparotomy was defined as: (1) time in emergency department (ED) ≤90 min and (2) admission directly to the operating room

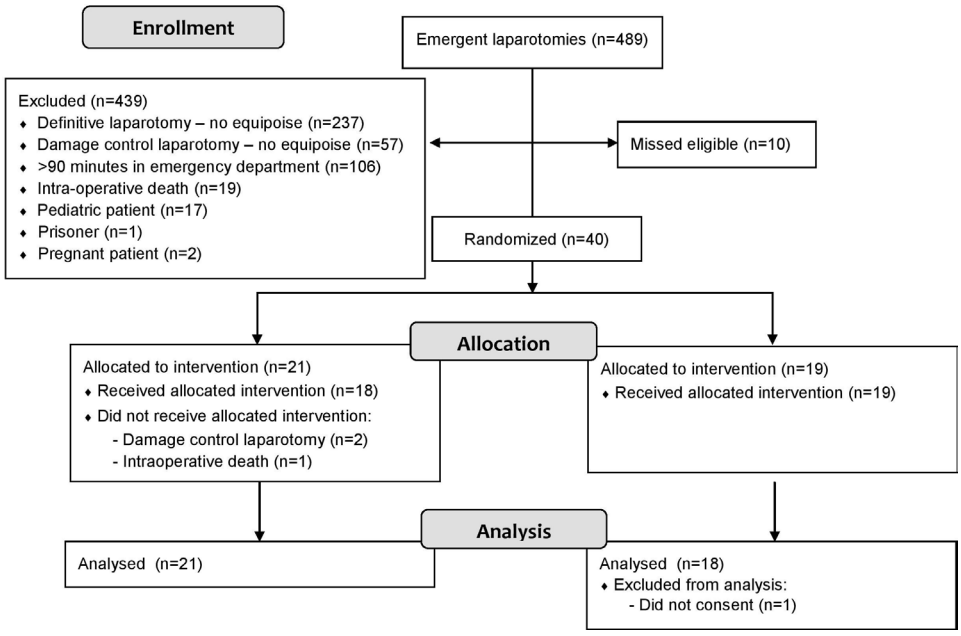

Figure 1 Consolidated Standards of Reporting Trials diagram.

from the ED or interventional radiology. Patients were included if they had an indication for DCL for which there was surgeon equipoise, including: (1) planned second look laparotomy, (2) planned second reoperation for abdominal contamination, (3) expedition of time to postoperative CT, (4) expedition of time to postoperative intensive care or (5) of isolated metabolic acidosis in the absence of ongoing transfusions or hypotension. Patients were excluded if a DCL was performed for the following indications: (1) need for gauze packing of the liver or retroperitoneum for hemorrhage control, (2) need for interventional radiology for hemorrhage control, (3) abdominal compartment syndrome prophylaxis (defined as inability to approximate fascia or >10 mm Hg increase in peak airway pressure during fascial closure) or (4) hemodynamic instability, when defined as persistent hypotension, ongoing transfusion requirement or continuous vasopressor use at the end of laparotomy. These inclusion and exclusion criteria were developed by consensus; surgeons agreed on absolute indications for both DCL and DEF as well as indications for DCL in which clinical equipoise was present.[4] Patients were also excluded if they were known prisoners, pregnant, burned >20% total body surface area or wearing an opt-out bracelet.

Study design and intervention

Details of the study protocol were previously published.[13] Briefly, this was a single-center, randomized trial to compare the effect of DCL with DEF on MAC or death within 30 days. Allocation occurred through sequentially numbered, opaque, sealed envelopes kept in the research assistants' office and opened in the operating room. A 1:1 allocation ratio using a permuted block design of four or six was used to ensure a comparable number of patients in each group. The allocation sequence was determined by an independent statistician, and the envelopes were prepared by an independent third party.

A research assistant, available 24 hours a day, 7 days a week, queried the trauma surgeon periodically throughout the emergency laparotomy to determine if the patient had met the predetermined criteria for surgeon equipoise. If the patient met all eligibility criteria, the surgeon enrolled the patient and the research assistant assigned the patient to DCL (control) or DEF (intervention) as determined by the numbered envelopes. All postoperative care was dictated by standard hospital protocols and guidelines. No additional lab work or imaging was ordered outside of routine clinical care.

Blinding of the trauma surgeons was not possible. Partly for this reason, the composite primary outcome was based on objective outcomes. Fascial dehiscence was determined by an independent surgeon not associated with the study. Additionally, secondary outcomes were identified based on standardized definitions used in the National Trauma Databank.

