Indications for Use of Damage Control Surgery in Civilian Trauma Patients: A Content Analysis and Expert Appropriateness Rating Study

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Introduction

In patients requiring operation for major injury, surgeons must decide whether to perform a definitive or damage control (DC) procedure.[1] In contrast to definitive surgery (where all injuries are repaired and the explored cavity closed), DC includes a brief initial operation used to rapidly control exsanguinating hemorrhage, a massive air leak, and/or gross contamination.[1, 2] The patient is subsequently admitted to the intensive care unit (ICU) for further resuscitation before returning to the operating room (OR) for additional surgery.[1] The commonly proposed goal of DC surgery is to prevent the onset of and/or interrupt the "vicious cycle" of hypothermia, acidosis, and coagulopathy.[3-5]

Although DC surgery is widely utilized and has been reported to result in improved survival in select, severely injured patients,[6-9] the procedure is associated with a high incidence of potentially severe complications (e.g., enteroatmospheric fistulae), hospital readmissions, and subsequent surgical procedures as well as a reduced quality of life among those with a planned ventral hernia.[1, 10-15] The unclear benefit-to-harm profile of DC surgery, combined with the fact that emergent surgical decisions must be made quickly and often with limited information,[16] makes it difficult to determine the optimal "operative profile" in many situations.[2] This difficulty has likely contributed to recent reports of a variation in use of DC surgery across trauma centers and concerns that the procedure is overutilized.[17-19]

Although the decision to perform DC surgery often requires the simultaneous consideration of multiple factors, there are also a number of relatively common clinical circumstances that have been reported to be indicative of the need for DC.[1] The identification of a complete list of these indications would provide a practical foundation

to focus future studies and (until results of these studies become available) guide surgical practice.[1] Thus, we conducted a content analysis and expert appropriateness rating study of the indications reported in peer-reviewed articles between 1983 and 2014. Our objectives were to create a comprehensive list of the indications suggested to date, determine which have been most commonly reported in the peer-reviewed literature, and evaluate the opinions of experts regarding the appropriateness (expected benefit-to-harm ratio) of the identified indications for use in surgical practice.

Methods

Content Analysis:

We performed a content analysis because it is a validated and reproducible, mixed qualitative/quantitative method of systematically synthesizing a large amount of information (i.e., the entire list of reported indications for use of DC surgery in the literature) into a reduced number of named, content-characteristic codes (i.e., unique indications for use of DC surgery).[20-23] A published protocol details our methods.[24]

Data Source:

In a previously conducted scoping review (high-level summary of the literature on indications for DC), we searched 11 bibliographic databases (1950-February 14, 2014), abstracts from five conferences held between 2009 and 2013, 12 trauma websites, Google Scholar, two clinical trials registries, and 30 textbooks.[1] Of the 27,732 citations identified, we included 175 peer-reviewed articles that reported 1,107 indications for use of civilian trauma DC surgery.[1] We excluded citations involving exclusively non-civilian trauma patients or those with burn, orthopedic, or neurologic injuries.[1, 24] We defined an indication as a clinical finding/scenario that advised use of DC over definitive surgery.[1, 24] DC surgery was defined as a multi-step operative intervention, which included a brief initial surgical procedure that aimed to control mechanical bleeding, a massive air leak, and/or gross contamination.[1, 24]

Codebook Development:

We developed a detailed codebook to guide coding of the 1,107 indications identified by the scoping review.[20] This was done using an abbreviated grounded theory method to allow codes to emerge inductively from the reported indications themselves.[21, 25, 26]

Two investigators (D.J.R., N.B.) independently grouped the indications according to whether they were based on prehospital, Emergency Department (ED), or intraoperative findings or events. They then independently sorted similar or identical indications together and used a mixture of manifest and latent open coding to independently create codes describing the unique indications within these sortings.[21, 24] These indication codes were subsequently grouped into higher order categories. Subcategories were created using constant comparative methodology.[25] This process continued iteratively until no new indication codes (or subcategories or categories of indication codes) could be identified.[23]

We used the system recommended by the RAND/University of California, Los Angeles Corporation Appropriateness Rating Method (RAM) to organize indication codes according to their principal clinical findings or injuries (e.g., juxtahepatic venous injury) and associated decision variables (e.g., hemodynamic instability).[24, 27] We assumed that injury patterns/mechanisms, vital signs, amounts or types of resuscitation provided, and laboratory test results were the principal clinical findings (in that order) when more than one finding was included in the definition of a code. For indications that included a cutoff (e.g., pH <7.2), we created a code for the underlying concept (i.e.,

acidosis) and a separate code (i.e., pH <X) with a linked numerical value (e.g., 7.2) for the cutoff.

