Randomized Controlled Trial Evaluating the Efficacy of Peritoneal Resuscitation in the Management of Trauma Patients Undergoing Damage Control Surgery

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BACKGROUND: Peritoneal resuscitation (PR) represents a unique modality of treatment for severely injured trauma patients requiring damage control surgery. These data represent the outcomes of a single institution randomized controlled trial into the efficacy of PR as a management option in these patients.

STUDY DESIGN: From 2011 to 2015, one hundred and three patients were enrolled in a prospective randomized controlled trial evaluating the use of PR in the treatment of patients undergoing damage control surgery compared with conventional resuscitation (CR) alone. Patient demographics, clinical variables, and outcomes were collected. Univariate and multivariate analysis was performed with a priori significance at $p \leq 0.05$.

RESULTS: After initial screening, 52 patients were randomized to the PR group and 51 to the CR group. Age, sex, initial pH, and mechanism of injury were used for randomization. Method of abdominal closure was standardized across groups. Time to definitive abdominal closure was reduced in the PR group compared with the CR group (4.1 ± 2.2 days vs 5.9 ± 3.5 days; $p \leq 0.002$). Volume of resuscitation and blood products transfused in the initial 24 hours was not different between the groups. Primary fascial closure rate was higher in the PR group (83% vs 66%; $p \leq 0.05$). Intra-abdominal complications were lower in the PR compared with the CR group (8% vs 18%), with abscess formation rate (3% vs 14%; $p < 0.05$) being significant. Patients in the PR group had a lower 30-day mortality rate, despite similar Injury Severity Scores (13% vs 28%; $p = 0.06$).

CONCLUSIONS: Peritoneal resuscitation enhances management of damage control surgery patients by reducing time to definitive abdominal closure, intra-abdominal infections, and mortality rates. (J Am Coll Surg 2017;224:396–404. © 2017 Published by Elsevier Inc. on behalf of the American College of Surgeons.)

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Hemorrhagic shock is a primary cause of morbidity and death after trauma.[1] Battlefield studies conducted during the Vietnam War and that continue through the more recent Iraqi and Afghanistan conflicts indicate that hemorrhagic shock is the leading preventable cause of death among US soldiers. Among the civilian populations of the world, substantial blood loss after injury remains the leading cause of death after injury, with mortality as high as 50%.[1] Historically, these deaths occur in 3 distinct groups of patients: patients who die at the scene of the trauma, patients who survive the initial trauma but die shortly after reaching the hospital, and patients who

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Abbreviations and Acronyms

CR = conventional resuscitation
HMGB-1 = high mobility group box 1 protein
IFABP = intestinal fatty acid binding protein
ISS = Injury Severity Score
MODS = multi-organ dysfunction syndrome
PR = peritoneal resuscitation

survive the initial trauma and resuscitation, but who proceed to die from complications that develop after completion of resuscitation.[2] More recent literature suggests that advances in surgical critical care, rapid patient evacuation, and technological advances might be decreasing the numbers of patients that die early in their course, and increasing the number of late deaths from multiple organ failure.[2,3] Technical features for hemorrhage control might have reached a plateau, and recent literature has focused on changing resuscitative efforts, including using fresh whole blood, adopting massive transfusion protocols, and reducing plasma to blood transfusion ratios.[4-6] Clearly, advances in resuscitative science must continue if we are to improve long-term survival for the growing number of patients surviving their initial injuries.

Resuscitation is often assessed clinically by the normalization of central hemodynamic parameters, such as mean arterial pressure, heart rate, and central venous pressure. However, mounting evidence suggests that restoration of central hemodynamics by aggressive use of crystalloid solutions or blood might not restore adequate perfusion to the visceral organs, particularly the gastrointestinal tract and liver.[7-9] Progressive visceral ischemia has been postulated to be the inciting event for development of multi-organ dysfunction syndrome (MODS) after shock and ischemia.[10-12] Multi-organ failure is the final common pathway for mortality after profound shock.

We have previously demonstrated the substantial vasoactive and organ protective effects produced by application of a hypertonic glucose-based peritoneal dialysis fluid to the peritoneal cavity (peritoneal resuscitation [PR]) in a hemorrhagic shock rodent model.[8,9,13-15] Peritoneal resuscitation has been demonstrated to correct many of the physiologic derangements that lead to eventual organ dysfunction, including endothelial cell dysfunction, tissue ischemia, reduction in capillary blood flow, derangements in fluid exchange and electrolyte handling, and increased inflammatory mediators. Clinically, our initial efforts have shown in a retrospective case-matched study that PR was associated with accelerated abdominal closure, reduced abdominal complications, and increased primary fascial closure rates after damage control surgery in trauma patients.[16] We have undertaken this prospective randomized trial to better determine whether PR could reduce systemic inflammation, improve abdominal closure rates, and reduce morbidity in patients treated with damage control celiotomy after severe injury.

METHODS

This IRB-approved (University of Louisville IRB #09.0178), single-center, nonblinded, block randomized, prospective study was conducted at the University of Louisville Hospital, a 414-bed American College of Surgeons-verified Level I trauma center from January 1, 2011 to December 30, 2015. One hundred and sixty-two patients older than 18 years of age and undergoing damage control celiotomy for trauma and suffering from hemorrhagic shock were evaluated for study inclusion. Hemorrhagic shock was defined within 4 hours of hospital admission by the presence of 3 of the following: tachycardia (>120 beats/min); hypotension (systolic blood pressure <90 mmHg or initiation of vasopressor); global hypoperfusion (pH <7.32, base deficit < −4, serum lactate >3.0 mmol/L, SvO_2 <60%); oliguria (urine output <0.5 mL/kg/h for 2 hours); and blood transfusion requirement of >4 U in the initial 2 hours post admission. Patients were excluded if they were pregnant, incarcerated at time of presentation, not expected to survive 24 hours on completion of initial operation, or if next of kin was unavailable for study consent on completion of initial operation (n = 34). Of the 128 eligible and consentable patients, 18 families declined participation, leaving 110 patients for randomization.

Abdominal closure technique was standardized using a vacuum-assisted closure dressing in all patients, which consisted of the following: a 19F silicone elastomer round Blake drain (Ethicon) was placed in the left upper lateral quadrant and directed around the root of the mesentery along the left pericolic gutter and down into the pelvis. A sterile x-ray cassette cover was placed over the abdominal contents, but under the fascia. A sterile operating room towel was placed over the plastic cover and another drain was placed within the towel. The entirety of the abdomen was covered with an occlusive dressing. The towel drain was placed to low-pressure continuous suction.

After randomization, patients allocated to receive PR had a continuous abdominal lavage initiated using commercially available 2.5% glucose-based peritoneal dialysis solution (Delflex; Fresenius USA; 25 g/L D-glucose, 0.567 g/L sodium chloride, 0.392 g/L sodium lactate, 0.0257 g/L calcium chloride, 0.0152 g/L magnesium chloride at a pH of 6, osmolality of 486 mOsm/L). A bolus of 800 mL dialysate fluid was instilled during the