Outcomes and sample size

The primary outcome of this study was MAC or death within 30 days. MAC, as a composite outcome, included: (1) deep or organ/space surgical site infection, (2) enteric suture line failure, (3) enterocutaneous/enteroatmospheric fistula, (4) fascial dehiscence or (5) unplanned return to the operating room after fascial closure for an intra-abdominal complication. Death was included as it was a competing outcome with MAC.

Secondary outcomes included non-abdominal morbidity (acute kidney injury, adult respiratory distress syndrome, deep vein thrombosis, pulmonary embolism, pneumonia and urinary tract infection) and hospital-free/intensive care unit-free/ventilator-free days.

Preliminary data from a matched analysis showed a MAC or death rate of 55% in patients undergoing DCL and 18% in patients undergoing DEF.[6] Given these baseline rates of the primary outcome, an alpha of 0.05, a power of 0.80 and a dropout rate of 10%, the total sample size needed was 56 patients (28 in each arm).

Statistical analysis

Differences in the primary and secondary outcomes were compared on an intent-to-treat basis using frequentist statistics including Wilcoxon rank-sum test, Pearson's χ^2 test and Fisher's exact test, for continuous, binary and sparse binary outcomes, respectively. Treatment effect was estimated using generalized

linear models and any imbalances in prerandomization variables were adjusted for evaluating the primary outcome. Because any prerandomization differences between treatment groups were necessarily due to chance, p-values for differences in baseline variables were not provided.

Partly because of the limited sample size of the trial and limitations of frequentist analyses, the frequentist analysis was augmented with a Bayesian analysis.[14–17] A neutral prior probability (a prior risk ratio (RR) of 1.0 indicating an equal probability of benefit or harm from DCL and DFE) was used to estimate the posterior probability of benefit or harm from the DCL and DEF based on trial results. To indicate the uncertainty about the prior RR of 1.0, we used a 95% credible interval (CrI) of 0.5 to 2.0, which encompasses the treatment effect for most therapies on major clinical outcomes. Use of a neutral prior with this CrI has the effect of regularizing or shrinking the relative risk estimates back toward 1.0 (the null). As such, these analyses provide a more conservative relative risk of the treatment hazards or benefits than the frequentist analyses.[17]

RESULTS

Over the study period, 4595 patients were screened of whom 489 underwent emergency laparotomy (figure 1). Forty patients met inclusion criteria and were enrolled—21 to DEF and 19 to DCL. Three patients randomized to DEF did not receive the intervention (two underwent DCL due to changes in the patient condition after randomization and one died in the operating room before the intervention could be performed). One patient randomized to DCL did not consent to further participation in the trial, including inclusion of outcome data in the analysis.

Prerandomization

There were no clinically significant differences in patient demographics or specific injuries between the two groups. While both groups suffered severe trauma (median Injury Severity Score for entire group 33 (IQR 20, 43)), the DEF group had a higher median Injury Severity Score (table 1).

In the prehospital setting, the DEF group was more hypotensive (DEF systolic blood pressure 100 mm Hg (IQR 81, 130) vs DCL 116 (IQR 100, 142)) and tachycardic (DEF pulse 120 beats per minute (IQR 78, 130) vs DCL 101 beats per minute (IQR 90, 124)). The DEF group also received more prehospital transfusions (DEF prehospital red blood cells 1 unit (IQR 0, 2) vs 0 (IQR 0, 1); DEF prehospital fresh frozen plasma 0 units (IQR 0, 2) vs DCL 0 (IQR 0, 1)).

On arrival to the ED, the DEF group continued to be more hypotensive than the DCL group (table 2). There were no clinically significant differences in laboratory values or time in the ED. The DEF group received more transfusions in the ED than the DCL group.

The DEF patients arrived to the operating room with a higher pulse, but no other clinically significant differences in first vital signs or first laboratory values (table 3). The DEF group received more intra-operative transfusions of red blood cells, fresh frozen plasma, and platelets.

Overall, the DEF group received more red blood cell (DEF median 8 units (IQR 6, 11) vs DCL 6 units (IQR 2, 11)) and fresh frozen plasma (DEF median 8 units (IQR 6, 11) vs DCL 6 units (IQR 1, 11)) transfusions from the time of injury to the end of the primary laparotomy.

