**MULTICENTER STUDY DATA COLLECTION TOOL**

**Multicenter Study:**
Outcomes Among Trauma Patients with Duodenal Leak Following Primary vs Complex Repair of Duodenal Injuries

Enrolling Center: __________________________
Enrolling Co-investigator: __________________________
Site ID: __________________________
Patient ID (SiteID-001, SiteID-002, etc): __________________________

**DEMOGRAPHICS and PMH**

Age: ______

Gender: Male / Female / Other

Race: Caucasian / Black / Asian / Native American or Alaska Native / Native Hawaiian or Pacific Islander / other

Ethnicity: Hispanic or Latino / Non-Hispanic

BMI: ______

PMH (check all that apply):

HTN: ______ DM: ______ CKD: ______

ESRD: ______ CAD: ______ CHF: ______

COPD: ______ Cancer: ______ Smoker: ______

Peptic Ulcer Disease: _______ Immunosuppressant Medication: _______

PSH: (list below)

**ADMISSION DATA:**

Mechanism of initial injury:

Blunt: YES / NO

Penetrating: YES / NO

Blunt Mechanism: MVC / MCC / Pedestrian struck / Assault / Fall / Crush injury / Other

Penetrating Mechanism: GSW / Stab Wound / Other
Admission Vital Signs

HR: _______  Systolic BP: _______  GCS: _______

Admission Lab values:

Hemoglobin: _______  pH: _______  Lactate: _______  Base Deficit: _______

ISS: _______  AIS Head: _______  AIS Chest: _______  AIS Abdomen: _______

Massive Transfusion Protocol Utilization: YES / NO

Intra-operative blood loss (index case in mL): _______
Total PRBC given in first 24 hours (in mL): _______
Total FFP given in first 24 hours (in mL): _______
Total Platelets given in first 24 hours (in mL): _______

INJURY DATA:

Duodenal Injury: YES / NO (should only be yes here)
  Percent Circumference Injured: _______
  Duodenal Injury Location: 1st portion / 2nd portion / 3rd portion / 4th portion
  Duodenal Injury Location Laterality: Anterior / Posterior / Medial / Lateral / Superior / Inferior
  Number of Duodenal Wounds: _______
  Duodenal Injury Involved the Amulla: YES / NO
  Duodenal Injury AAST Grade: I / II / III / IV / V

Pancreatic Injury: YES / NO
  Pancreatic Injury Location: Head / Body / Tail / Uncinate Process
  Number of Pancreatic Wounds: _______
  Pancreatic Ductal Injury: YES / NO
  Pancreatic Injury AAST Grade: I / II / III / IV / V

Solid Organ Injury: YES / NO
Hollow Viscus Injury (other than duo): YES / NO
Genitourinary Injury: YES / NO

Other Injuries: (Check All that Apply and circle correlating AAST Injury Grades if provided)
None: _______
Kidney: _______ I / II / III / IV / V  Adrenal: _______
Stomach: _______  Jejunum or Ileum: _______
Rectum: _______  Gallbladder: _______
Ureter: _______  Urethra: _______
Intra-abdominal Vascular Injury: _______ I / II / III / IV / V
Intra-thoracic Vascular Injury: _______
Extremity Vascular Injury: _______
Cardiac: _______  Lung: _______
Spine: _______  Orthopedic: _______
Rib/Sternal: _______  Diaphragm: _______
INDEX OPERATIVE MANAGEMENT

Time from injury to initial operation (in minutes): _______

Index Operation: Laparotomy / Laparoscopy

Duodenal Injury Managed During Index Operation: YES / NO

Index Operation Damage Control Laparotomy: YES / NO

Operative management of duodenal injury (Select One):

- Primary repair alone
- Pyloric exclusion with gastrojejunostomy
- Duodouodenectomy with enteric anastomosis
- Duodenal diverticulitization
- Retrograde duodenostomy drainage tubes with distal feeding tube placement
- Whipple (pancreaticoduodenectomy)
- Other – describe:

Operative interventions during index operation (check all that apply):