The initial set of independently created codes were compared and discussed by both investigators until consensus regarding the number, types, and definitions of codes was achieved. These consensus codes were then sent to the other principal investigators who were asked to identify poorly worded, unclear, or redundant indication codes. Based on this feedback, the coded indications were revised and/or reduced in number. The codebook is included in **Supplemental Digital Content 1**.

Coding of the Indications Reported in the Literature:

Two investigators (D.J.R., N.B.) subsequently used the coding instructions, indication code definitions, and example indications in the codebook to independently code all of the 1,107 indications identified by the scoping review. New codes were added (or existing codes refined) when indications were encountered that did not fit into an existing code.[21] Coding disagreements were resolved by consensus.

We calculated kappa (κ) statistics to quantify inter-investigator coding reliability.[28] We used counts and percentages to describe the prevalence of indication, subcategory, and category codes in the literature. Decision thresholds for reported indications with included cutoffs (e.g., pH <X) were summarized using medians and interquartile ranges (IQRs).[24] Stata version 13.1 (Stata Corp., College Station, TX) was used for statistical analyses.

Expert Appropriateness Rating Study:

Panel Formation:

To evaluate the opinions of experts regarding the appropriateness of the indication codes for use in practice, we invited a panel of 10 geographically-diverse experts to participate in an appropriateness rating study. Panelists were identified by consulting the peer-reviewed trauma and DC literature, major trauma and surgery textbooks, and websites of key trauma care associations in the United States, Canada, and Europe.[1] Each expert was widely known to have significant experience in the practice of trauma surgery and in training surgeons in the conduct of operative trauma care. The panel included senior members (including five current or past presidents and one current vice president) of the American Association for the Surgery of Trauma (AAST), Australasian Trauma Society, Eastern Association for the Surgery of Trauma, European Society for Trauma and Emergency Surgery, International Association for Trauma Surgery and Intensive Care, Trauma Association of Canada, Trauma Society of South Africa, and the Western Trauma Association.

Appropriateness Survey Administration:

Panelists who agreed to participate were sent a link to an electronic survey containing the indication codes created during content analysis (see **Supplemental Digital Content 2** for the survey). For each indication code, they were asked to rate the benefit-to-harm ratio of conducting DC over definitive surgery in an adult requiring or currently undergoing operation for a torso injury and/or major peripheral vascular injury using the validated 1-9 scale recommended by the RAM (where 1 means the expected

harms of conducting DC surgery greatly outweigh the benefits, 5 means the expected benefits and harms are about equal, and 9 means the expected benefits greatly outweigh the harms).[27] Panelists were instructed to answer on behalf of a typical trauma or general surgeon who would take call at a trauma center. For indications that included a cutoff value in its definition (e.g., temperature <X°C), only the median value calculated across those reported in the literature was rated. An assessment of the survey's clarity, flow, and administrative ease was performed through pre-testing during which four independent trauma or general surgeons completed the survey and provided written feedback.

Analysis of Appropriateness Ratings:

Using the panelists' ratings, we classified indication codes as appropriate (panel median of 7-9, without disagreement), uncertain (panel median of 4-6 or any median with disagreement), or inappropriate (panel median of 1-3, without disagreement). Disagreement was defined as three or more panelists rating the indication 1-3 and another three or more rating it 7-9.[27]

Results

Prevalence of Indications Reported in the Literature:

Of the 1,107 indications for DC surgery identified by the scoping review, 195 (17.6%) were based on pre- and 719 (65.0%) on intraoperative findings or events. For the remaining 193 (17.4%), the setting for their application could not be determined. In total, we created 123 indication codes describing 36 unique preoperative and 87 unique intraoperative indications for DC surgery. **Figure 1** displays the flow of indications through the content analysis and expert appropriateness rating study while **Table 1** and **Table 2** display the prevalence of pre- and intraoperative categories, subcategories, and unique types of indications reported in the literature, respectively (see the Table in **Supplemental Digital Content 3** for indications where the setting could not be determined). Agreement between investigators regarding coding of the 1,107 indications was excellent (median κ-statistic=1; range, 0.67 to 1), with 94.7% of κ-statistics being equal to 1 (indicating perfect inter-rater reliability).

