PROPOSAL FOR A PROSPECTIVE TRIAL FOR NON-DIVERSION MANAGEMENT OF EXTRAPERITONEAL PENETRATING RECTAL INJURIES

MULTI-INSTITUTIONAL TRIALS COMMITTEE OF THE AMERICAN ASSOCIATION FOR THE SURGERY OF TRAUMA

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Background and Significance

Current guidelines for the management of civilian penetrating rectal injuries include repair of the injury when easily accessible, fecal diversion and pre-sacral drainage. These guidelines continue to evolve with emphasis on a more conservative approach to the operative management of these injuries. Intraperitoneal rectal injuries are managed, as are most other proximal large bowel injuries with primary repair as the only maneuver necessary for an optimal outcome. Primary repair of extraperitoneal injuries is often difficult, due to the confined pelvic space, adjacent sacral venous plexus and adjacent urogenital structures. The optimal management methodology for extraperitoneal penetrating rectal injuries remains controversial. Several authors have questioned the efficacy of presacral drainage in the management of these injuries\textsuperscript{1-6}. Recently, a randomized prospective study that evaluated the efficacy of presacral drainage concluded that presacral drainage did not impact the incidence of infectious complications\textsuperscript{6}. At many trauma centers, presacral drainage is no longer standard therapy for penetrating extraperitoneal rectal injury.

In the past, several authors have suggested that penetrating extraperitoneal rectal injuries could be managed without fecal diversion\textsuperscript{7-10}. Haas and Fox have reported successful management of extraperitoneal rectal injuries without operative intervention\textsuperscript{7}. Burch has suggested that many extraperitoneal penetrating rectal injuries can heal satisfactorily without surgery, but selecting the appropriate patients may be difficult\textsuperscript{9}. Several authors have advocated selective management of transpelvic gunshot wounds in patients without clinical signs of peritonitis\textsuperscript{11-12}. A threshold of 10,000 RBCs per cubic millimeter was used as criteria for peritoneal penetration in that study. Velmahos et. al., published a prospective series of 37 patients in which indication for operative intervention for transpelvic gunshot wounds was based solely on clinical examination (clinical findings of peritonitis, hemodynamic instability, gross hematuria and rectal bleeding).\textsuperscript{11} They found clinical examination performed on these patients to have 100% sensitivity in detecting the need for exploratory laparotomy. The authors concluded a policy of selective management is safe, even for patients that have a high likelihood for intraabdominal organ injury. In the Velmahos series, invasive testing was not used to identify rectal injuries. Thus, one can only assume extraperitoneal rectal injuries that did not manifest rectal bleeding were successfully managed without fecal diversion or presacral drainage. Recently, a published series of consecutive penetrating extraperitoneal rectal injuries demonstrated that these injuries could be managed successfully without fecal diversion\textsuperscript{13}. In that series, all rectal injuries were identified by proctoscopy or physical examination and isolated extraperitoneal rectal injuries were managed non-operatively. Due to the rarity of penetrating rectal injuries encountered at most trauma centers, it is difficult for any one center to accrue enough of these injuries to
generate a series from which to draw significant conclusions. Consequently, this investigation would be best approached in a multi-center fashion.

**Objective**

1. To prospectively determine if non-destructive penetrating injuries of the extraperitoneal rectum can be managed successfully without fecal diversion.
2. To prospectively determine if isolated extraperitoneal penetrating rectal injuries can be successfully managed without operative intervention.

**Inclusion Criteria**

1. Patients greater than 18 years of age (18 years of age or older).
2. Patients with a penetrating extraperitoneal rectal injury that is non-destructive (<25% circumferential injury).

**Exclusion Criteria**

1. Patients less than 18 years of age.
2. Patients without extraperitoneal penetrating rectal injury.
3. Patients with a destructive (>25% circumferential injury) extraperitoneal rectal injury.
4. Patients with associated bladder injury.
Experimental Design/Methods

Proposed Prospective Trial

Study Group

Patients suspected of having sustained a penetrating rectal injury will be placed in a protocol that contains one of two management arms based upon clinical suspicion for intraperitoneal injury. In the first arm of the management protocol, patients with clinical examination consistent with intraperitoneal organ injury and suspected extraperitoneal rectal injury will be delivered to the operating room for proctoscopy followed by exploratory laparotomy. Assuming hemodynamic stability, CT scan of the abdomen and pelvis or cystogram to assess for bladder injury will be performed prior to operating room transfer. Patients diagnosed with bladder injuries based upon the CT scan will be excluded from the study. Intraperitoneal rectal injuries will be repaired primarily. Extraperitoneal rectal injuries will be left to heal by secondary intention with no attempt at exposure of the injury. Fecal diversion and presacral drainage will not be performed. Patients will receive intravenous antibiotics for twenty-four hours post-injury. Patients will be allowed nothing by mouth until passing flatus. At that time (typically post-operative day 5 to 7), barium enema will be performed and diet advanced accordingly. Barium enema will be performed at a minimum of five days post-injury. If the barium enema shows signs of a leak, the patient will be advanced to a clear liquid diet and barium enema will be repeated on post-operative day ten (see Fig. 1). Antibiotics will not be administered if the barium enema shows contrast extravasation.