- Liver packing, hepatorrhaphy, or liver resection
- Splenectomy
- Jejunal or ileal repair or resection
- Colon or rectum repair or resection
- Diaphragm repair
- Partial or total nephrectomy
- Bladder or ureter repair/procedure
- Distal pancreatectomy
- Central pancreatectomy
- Intra-abdominal vascular injury ligation repair, shunt or bypass
- Preperitoneal packing
- Pelvic packing
- Pericardial window
- Thoracotomy
- Sternotomy
- Esophageal injury repair or resection
- Lung resection or repair
- Cardiac repair
- Intrathoracic vascular injury management
- Extremity vascular injury management
- Neck vascular injury management
- Other

Total number of OR operations: _______

Operative interventions during SUBSEQUENT operations (check all that apply):

- Ex laps, washouts only
- Liver packing, hepatorrhaphy, or liver resection
- Splenectomy
- Jejunal or ileal repair or resection
- Colon or rectum repair or resection
- Diaphragm repair
<table>
<thead>
<tr>
<th>Procedure/Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial or total nephrectomy</td>
</tr>
<tr>
<td>Bladder or ureter repair/procedure</td>
</tr>
<tr>
<td>Distal pancreatectomy</td>
</tr>
<tr>
<td>Central pancreatectomy</td>
</tr>
<tr>
<td>Intra-abdominal vascular injury ligation repair, shunt or bypass</td>
</tr>
<tr>
<td>Preperitoneal packing</td>
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</tr>
<tr>
<td>Intrathoracic vascular injury management</td>
</tr>
<tr>
<td>Extremity vascular injury management</td>
</tr>
<tr>
<td>Neck vascular injury management</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

**How was the abdomen ultimately closed? (Select One):**
- Primary Closure
- Bridging biologic or vicryl mesh closure
- Died prior to abdominal closure
- Synthetic Mesh closure
- Skin only closure
- Other: describe:

Number of Peri-duodenal extraluminal operative drains placed in OR: _______

**DUODENAL LEAK COMPLICATION DETAILS:**

Duodenal Leak: YES / NO (answer the following questions if yes)
- Post operative Day the Leak was identified: _______
- Study identifying duodenal leak: CT / Fluoroscopy / MRI / Endoscopy / In OR / Clinically via drain output
- IR drain placement for duodenal leak: YES / NO
  - Number of IR peri-duodenal drains placed: _______
  - Number of IR procedures for peri-duodenal drains: _______
- Were Surgical or IR peri-duodenal drains dislodged? YES / NO
  - Number of times drains were dislodged: _______
- Was an ERCP performed: YES / NO
- Antibiotic usage for duodenal leak: YES / NO
  - Duration of Antibiotic Therapy for duodenal leak (days): _______
  - Number of days until fistula/duodenal leak resolved (total inpatient and outpatient days): _______

**OTHER COMPLICATIONS:**
Complications: (check all that apply)
- Intraabdominal Abscess
- GI Bleed
- Marginal Ulcer
- Ileus
- Abdominal Compartment Syndrome
- Enteric Fistula (DOES NOT include DUO leak/fistula)
- Anastomotic Leak
- DVT
- PE
- AKI
RRT
Liver Dysfunction (transaminases elevated >15 times normal)
Sepsis
Pneumonia
Bacteremia
UTI
ARDS
MI

HOSPITAL COURSE / NUTRITION INFORMATION:
Number of days with surgical site and/or IR drains (totaled for inpatient and outpatient): _________
If the patient had a pyloric exclusion, was an open channel noted on follow up imaging? (Flow through the stomach to the duodenum where the pyloric exclusion had been): YES / NO
   Post-operative day the open channel was identified from the surgery in which a pyloric exclusion was performed: _________
Tracheostomy performed: YES / NO
Feeding tube placed (Gtube or Jtube): YES / NO
Nutrition Consulted: YES / NO
Nutric Score:
Albumin nadir during hospitalization: _________
Prealbumin nadir during hospitalization: _________
Retinol-binding protein nadir during hospitalization: _________
Transferrin nadir during hospitalization: _________
Number of days NPO: _________
Number of days without any nutrition: _________
Post-operative day from index surgery that nutrition was first started: _________
Was enteral tube feeds given? YES / NO
   Days of Enteral nutrition: _________
Was IV nutrition given? YES / NO
   Dasy of IV nutrition: _________
Number of days until eating a regular diet by mouth: _________