Preoperative Indications:

Most of the reported preoperative indications were based on the degree of physiologic insult (38.5%), injury pattern (20.0%), and overall injury or disease burden (12.8%) of the patient identified during the primary or secondary survey. Others were dependent on information relayed about prehospital findings or events (10.3%), hospital facility and/or staff resources (9.7%), and the amount and/or type of resuscitation administered (7.7%).

The most prevalent preoperative indication in the literature was significant hemodynamic instability (median systolic blood pressure <90 mmHg; IQR, 90-90 mmHg) (14.9%) in the ED. Preoperative hypothermia (median temperature <34°C; IQR, 34-35°C) (7.2%), acidosis (median pH <7.2; IQR, 7.2-7.2) (4.6%), and coagulopathy (5.1%) were also commonly reported. The preoperative injury pattern most frequently suggested to indicate use of DC surgery was multiple injuries spanning across more than one anatomical region or body cavity that each required surgery with or without angioembolization (10.3%). Other relatively commonly reported preoperative indications included a high Injury Severity Scale (ISS) score (median >25; IQR, 25-35) (7.2%), a mass casualty incident (6.2%), requirement for an ED thoracotomy (3.6%), a prehospital cardiopulmonary arrest (3.1%), and transfusion of a large volume of packed red blood cells (PRBCs) before beginning operation (median >10 units; IQR, 2-16 units) (2.1%).

Intraoperative Indications:

Most of the reported intraoperative indications were dependent on the degree of patient physiologic insult (38.8%); injury pattern identified during operation (28.2%); amount, rate, and/or type of resuscitation provided to the patient (14.7%); need for staged abdominal or thoracic wall reconstruction (5.2%) or to reassess the extent of bowel viability after a period of further resuscitation in the ICU (2.7%); and the (anticipated) time required to complete definitive surgery (4.9%).

The most commonly reported intraoperative indications included the finding of coagulopathy (14.7%), acidosis (8.1%), hypothermia (6.3%), or all three signs combined (3.6%). These signs were most often defined as a median prothrombin time (PT) and/or

partial thromboplastin time (PTT) >1.5 (IQR, 1.5-2) times normal and/or the absence of visible blood clots/diffuse oozing from all injured tissues, pH <7.2 (IQR, 7.2-7.25), and temperature <34°C (IQR, 34-35°C), respectively. A smaller number of intraoperative indications were dependent on the finding of hypothermia (0.4%) or acidosis (0.7%) at the beginning of operation or a persistent hypothermia (0.3%) or acidosis (0.6%) during operation.

Several intraoperative injury patterns were also reported to indicate use of DC surgery. These most often included a difficult to access major venous (intrahepatic, retrohepatic, retroperitoneal, or pelvic) injury (4.5%); devascularization or massive disruption of the pancreas, duodenum, or pancreaticoduodenal complex (2.8%); and an abdominal vascular injury, either alone (1.4%) or in combination with one (1.7%) or two (0.6%) associated major abdominal solid and/or hollow organ injuries. Moreover, 5.4% were dependent on the presence of multiple injuries spanning across more than one anatomical region or body cavity.

A total of 7.2% of the reported intraoperative indications were dependent on the cumulative administration of a large volume of PRBCs (median >10 units; IQR, 10-16 units). Others included administration of a large volume of PRBCs and/or whole blood (1.4%) or other blood products (0.7%) (median >5 L; IQR, 4-5 L) or PRBCs and whole blood, other blood products, and crystalloids combined (median >12 L; IQR, 12-13.5 L) (0.7%). Finally, 1.5% were based on the requirement for rapid PRBC transfusion rates (median >2.4 units/h; IQR, 1.7-2.9 units/h).