Compared with the DCL group, the DEF group had a higher rate of colectomy (DEF 43% vs DCL 22%), renorrhaphy or nephrectomy (DEF 25% vs DCL 6%) and splenectomy (DEF 52% vs DCL 28%) (table 4). The DEF group had a lower rate of hepatorrhaphy (DEF 24% vs DCL 39%). The most common indication for inclusion in the trial was isolated metabolic acidosis in the absence of ongoing transfusions or hypotension followed by planned second look laparotomy.

Table 1 Demographics and injury severity

	DCL (n=18)	DEF (n=21)
Demographics		
Age, years	32 (28, 40)	29 (24, 48)
Sex		
Woman	4 (22%)	4 (19%)
Man	14 (78%)	17 (81%)
Mechanism		
Blunt	10 (56%)	12 (57%)
Penetrating	8 (44%)	9 (43%)
Injuries		
Liver	10 (56%)	10 (48%)
Grade of liver injury	3 (2, 3)	2 (1, 3)
Spleen	10 (56%)	11 (52%)
Grade of spleen injury	3 (1, 3)	4 (2, 5)
Kidney	6 (33%)	7 (33%)
Grade of kidney injury	2 (1, 4)	4 (3, 5)
Small bowel	8 (44%)	9 (43%)
Large bowel	6 (33%)	7 (35%)
Pancreas	3 (17%)	7 (33%)
Stomach	3 (17%)	5 (24%)
Major venous injury	0 (0%)	1 (5%)
Major arterial injury	1 (6%)	0 (0%)
Femur	4 (22%)	4 (19%)
Pelvis	7 (39%)	8 (38%)
Traumatic brain injury	5 (28%)	6 (29%)
Injury severity		
Head AIS	0 (0, 4)	1 (0, 3)
Chest AIS	3 (1, 3)	3 (0, 3)
Abdomen AIS	4 (3, 4)	3 (3, 4)
Injury Severity Score	29 (22, 41)	34 (20, 43)

Continuous data presented as: median (IQR); categorical data presented as: number (%).
AIS, Abbreviated Injury Scale; DCL, damage control laparotomy; DEF, definitive laparotomy.

Postrandomization

There were no differences in initial postoperative vital signs. The DEF group had a higher initial postoperative lactic acid (DEF 3.9 mmol/L (IQR 3.1, 4.8) vs DCL 2.6 mmol/L (IQR 1.6, 3.6), p=0.010), but no difference in base excess, hematocrit, platelet level or any thrombelastography value. In the first 24 hours after surgery, the DEF group received more transfusions of red blood cells (DEF 1 unit (IQR 0, 2) vs DCL 0 unit (IQR 0, 0), p=0.036) and fresh frozen plasma (DEF 2 units (IQR 1, 4) vs DCL 0 unit (IQR 0, 2), p=0.013).

Outcomes

The DEF group had a clinically but not statistically significant higher rate of the primary outcome MAC or death within 30 days (RR 1.71, 95% CI 0.81 to 3.63, p=0.159; Bayesian RR

Table 2 Emergency department vital signs, laboratory values and resuscitation

	DCL (n=18)	DEF (n=21)
Arrival vital signs		
Temperature, °F	97.8 (97.5, 98.4)	97.8 (97.2, 98.1)
Systolic blood pressure, mm Hg	95 (82, 110)	80 (69, 99)
Pulse, bpm	115 (85, 124)	114 (92, 135)
Glasgow Coma Scale	9 (3, 15)	9 (3, 15)
Arrival laboratory values		
Lactic acid	3.9 (2.7, 6.14)	4.8 (3.1, 6.6)
Base excess	−6 (−9 to −5)	−5 (−9 to −4)
Hematocrit	38.6 (38.3, 40.2)	38.1 (33.6, 41.6)
Platelet level	240 (215, 263)	220 (183, 245)
Activated clotting time	105 (105, 121)	113 (105, 121)
Alpha angle	73 (73, 75)	73 (67, 76)
Maximum amplitude	64 (59, 65)	64 (57, 66)
Per cent lysis at 30 min	1.2 (0.3, 2.6)	0.9 (0.0, 2.4)
Resuscitation		
Red blood cells, units	1 (0, 2)	1 (1, 2)
Fresh frozen plasma, units	1 (0, 2)	2 (1, 2)
Other		
Positive FAST	10 (56%)	12 (57%)
CT	6 (33%)	5 (24%)
Time, min	24 (12, 37)	23 (12, 39)

Continuous data presented as: median (IQR); categorical data presented as: number (%).
DCL, damage control laparotomy; DEF, definitive laparotomy; F, Fahrenheit; FAST, focused abdominal sonography for trauma.