OUTCOMES:
Hospital LOS: ____________________  ICU LOS: ____________________
Ventilator Days:___________________  Mortality (circle one):  YES / NO
Discharge Disposition: Home / Rehab / Skilled nursing facility / Long term care facility / Hospice / Other
30 Day Readmission: YES / NO
Number of ED visits and readmissions for duodenal related complications up to 1 year following discharge: _________
Number of outpatient office visits related to duodenal injury: _________
Was “patient reported outcome” survey administered as outpatient after discharge?: YES / NO
EAST MULTICENTER STUDY
DATA DICTIONARY

Outcomes Among Trauma Patients with Duodenal Leak Following Primary vs Complex Repair of Duodenal Injuries

Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

<table>
<thead>
<tr>
<th>Entry space</th>
<th>Definition / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site ID</td>
<td>Each site’s assigned number</td>
</tr>
<tr>
<td>Patient ID</td>
<td>5-digit number starting with your Site ID, ie 12-001, 12-002, 12-003, etc</td>
</tr>
</tbody>
</table>

DEMOGRAPHICS and PMH

Age                                  | Age of patient enrolled                                                                  |
Gender                               | Gender of Patient enrolled                                                               |
Race                                 | Race of patient enrolled                                                                 |
Ethnicity                            | Ethnicity of patient enrolled                                                           |
BMI                                  | BMI of patient enrolled                                                                 |

PMH

Hypertension                        | History of high blood pressure                                                          |
Diabetes mellitus                   | A long-term metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin |
Chronic Kidney Disease              | Mild, moderate or severe kidney dysfunction as defined by the Kidney Disease Improving Global Outcomes (KDIGO) definition |
CKD requiring Dialysis              | Chronic kidney disease requiring dialysis prior to hospitalization                      |
Peptic Ulcer Disease                | Sores or ulcers in the stomach or duodenum                                               |
Coronary Artery Disease             | An impedance or blockage of one or more blood vessels that supplies blood to the heart |
Congestive Heart Failure            | A chronic and progressive condition in which the heart is inefficient at pumping blood and oxygen to meet the body’s demands |
COPD                                | Chronic Obstructive Pulmonary Disease is a chronic inflammatory lung disease that causes obstructed airflow from the lungs |
Cancer                              | Any cancer history                                                                       |
Immunosuppressant Medication        | Steroids, chemotherapy, or any other immunosuppressant medication                       |
Smoker                              | Active or prior history of smoking                                                      |
Prior Abdominal Operations          | Yes or No (free text)                                                                   |
<table>
<thead>
<tr>
<th><strong>ADMISSION DATA</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trauma Mechanism</strong></td>
<td>Blunt, Penetrating, or Both</td>
</tr>
<tr>
<td><strong>Blunt</strong></td>
<td>Options include:</td>
</tr>
<tr>
<td></td>
<td>MVC (Motor Vehicle Collision)</td>
</tr>
<tr>
<td></td>
<td>MCC (Motorcycle Collision / Crash)</td>
</tr>
<tr>
<td></td>
<td>Motor Vehicle vs. Pedestrian (Pedestrian Struck)</td>
</tr>
<tr>
<td></td>
<td>Fall</td>
</tr>
<tr>
<td></td>
<td>Assault</td>
</tr>
<tr>
<td></td>
<td>Crush Injury</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td><strong>Penetrating</strong></td>
<td>Options include:</td>
</tr>
<tr>
<td></td>
<td>GSW (Gunshot wound)</td>
</tr>
<tr>
<td></td>
<td>Stab (Stab Wound)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td><strong>Admission Heart Rate</strong></td>
<td>Admission Heart Rate</td>
</tr>
<tr>
<td><strong>Admission Blood Pressure</strong></td>
<td>Admission Blood Pressure</td>
</tr>
<tr>
<td><strong>Admission GCS</strong></td>
<td>Admission Glasgow Coma Scale</td>
</tr>
<tr>
<td><strong>Hemoglobin</strong></td>
<td>Admission Hemoglobin value (g/dL)</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>Admission pH value (arterial preferred, but venous venous value acceptable if no arterial value available)</td>
</tr>
<tr>
<td><strong>Lactate</strong></td>
<td>Admission lactate (mmol/L)</td>
</tr>
<tr>
<td><strong>Base Deficit</strong></td>
<td>Admission Base Deficit (mmol/L)</td>
</tr>
<tr>
<td><strong>ISS</strong></td>
<td>Numerical value for calculated ISS (ISS = Injury Severity Score)</td>
</tr>
<tr>
<td><strong>AIS Head</strong></td>
<td>Numerical Value for AIS body region = Head (AIS = Abbreviated Injury Score)</td>
</tr>
<tr>
<td><strong>AIS Chest</strong></td>
<td>Numerical Value for AIS body region = Chest (AIS = Abbreviated Injury Score)</td>
</tr>
<tr>
<td><strong>AIS Abdomen</strong></td>
<td>Numerical Value for AIS body region = Abdomen (AIS = Abbreviated Injury Score)</td>
</tr>
<tr>
<td><strong>Massive Transfusion Protocol</strong></td>
<td>Yes or No whether the institution’s massive transfusion protocol was instituted on admission</td>
</tr>
<tr>
<td><strong>Intra-operative blood loss (mL)</strong></td>
<td>Recorded intra-operative blood loss for the index procedure in mL</td>
</tr>
<tr>
<td><strong>PRBC in 24 hours</strong></td>
<td>Total packed red blood cell product given in first 24 hours of admission (to be recorded in mL) (of note 1 unit is about 400mL)</td>
</tr>
<tr>
<td><strong>FFP in 24 hours</strong></td>
<td>Total fresh frozen plasma product given in first 24 hours of admission (to be recorded in mL) (of note 1 unit is about 200mL)</td>
</tr>
</tbody>
</table>
Platelets in 24 hours  