Inability to close the abdominal wall without tension (3.6%) was also a commonly reported intraoperative indication. Others included an anticipated prolonged operative

time with an associated suboptimal response to resuscitation (1.5%) or an operative (1.3%) or combined resuscitation and operative (1.3%) time exceeding a median of 90 (IQR, 90-90) minutes.

Expert Appropriateness Rating Study:

Of the 10 experts invited to participate in the appropriateness rating study, nine agreed. **Table 3** shows characteristics of the nine panelists. In total, 27 (75.0%) preoperative (**Table 1**) and 74 (85.1%) intraoperative (**Table 2**) indication codes were assessed by the panel to be appropriate. There was no disagreement between experts on the ratings of any of the indications.

The pre- and intraoperative indications commonly reported in the literature that were assessed to have an uncertain appropriateness included a high ISS score, the intraoperative identification of multiple injuries spanning across more than one anatomical region or body cavity that each require surgery with or without angioembolization, an abdominal vascular injury, requirement for rapid transfusion rates, an anticipated prolonged operative time (without a suboptimal response to resuscitation), and an operative time or combined resuscitation and operative time exceeding 90 minutes. The indication codes assessed to have the greatest expected benefit-to-harm ratio (median panel RAM score of 9) included administration of >10 U of PRBCs in the preoperative setting or >12 L of PRBCs and/or whole blood, other blood products, and crystalloids combined across the pre- and intraoperative settings; pre- or intraoperative hypothermia, acidosis, and/or coagulopathy; a difficult to access major venous injury; a combined pancreaticoduodenal injury with massive hemorrhage from the head of the

pancreas; devascularization or massive disruption of the pancreas, duodenum, or pancreaticoduodenal complex; a major liver or combined pancreaticoduodenal injury with intraoperative hemodynamic instability; development of intraoperative ventricular arrhythmias or persistent cellular shock; inability to close the abdominal or thoracic wall without tension; development of abdominal or thoracic compartment syndrome during attempted wall closure; and need to reassess the extent of bowel viability after a period of further resuscitation in the ICU.

Discussion

In this study, we identified 101 unique pre- and intraoperative indications from a total of 1,107 reported in the literature that were independently assessed by a panel of experts to appropriately indicate use of DC surgery in civilian trauma patients. These indications were most often based on the degree of patient physiologic insult, injury pattern identified during operation, amount of resuscitation provided to the patient, and the need for staged abdominal wall reconstruction or to reassess the extent of bowel viability after a period of further resuscitation in the ICU. **Table 4** provides a summary of the highest rated indications.

Nearly half (47.5%) of the 101 candidate indications required that the patient exhibit hypothermia, acidosis, and/or laboratory or clinical coagulopathy in the pre- or intraoperative setting. These signs were most commonly defined in the literature as a temperature <34°C, pH <7.2, PT and/or PTT >1.5 times normal, and the absence of visible blood clots during operation/diffusing oozing from all injured tissues, respectively. While persistent hypothermia or acidosis during operation have been proposed as key determinants of the need for DC,[29-31] the panel rated both pre- and intraoperative hypothermia or acidosis to be appropriate indications. The above findings suggest that measuring the core temperature, pH, and coagulation status of injured patients upon presentation to the ED and again during operation may facilitate surgical decision-making.

Many surgeons believe that patient outcomes are improved if the decision to perform DC surgery is made before the patient develops hypothermia, acidosis, and coagulopathy.[2, 32-34] In this study, the reported indications that were independent of these

signs and assessed to be highly appropriate included a difficult to access major venous injury; a devascularized or destroyed pancreas, duodenum, or pancreaticoduodenal complex; a combined pancreaticoduodenal injury with associated massive hemorrhage from the head of the pancreas; and a major liver or combined pancreaticoduodenal injury with intraoperative hemodynamic instability. Other indications assessed to be appropriate included an injury pattern requiring both surgery and angioembolization to achieve hemostasis and a major liver injury with two or more associated solid and/or hollow abdominal organ injuries. These injury patterns are characteristic of those with competing management priorities, that have the potential for intraoperative exsanguination during attempted definitive repair (or that respond better to therapeutic packing), or that require a pancreaticoduodenectomy, a procedure infrequently performed by most trauma surgeons (and likely unable to be tolerated by many severely injured patients).[35-38]