Table 3 Operating room arrival, resuscitation and response

	DCL (n=18)	DEF (n=21)
Beginning of operation		
First temperature, °F	95.7 (94.3, 98.1)	95.9 (94.3, 97.3)
First SBP, mm Hg	103 (92, 120)	98 (77, 132)
First pulse, bpm	102 (87, 112)	118 (92, 132)
First lactic acid	3.6 (2.6, 6.8)	5.3 (3.9, 6.2)
First base excess	−6 (−11 to −4)	−6 (−10 to −4)
First hematocrit	33 (31, 38)	33 (28, 35)
Resuscitation		
Fluid, mL	1600 (800, 2100)	2000 (1300, 2600)
Red blood cells, units	5 (1, 7)	6 (4, 7)
Fresh frozen plasma, units	5 (0, 8)	6 (4, 7)
Platelets, units	4 (0, 6)	6 (0, 6)
Tranexamic acid	1 (6%)	3 (14%)
Blood loss, mL	800 (300, 2000)	800 (400, 1500)
End of operation		
Last temperature, °F	96.9 (95.7, 97.7)	97.1 (95.9, 98.2)
Last SBP, mm Hg	110 (98, 133)	109 (96, 120)
Last pulse, bpm	89 (82, 100)	94 (89, 104)
Last lactic acid	3.3 (2.6, 5.1)	3.6 (3.1, 5.0)
Last base excess	−4 (-6, -3)	−3 (-5, -2)
Last hematocrit	29 (26, 35)	31 (27, 36)

Continuous data presented as: median (IQR); categorical data presented as: number (%).
DCL, damage control laparotomy; DEF, definitive laparotomy; F, Fahrenheit; SBP, systolic blood pressure.

1.22, 95% CrI 0.82 to 1.57, posterior probability 85%) (table 5). After adjustment for imbalances between the two groups (Injury Severity Score and prerandomization blood products), there was a lower but still worrisome probability that DEF increased MAC or death within 30 days (RR 1.54, 95% CI 0.71 to 3.32, p=0.274; Bayesian RR 1.06, 95% CrI 0.80 to 1.40, posterior probability 66%). The difference in the primary outcome reflected a higher rate of death within 30 days in the DEF group (DCL 0% vs DEF 33%, p=0.010). Of the seven deaths in the DEF group, five (71%) were associated with a transition to comfort care.

There was no difference in MAC (not including deaths) between the two groups (RR 1.14, 95% CI 0.49 to 2.68, p=0.758; Bayesian RR 1.05, 95% CrI 0.69 to 1.49, posterior probability 54%). After adjustment for imbalances between the two groups, there continued to be no difference in MAC (not including deaths; RR 1.19; 95% CI 0.50 to 2.83, p=0.700; Bayesian RR 1.04, 95% CrI 0.76 to 1.40, posterior probability 59%). Additionally, there were no differences in secondary outcomes or hospital-free/intensive care unit-free/ventilator-free days.

The trial was stopped on May 31, 2019 for futility of accruing the preplanned sample size due to reduced numbers of eligible patients within the prior 12-month period.

DISCUSSION

This first, pilot RCT of patients undergoing emergency laparotomy for trauma was inconclusive. While there was no significant difference in MAC or death within 30 days, conservative Bayesian analyses adjusted for baseline differences in Injury Severity Score and prerandomization blood products indicate a 66% probability that DEF increased MAC or death within 30 days. There were also significantly more deaths in the DEF group. These worrisome findings were counter to our hypothesis—worse outcomes were not found with DCL and it may, in fact, have been beneficial. A larger, definitive randomized trial to delineate these findings is needed. Importantly, this trial demonstrated that 24/7 randomization during an emergency trauma laparotomy was feasible.