Total platelet product given in first 24 hours of admission (to be recorded in mL) (of note 1 unit is about 200mL)

INJURY DATA:

Duodenal Injury  
A duodenal injury requiring operative management. Which will be further described by: percent circumference injured, duodenal injury location (1st, 2nd, 3rd, or 4th portion), duodenal injury location laterality (anterior, posterior, superior, inferior, medial, or lateral), number of wounds.

Duodenal AAST Grade  
I - single hematoma or partial thickness laceration  
II - hematoma in more than one portion or laceration < 50% circumference  
III - laceration 50-75% D2 or 50-100% D1, 3, or 4,  
IV - >75% D2 or involves ampulla or distal CBD  
V - major disruption of duodeno-pancreatic complex, devascularization

Pancreatic Injury  
Any pancreatic injury. Which will be further described by: injury location (head, body, tail, uncinate process), number of wounds, whether there was a ductal injury or not.

Pancreatic AAST Grade  
I - Hematoma minor contusion without duct injury, or laceration without duct injury  
II - Hematoma major contusion without duct injury or laceration major without duct injury or tissue loss  
III - Laceration: distal transection or parenchymal injury with duct injury  
IV - Laceration: proximal transection or parenchymal injury involving ampulla  
V - Laceration: massive disruption of pancreatic head

Solid Organ Injury  
Any injury to the liver, spleen, kidney or adrenal

Hollow Viscus Injury  
Any injury to esophagus, stomach, gallbladder, jejunum, ileum, colon, rectum

Genitourinary Injury  
Ureter, bladder, or urethral injury

Intra-abdominal vascular injury  
I: unnamed SMA/SMV/IMA/IMV branch injury, phrenic art or v, lumbar art or v, gonadal art or v, ovarian art or v  
II: R, L or common hepatic art, splenic art or v, R/L gastric art, GDA, IMA or IMV, named branches like ileocolic art or v  
III: SMV, renal art or v, iliac art or v, hypogastric art or v, vena cava infrarenal  
IV: SMA, celiac axis, vena cava suprarenal or infrahepatic, infrarenal aorta  
V: portal vein, hepatic v, retrohepatic or suprahepatic vena cava, suprarenal or subdiaphragmatic aorta

INDEX OPERATIVE MANAGEMENT:

Time from injury to OR  
Time from injury to initial OR case (in minutes)