In the second arm of the management protocol, patients with transpelvic missile trajectory and clinical examination inconsistent with intraperitoneal injury will undergo CT scan of the abdomen/pelvis and proctoscopy in the emergency room. CT scan is performed to assess for bladder injuries and assess trajectory of missile. Patients with bladder injuries will be excluded from the study. Extraperitoneal rectal injuries will then be treated in a similar fashion to extraperitoneal rectal injuries in the first management arm. If the CT scan is consistent with intraperitoneal injury, the patient will undergo exploratory laparotomy and treated as in the first arm of the protocol. If the CT scan is negative for intraperitoneal injury and proctoscopy identifies a rectal injury, the patient will be diagnosed with an isolated extraperitoneal rectal injury, admitted for observation and placed on a clear liquid diet. Barium enema will be performed on post admission day five. If the barium enema is negative, patients will be advanced to a regular diet and discharged home. Otherwise, barium enema will be repeated at post admission day ten (see Fig. 2). If abd/pelvic CT
scan and proctoscopy are negative, the patient will be admitted for overnight observation (see Fig. 2).

Control Group

Patients, who are diagnosed with extraperitoneal rectal injuries and meet study inclusion criteria, may undergo diverting loop colostomy. Proximal loop colostomy may be performed at the discretion of the treating surgeon. Patients that meet study inclusion criteria and undergo proximal diverting loop colostomy will be placed in the control study group.

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Clinical suspicion of intraperitoneal injury

To OR for Ex Lap
Abd/Pelv CT or Cystography in ER prior to OR
(Assuming hemodynamic stability)
Proctoscopy in OR prior to Ex Lap
(Assuming hemodynamic stability)

Intraperitoneal rectal injuries repaired
Extraperitoneal rectal injuries left to heal by 2° intention
No fecal diversion or presacral drains
Barium enema @ 5-7 days post-op

Fig.1: 1st Management arm of Study group: Transpevlic GSW with suspected intraperitoneal injury
No clinical suspicion of intraperitoneal injury

CT Scan Abd/Pelv & Proctoscopy performed in ER

CT Scan + for intraperitoneal injury; Proctoscopy+/-

To OR for Ex Lap
No fecal diversion or presacral drain for extraperitoneal rectal injury

Proctoscopy positive; CT Scan negative for intraperitoneal injury

Admit for observation
Clear Liquid diet x 5 days
Barium Enema @ 5 days

Both studies negative

Admit for observation

Fig. 2: 2nd Management arm of Study group: Transpelvic GSW with unsuspected intraperitoneal injury
Consent Procedures

This is a prospective study that mandates procedures and possible surgical intervention. Ultimately the decision to surgically intervene and method of surgical intervention will be up to the treating physician. All patients who are entered in this study will undergo informed consent prior to admission in this study. Data will be recorded on a data sheet and transferred to a database that is devoid of patient identifying information.

Risks

The risks associated with the management of rectal injuries are abscess formation. Intraperitoneal abscess formation is typically associated with fecal contamination with an incidence of 5-25%. Extraperitoneal abscess formation is much less common occurring in 0-5% of penetrating rectal injury patients. If a colostomy is performed in penetrating rectal injury patients, parastomal complications can occur.

References

6) Gonzalez, RP, Falimirski ME, Holevar MR. The role or presacral drainage in the management of penetrating rectal injuries. J Trauma. 1998;45:656-661
PENETRATING EXTRAPERITONEAL RECTAL INJURY DATA FORM

Institutional Information

Institution Name:___________________________
Investigator:___________________________
Level of Trauma Center: I II III IV Non-TC

Patient Demographics

Age:_____  Sex:_____  Date of Injury_____/_____/______  Date of Discharge_____/_____/_____
Hospital Length of Stay (days)_____________
Mechanism: GSW ________   SW_________   SGW __________

Clinical Data

Abdominal PE:_____________________________________________________
Rectal Exam:_______________________________________________________
Method of Rectal Injury Diagnosis:______________________________________
(proctoscopy, rectal examination or both)

DPL:  Y      N       DPL Results (if done):_____________________________________
Proctoscopy: Y    N
Results (if done):_____________________________________________________
Extent of Rectal Injury:   < 25% circumferential___________
                        >  25% circumferential___________

CT Scan:  Y    N
Results (if done):_____________________________________________________
Cystogram:  Y    N
Results (if done):_____________________________________________________
Abdominal Injuries:_____________________________________________________
____________________________________________________________________
____________________________________________________________________
ISS:__________
PATI:__________

Extra-Abdominal Injuries:____________________________________________________
________________________________________________________________________

Ex Lap: Y:_____ N:_____

Fecal Diversion: Y:______ N:_______ Type of Colostomy:_____________________

Abdominal Procedures:_______________________________________________________
________________________________________________________________________

Barium Enema: ____/____/_____ Result:_____________________________________

Date of PO Intake:_________________________________________________________

Rectal Injury Complications_________________________________________________
________________________________________________________________________
________________________________________________________________________

General Complications:_____________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Colostomy Closure

Colostomy Closure: Not Applicable____________________
Date of Colostomy Closure:_____/_____/_____

Complications of Colostomy Closure:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________