While the deaths were individually reviewed by the Data Safety and Monitoring Board and thought to be not directly due to the intervention, the finding was nonetheless concerning. Five of the seven deaths were associated with a transition to comfort care in light of concomitant injuries or complications. With our small sample size, the significant increase in deaths may be due to the intervention, baseline differences and/or chance. There was considerable imprecision around the effect of DCL on death. While we observed no statistically significant differences in organ/space surgical site infection (DEF 38% vs DCL 28%, p=0.496), reopening after fascial closure (DEF 29% vs DCL 11%, p=0429) and fascial dehiscence (DEF 20% vs DCL 0%, p=0.110), each outcome was more common in the DEF group. This imprecision and uncertainty about the effect of DEF and the fragility of the trial results were reflected in the Bayesian analyses and their 95% CrIs. The RR point estimates of the unadjusted and adjusted primary outcome were 1.22 and 1.06, respectively. The 95% CrI in the adjusted analyses ranged from a 20% reduction to a 40% increase in MAC or death within 30 days. Both the unadjusted and adjusted Bayesian results are more consistent with an experienced clinician interpreting a

Table 4 Operating room procedures

	DCL (n=18)	DEF (n=21)
Procedures		
Hepatorrhaphy	7 (39%)	5 (24%)
Gastrorrhaphy	3 (17%)	5 (24%)
Enterrorhaphy	3 (17%)	6 (29%)
Enterectomy	5 (28%)	4 (19%)
Colorrhaphy	1 (6%)	0 (0%)
Colectomy	4 (22%)	9 (43%)
Renorrhaphy	0 (0%)	3 (14%)
Nephrectomy	1 (6%)	2 (10%)
Splenorrhaphy	2 (11%)	0 (0%)
Splenectomy	5 (28%)	11 (52%)
Major venous repair	0 (0%)	1 (5%)
Major arterial repair	0 (0%)	0 (0%)
Thoracotomy/Sternotomy	1 (6%)	2 (10%)
Damage control specific		
Indication for DCL		
Second look	7 (39%)	5 (24%)
Hemodynamic instability	8 (44%)	10 (48%)
Expedite CT/ICU	2 (11%)	6 (29%)
Contamination	1 (6%)	0 (0%)
Initial delayed fascial closure	17 (100%)	2/2 (100%)
Intestinal discontinuity	2/7 (29%)	2/3 (67%)

Categorical data presented as: number (%).
DCL, damage control laparotomy; DEF, definitive laparotomy; ICU, intensive care unit.

Table 5 Outcomes

	DCL (n=18)	DEF (n=21)	P value
Primary outcome and components (<30 days)			
MAC or death <30 days	6 (33%)	12 (57%)	0.137
Organ/Space surgical site infection	5 (28%)	8 (38%)	0.496
Enteric suture line failure	0 (0%)	0 (0%)	–
Enterocutaneous fistula	0 (0%)	0 (0%)	–
Reopened	2 (11%)	6 (29%)	0.429
Bleeding	0	2	
Dehiscence	0	2	
Sepsis	1	2	
Ischemic bowel	1	0	
Fascial dehiscence	0 (0%)	4 (20%)	0.110
MAC	6 (33%)	8 (38%)	0.757
Deaths	0 (0%)	7 (33%)	0.010
Secondary outcomes (<30 days)			
Superficial surgical site infection	1 (6%)	4 (19%)	0.349
Ileus	6 (33%)	7 (33%)	1.000
Pulmonary embolus	1 (6%)	1 (5%)	1.000
Deep vein thrombosis	0 (0%)	2 (10%)	0.490
Sepsis	9 (50%)	11 (52%)	0.882
Acute renal failure	3 (17%)	7 (33%)	0.290
Multiorgan failure	4 (22%)	6 (29%)	0.726
Lengths of stay			
Hospital-free days	13 (0, 19)	0 (0, 11)	0.089
Intensive care unit-free days	24 (0, 25)	12 (0, 24)	0.170
Ventilator-free days	27 (3, 28)	22 (0, 27)	0.230
In-hospital mortality			
Deaths	1 (6%)	7 (33%)	0.049
Cause of death			1.000
MOF/Sepsis	0 (0%)	1 (14%)	
Stroke	0 (0%)	0 (0%)	
Traumatic brain injury	0 (0%)	0 (0%)	
Respiratory failure	0 (0%)	1 (14%)	
Transition to comfort care	1 (100%)	5 (71%)	
Time to death, hours	1247 (–)	95 (90, 207)	0.124

Continuous data presented as: median (IQR); categorical data presented as: number (%).
DCL, damage control laparotomy; DEF, definitive laparotomy; MAC, major abdominal complications; MOF, multiorgan failure.

small clinical trial with the observed absolute risk difference and relative risk than the frequentist analyses.