Index (first) Operation  
Laparotomy vs Laparoscopy

Duodenal Injury Managed During Index Operation  
Duodenal injury surgical procedure performed during first surgical case
<table>
<thead>
<tr>
<th>Damage Control Laparotomy</th>
<th>Abdominal closure was not completed during the initial index operation. Hemostasis and contamination was achieved and the abdomen was temporarily closed with an abthera VAC, IV bag, or other temporary closure device to facilitate early re-exploration and urgent / emergent re-evaluation (i.e. assessment of bowel viability)</th>
</tr>
</thead>
</table>
| Operative management of duo injury | Options include:  
Primary repair alone  
Pyloric exclusion with gastrojejunostomy  
Duodouodenectomy with enteric anastomosis  
Duodenal diverticulitization  
Retrograde duodenostomy drainage tubes with distal feeding tube placement  
Whipple (pancreaticoduodenectomy)  
Other |
| Operative Interventions Performed During the Index Operation (Other than duodenal management) | Select any that apply:  
Liver packing, hepatorrhaphy, or liver resection  
Splenectomy  
Jejunal or ileal repair or resection  
Colon or rectum repair or resection  
Diaphragm repair  
Partial or total nephrectomy  
Bladder or ureter repair/procedure  
Distal pancreatectomy  
Central pancreatectomy  
Intra-abdominal vascular injury ligation repair, shunt or bypass  
Preperitoneal packing  
Pelvic packing  
Pericardial window  
Thoracotomy  
Sternotomy  
Esophageal injury repair or resection  
Lung resection or repair  
Cardiac repair  
Intrathoracic vascular injury management  
Extremity vascular injury management  
Neck vascular injury management  
Other |
| Operative Interventions Completed During Subsequent Operations (Does NOT include those performed During the first operation) | Select all that apply:  
Ex lap, washouts only  
Splenectomy  
Jejunal or ileal repair or resection  
Colon or rectum repair or resection  
Diaphragm repair  
Partial or total nephrectomy  
Bladder or ureter repair/procedure  
Distal pancreatectomy  
Central pancreatectomy  
Intra-abdominal vascular injury ligation repair, shunt or bypass  
Preperitoneal packing |
Pelvic packing
Pericardial window
Thoracotomy
Sternotomy
Esophageal injury repair or resection
Lung resection or repair
Cardiac repair
Intrathoracic vascular injury management
Extremitiy vascular injury management
Neck vascular injury management
Other

Abdominal Closure Options include:
Primary repair (fascia primarily sutured together)
Bridging biologic or vicryl mesh closure
Synthetic Mesh Closure
Skin Only Closure
Died prior to abdominal closure
Other

Number of periduodenal extraluminal Operative drains placed in OR Number of periduodenal extraluminal operative drains placed in OR

**DUODENAL LEAK COMPLICATION DETAILS:**

Duodenal Leak Complication Indicate yes or no
Post-operative day the duodenal Leak Was identified Post-operative day from the first surgery that the duodenal leak was identified
Study that identified the duodenal leak Can Select:
CT scan, Fluoroscopy upper GI/small bowel follow through, MRI, endoscopy, in the OR during a takeback operation, or at the bedside clinically based on change in drain output consistent with bile.
IR drain placement for duodenal leak Additional drain placed near the duodenal leak to help manage it by interventional radiology team. Indicate yes or no.
Number of IR procedures for periduodenal drains Number of times patient went to IR for periduodenal drain placement or adjustment
Periduodenal drain dislodgement Were the surgical or IR drains dislodged during hospitalization? Indicate Yes or no
ERCP performed Indicate yes or no to whether a ERCP was performed
Antibiotic usage for duodenal leak Indicate yes or no to whether antibiotics were given to the patient with the indication of duodenal leak
Duration of antibiotic therapy Duration of Antibiotic therapy for duodenal leak in days
Number of days until fistula/duodenal leak resolution Number of days until fistula/duodenal leak closure/resolution. This is total number of days including inpatient and outpatient.
### OTHER COMPLICATIONS:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-abdominal abscess</td>
<td>Intra-abdominal abscess identified on imaging</td>
</tr>
<tr>
<td>GI bleed</td>
<td>GI bleed (upper or lower) diagnosed clinically</td>
</tr>
<tr>
<td>Marginal Ulcer</td>
<td>New ulceration at the gastrojejunal anastomosis</td>
</tr>
<tr>
<td>Ileus</td>
<td>Clinical or image identified ileus resulting in diet restriction</td>
</tr>
<tr>
<td>Abdominal Compartment Syndrome</td>
<td>Abdominal compartment hypertension causing end organ dysfunction and operative intervention for decompression</td>
</tr>
<tr>
<td>Enteric Fistula</td>
<td>Enteric fistula (NOT including duodenal leak or fistula)</td>
</tr>
<tr>
<td>Anastomotic Leak</td>
<td>Enteric anastomotic leak (NOT including duodenal leak)</td>
</tr>
<tr>
<td>Deep Vein Thrombosis (DVT)</td>
<td>Radiographic proven DVT (ultrasound, Computed tomography, venography, etc)</td>
</tr>
<tr>
<td>Pulmonary Embolism (PE)</td>
<td>Radiographic proven PE (ultrasound, computed tomography, venography, etc)</td>
</tr>
<tr>
<td>Acute Kidney Injury (AKI)</td>
<td>AKI as defined by the KDIGO criteria</td>
</tr>
<tr>
<td>Renal Replacement Therapy (RRT)</td>
<td>The patient required dialysis newly initiated during this hospitalization.</td>
</tr>
<tr>
<td>Liver Dysfunction</td>
<td>Elevated transaminases 15 times greater than normal</td>
</tr>
<tr>
<td>Sepsis</td>
<td>Has a confirmed infectious process AND two or more of the following:</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Hospital Acquired Pneumonia: Confirmed by the presence of the following after 48 hours of hospitalization:</td>
</tr>
<tr>
<td>Bacteremia</td>
<td>Defined as positive blood cultures</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>Defined as positive urinary cultures</td>
</tr>
</tbody>
</table>
**Acute Respiratory Distress Syndrome (ARDS)**