Additional indications assessed to be highly appropriate and independent of hypothermia, acidosis, and coagulopathy included the requirement for large volume fluid resuscitation in the pre- and/or intraoperative settings. These indications are likely related to the potential risks of dilutional coagulopathy, abdominal visceral edema, and intra-abdominal hypertension and abdominal compartment syndrome in patients given large volumes of PRBCs and/or crystalloid fluids.[39-42] Other commonly reported indications assessed to be highly appropriate included inability to close the abdominal fascia without tension or development of signs of abdominal compartment syndrome during attempted abdominal wall closure.[43] Finally, although it has commonly been suggested that prolonged operations should be avoided in severely injured patients, the panel only rated an anticipated prolonged operative procedure as being an appropriate indication for DC

surgery when the patient also had a suboptimal response to resuscitation. This suggests that experts believe that if severely injured patients do not present already in physiological extremis, it may be appropriate to complete a definitive operation as long as they demonstrate an adequate response to resuscitation.

The reported indications assessed to be appropriate by the panel in this study may be used to inform further research. Subsequent steps should include determining the surgical community's willingness to conduct prospective observational studies of the outcomes associated with performing DC versus definitive surgery for patients with these indications. These studies would inform whether experimental studies are feasible or warranted to further evaluate DC surgery. A similar process was successfully used to guide development of indications for coronary artery bypass grafting.[44] Future studies should also build upon our work by evaluating how the principal clinical findings and associated decision variables identified to be used by surgeons when deciding between DC and definitive surgery may further interact to influence surgical decisions. The literature to date has largely focused on indications containing a single clinical finding or variable (e.g., an abdominal vascular injury) or combinations of a small number of clinical variables (e.g., an abdominal vascular injury and intraoperative hemodynamic instability). However, this may represent an over-simplification of surgical decision-making as surgeons may simultaneously consider multiple variables and attribute different importance to each.

This study has potential limitations. First, although it is the first to comprehensively evaluate indications for DC surgery, we did not assess the association between the identified indications and patient outcomes. Second, as the goal of the expert

appropriateness rating study was to assess the face validity of the reported indications, we only performed one round of ratings. The indications may have therefore been rated conservatively, and some with borderline appropriate/uncertain scores may have changed if we performed additional rounds.[27] Despite this, it seems unlikely that those assessed to be highly appropriate would have changed given that there was no disagreement between panelists and the ratings exhibited little variability and were made anonymously and independently. Third, because the panelists were senior and experienced surgeons, their opinions may differ from those of more recently trained surgeons with less clinical experience or who work in different clinical settings. Future research should therefore compare the results of this study with those obtained from a broader sample of practicing surgeons.[45] Finally, as the physiologic and survival benefit of thromboelastography and DC resuscitation in trauma patients is currently an area of active investigation, indications for DC surgery are likely to evolve in the future with ongoing research and innovation.[46-51]

Conclusion:

This study identified a comprehensive list of candidate indications for use of DC surgery that were suggested by authors of peer-reviewed articles and assessed by a panel of independent experts to be appropriate. Most were related to the finding of severe patient physiological derangement in the pre- or intraoperative settings, the amount of resuscitation fluids administered, or the inability to complete the needed definitive procedure safely, efficiently, or expediently in one operation. These indications provide a

practical foundation to guide surgical practice while studies are conducted to evaluate their impact on patient care and outcomes.

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Figure Legends:

Figure 1. Flow of Indications Through the Content Analysis and Expert Appropriateness Rating Study.

List of Supplemental Digital Content

Supplemental Digital Content 1. Indications for Civilian Trauma Damage Control Surgery Codebook. .docx file type.

Supplemental Digital Content 2. Expert Appropriatness Rating Study Survey Instrument. .pdf file type.

Supplemental Digital Content 3. Table Summarizing Candidate Indications for Use of Damage Control Surgery for Which the Setting Could Not Be Determined. .docx file type.