While the results of this pilot trial were counter to the hypothesis, it provided important information to plan a larger, definitive trial. First, clinical equipoise among a group of surgeons was able to be achieved; the use of standardized indications for DCL was established prior to this trial in a quality improvement initiative.[11] Results from a multicenter, prospective, observational study suggests that clinical equipoise for the same indications was also present outside our institution. These same indications may be appropriate for a larger, multicenter randomized trial DCL.[3] Second, social media allowed for efficient community consultation and public notification (both required to obtain an EFIC) in order to obtain greater reach at lesser cost than methods used in prior RCTs at our institution.[12 18–20]

Lastly, we augmented our statistical approach with Bayesian analyses to avoid the pervasive misinterpretation of frequentist analyses.[16] Bayesian methods provide a formal method to estimate the probability of a treatment benefit or harm not directly assessed in frequentist analyses. Bayesian methods address the questions clinicians ask and quantify the uncertainty of a treatment effect estimate. As no unbiased prior estimates of treatment effect were available from prior trials, we used a neutral prior centered on a relative risk of 1.0 (meaning we assumed no difference between interventions) and with a 95% CrI of 0.5 to 2.0 (as large treatment effects outside this range are uncommon for important clinical outcomes). While a frequentist would conclude that there was no statistically significant difference between DEF and DCL, there was an 85% probability that DEF increased MAC or death compared with DCL in the unadjusted Bayesian analysis assuming no important baseline differences.

This trial was limited by its narrow scope, small size and a failure to accrue the targeted sample size. This trial focused on a very specific group of patients—those for whom surgeons had equipoise for DEF and DCL. Before planning this trial, there was significant variation in the use of DCL at our institution.[4] The 3 years of work leading up to this study led to the stakeholder-driven creation of acceptable inclusion criteria and sample size estimation. This work also changed the practice around DCL at our institution, namely use of consensus-based absolute and relative indications for DCL, which led to the decreased utilization of DCL from 39% to 17%. In addition to these internal changes, external events negatively affected enrollment. For unknown reasons, there was a temporary decrease in emergency laparotomies being performed at the trauma center, an occurrence that has now reversed. The trial was also limited by an imbalance of baseline characteristics in randomized groups and a lack of blinding. Inability to blind was addressed by having objective

definitions for outcomes and using independent surgeons for the evaluation of those that were more subjective. Lastly, the trial was stopped due to funding having ended and futility in accruing the estimated sample size within another 12 months.

In conclusion, our single-center pilot RCT was inconclusive and failed to provide definitive evidence to support our hypothesis. DCL was not worse than DEF and may have been beneficial. In the absence of any other RCT of DCL, our pilot trial indicates that a larger, multicenter trial is both feasible and necessary to compare DCL and DEF for patients with severe abdominal trauma. Until such a trial can confirm or refute the findings of this first RCT of DCL, we plan to liberalize our indications for DCL.

Acknowledgements We would like to acknowledge Laura Vincent, RN for time and effort on this trial.

Contributors Trial design: JAH, JET, CEW and JBH. Drafting/Critical revision of manuscript: JAH, SDA, S-JMD, KDI, CP, CEG, JET, EAT, DEM, LJM, RA, MKM, LSK, CEW and JBH. Final approval of manuscript: JAH, SDA, S-JMD, KDI, CP, CEG, JET, EAT, DEM, LJM, RA, MKM, LSK, CEW and JBH. Agreement to be accountable for work: JAH, SDA, S-JMD, KDI, CP, CEG, JET, EAT, DEM, LJM, RA, MKM, LSK, CEW and JBH.

Funding JAH's time was supported by the Center for Clinical and Translational Sciences, which is funded by National Institutes of Health Clinical and Translational Award UL1 TR000371 and KL2 TR000370 from the National Center for Advancing Translational Sciences.

Disclaimer The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Advancing Translational Sciences or the National Institutes of Health.

Competing interests JBH is a co-founder and on the Board of Directors of Decisio Health, on the Board of Directors of QinFlow and Zibrio, a Co-inventor of the Junctional Emergency Tourniquet Tool, an adviser to Safeguard, Arsenal Medical, Cellphire, Spectrum, CSL and PotentiaMetrics.

Patient consent for publication Not required.

Ethics approval The McGovern Medical School Institutional Review Board approved this trial allowing for exception from informed consent with delayed patient or legally authorized representative consent (HSC-GEN-16-0104).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. No data will be provided.

ORCID iD

John A Harvin http://orcid.org/0000-0002-2081-6256

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