**Continuity versus Discontinuity for Bowel Injury in Damage Control Laparotomy:**

**A Prospective Multi-Institutional Study**

PI:

 Elizabeth Benjamin MD PhD FACS

 LAC+USC Medical Center

 2051 Marengo Street

 IPT C5L-100

Los Angeles, CA 90033

323-409-8604

Elizabeth.Benjamin@med.usc.edu

Co-PI:

 Demtrios Demetriades MD PhD FACS

LAC+USC Medical Center

 2051 Marengo Street

 IPT C5L-100

Los Angeles, CA 90033

323-409-7761

Demetrios.Demetriades@med.usc.edu

Co-PI:

 Joseph Dubose MD FACS

 Assistant Professor of Surgery

 Joseph.J.DuBose@uth.tmc.edu

***Brief Summary***

*Introduction:* Damage control surgery is the standard of care in the unstable trauma patient with hollow viscus injury. Optimal management of the hollow viscus injury, specifically with discontinuity, anastomosis, or diversion, however, remains controversial. Although several potential risk factors for anastamotic dehiscence have been identified, there are no prospective studies investigating the outcomes of patients managed with bowel discontinuity versus anastomosis during damage control laparotomy.

*Study Design:* Prospective, Multi-Institutional Study

*Aim:* To determine the physiologic consequence of bowel discontinuity after damage control laparotomy. To determine the differences in anastamotic dehiscence, abdominal sepsis, and ischemia after damage control laparotomy with bowel discontinuity versus immediate reconstruction.

*Methods:* All patients undergoing damage control laparotomy for trauma with concurrent hollow viscus injury will be eligible for the study. Demographic, physiologic, operative, and post-operative data will be collected including transfusion and resuscitative fluids, vasopressors, pre and operative time, overall injury burden and operative interventions. The study population will be stratified based on management of the bowel on initial operation (discontinuity vs. continuity) with a secondary stratification based on final bowel management (primary anastomosis vs. end ostomy vs. anastamosis with protective ostomy). Bivariable and multivariable analyses will be performed to determine differences in bowel ischemia, anastamotic dehiscence, abdominal sepsis, and mortality as well as to identify independent risk factors for outcome variables.

***Background and Significance***

Damage control surgery is the current standard of care after severe traumatic injury. The primary goals of damage control include temporization of injury and patient stabilization with the intent to return to the operating room at a future date for definitive management. For bowel injury, the traditional damage control operation is to resect the injured segment and leave the intestine in discontinuity until resuscitation and repeat operation. This limits continued contamination and allows for repair or temporization of more immediate injury. After the patient has been stabilized and ongoing hemorrhage controlled, the patient can return to the operating room for definitive management of the bowel segments. Traditional conservative management would also dictate that bowel anastomosis be deferred in the post open-abdomen time period in favor of ostomy creation. This management stems from the conventional teaching that destructive injuries, or those with concurrent hemodynamic instability, are best managed with fecal diversion procedures. These practices have been challenged with an expansion of the clinical scenarios for which primary anastomosis or repair is acceptable. In a AAST prospective multicenter study, the authors investigated complications following penetrating colon injury managed with primary anastomosis versus diversion at index operation(1). No difference in abdominal complications was noted, regardless of surgical management strategy. Independent risk factors for abdominal complications included severe fecal contamination, significant transfusion, and inadequate antibiotic prophylaxis.

A Western Trauma Association retrospective multi-institutional study investigated the management of bowel injury after damage control laparotomy in 204 patients(2). Patients were analyzed based on bowel management (immediate repair, anastamosis, delayed anastamosis, ostomy, or combination) and the subsequent leak rates. The authors noted that the majority of leaks occurred in patient with delayed reconstruction and that the rate increased with more distal anastomosis, observing a 3% leak rate in both the small bowel and right colon and a 20% and 45% rate in the transverse and left colon, respectively. Further, pre and intra-operative indicators of shock were associated with anastamotic dehiscence. Finally, although patient with anastomosis and early abdominal closure often did well, leak rates increased dramatically in patients with delayed abdominal closure after 5 days. These data were supported by a subsequent single center review of 247 patients with hollow viscus injury managed with damage control laparotomy(3). Similarly, the authors noted an increased rate of anastamotic dehiscence with more distal anastomoses and with delayed fascial closure. The theory that an intra- and post-operative shock state may also contribute to a higher rate of anastamotic dehiscence was further supported by and 2013 retrospective review of colonic injuries managed with damage control procedures that found increased anastamotic distruption in patients requiring vasopressors after the initial operation(4).

In a recently completed multi-center, AAST retrospective study comparing patients left in discontinuity and those with primary anastamosis after damage control laparotomy, a significantly higher rate of bowel ischemia was noted in the discontinuity group (Demetriades et al, AAST multi-center trial). Deep organ space infection, anastamotic leak rate, and mortality were not different between groups.

The proposed study will prospectively evaluate all patients with bowel injury that undergo damage control laparotomy. During the index operation, patients will be acutely managed with immediate reconstruction or discontinuity. Patient outcomes will be prospectively observed to determine differences in bowel ischemia, distention, abdominal sepsis, anastamotic integrity, post-operative complications, and mortality. The goal of this study is to determine if immediate reconstruction is comparable or yields improved outcomes versus traditional management with discontinuity.

***Rational***

 Damage control management of abdominal trauma has become standard of care with temporization of injury followed by delayed definitive management. The optimal management of bowel injury in the damage control setting, however, remains unclear. Traditionally, bowel injury is managed with resection and discontinuity during the initial operation with delayed restoration of continuity after stabilization. This essentially creates a closed loop obstruction in the short term with potential for bowel edema, dilation, and bacterial translocation. In retrospective analysis, patients managed with initial discontinuity experienced more bowel ischemia and those managed with immediate restoration of continuity had no increase in bowel related complications. These preliminary findings have provided the basis for the current prospective observational multi-institutional trial designed to further investigate the optimal management of bowel injury during damage control laparotomy.

***Description***

We propose a multicenter prospective observational study to determine the optimal management after bowel resection during damage control laparotomy for trauma. We will compare patients managed with temporary discontinuity with those managed with establishment of continuity at the index operation.

*Patient Selection:*

All patients undergoing damage control laparotomy for trauma with concurrent bowel injury are eligible for the study. Pregnant and pediatric patients < 16yrs will be excluded. Patients that die within 48 hours of the index operation will be excluded. Patients will be stratified based on management of the bowel injury (continuity vs discontinuity) at the index operation. Patients will be further stratified based on final management of intestinal injury including anastamosis, end or loop ostomy.

*Study variables:*

The following variables will be abstracted for the study: age, mechanism of injury, height, weight, regional AIS score, ISS, admission and operating room vital signs, time from admission to operation start time, preoperative resuscitative fluids and blood products.Intraoperative variables will include operative time, resuscitative fluids and products, pressor administration, additional injuries/operations, method of abdominal closure. Operative notes will be reviewed for details of injury location, resections performed, and management of remaining bowel. Primary outcome measures include mortality, anastamotic dehiscence, and deep organ space infection. Additional outcomes will include hospital and ICU length of stay, number additional abdominal operations, morbidity, and ventilator days.

*Limitations:*

The decision to manage the bowel injury with discontinuity versus primary anastamosis will be largely based on surgeon preference however, as this is not designed as a randomized trial, patient factors or intraoperative findings may influence bowel management. In order to accommodate this potential bias, we will correct for patient and injury characteristics and, in addition, include questions regarding reasoning for management decisions.

***References:***

1. Demetriades D, Murray JA, Chan L, Ordonez C, Bowley D, Nagy KK, et al. Penetrating colon injuries requiring resection: diversion or primary anastomosis? An AAST prospective multicenter study. The Journal of trauma. 2001;50(5):765-75.

2. Burlew CC, Moore EE, Cuschieri J, Jurkovich GJ, Codner P, Crowell K, et al. Sew it up! A Western Trauma Association multi-institutional study of enteric injury management in the postinjury open abdomen. The Journal of trauma. 2011;70(2):273-7.

3. Anjaria DJ, Ullmann TM, Lavery R, Livingston DH. Management of colonic injuries in the setting of damage-control laparotomy: one shot to get it right. The journal of trauma and acute care surgery. 2014;76(3):594-8; discussion 8-600.

4. Fischer PE, Nunn AM, Wormer BA, Christmas AB, Gibeault LA, Green JM, et al. Vasopressor use after initial damage control laparotomy increases risk for anastomotic disruption in the management of destructive colon injuries. American journal of surgery. 2013;206(6):900-3.