Defined by the Berlin Criteria

Mild ARDS: 201 - 300 mmHg (≤ 39.9 kPa)
Moderate ARDS: 101 - 200 mmHg (≤ 26.6 kPa)
Severe ARDS: ≤ 100 mmHg (≤ 13.3 kPa)

New onset of bilateral infiltrates (patchy, diffuse, or homogenous) consistent with pulmonary edema - No clinical evidence of left atrial hypertension

**Myocardial Infarction (MI)**

New MI during this hospitalization as defined by:

- A rise of cardiac biomarker values (preferably troponin) with at least one of the following:
  - Symptoms of ischemia
  - New or presumed new significant ST-segment-T wave (ST-T) changes or new left bundle branch block
  - Development of pathological Q waves in the EKG
  - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
  - Identification of an intracoronary thrombus by angiography or autopsy

**HOSPITAL COURSE / NUTRITIONAL INFORMATION:**

- **Number of Days with Surgical site**
  - Total number of days with surgical drains and/or IR drains in place.
  - This includes both inpatient and outpatient days.

- **Open Channel**
  - If the patient had a pyloric exclusion, did follow up imaging demonstrate an open channel with flow from the stomach into the duodenum through the area where the exclusion had been performed.

- **Post-operative day open Channel Was identified**
  - Post-operative day the open channel was identified from the day of the surgery in which the pyloric exclusion was performed.

- **Tracheostomy performed**
  - Indicate yes or no.

- **Feeding tube placed**
  - Indicate whether a feeding tube was placed yes or no.
  - This includes gastrostomy tubes or jejunal tubes.

- **Nutrition Consulted**
  - Indicate yes or no to whether the nutrition/dietary team was consulted.

- **Nutric Score**
  - If available per nutrition notes. Include nutric score as determined by Age apache II, SOFA, number of co-morbidities, days from hospital to ICU admission, (IL-6).

- **Albumin nadir**
  - The lowest albumin level during hospitalization (g/dL)

- **Prealbumin nadir**
  - The lowest prealbumin level during hospitalization (mg/dL)

- **Retinol-binding protein nadir**
  - The lowest retinol-binding protein level during hospitalization (mg/dL)

- **Transferrin nadir**
  - The lowest transferrin level during hospitalization (mg/dL)

- **Number of Days NPO**
  - Number of days nothing per oral (by mouth)

- **Number of Days without any nutrition**
  - Number of days with a diet, enteral tube feeds, or IV nutrition
<table>
<thead>
<tr>
<th><strong>Post-operative day that nutrition was first started</strong></th>
<th>Post-operative day from index surgery that nutrition was first started</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enteral feeds given</strong></td>
<td>Indicate yes or no whether the patient received enteral feeds (Tube feeds)</td>
</tr>
<tr>
<td><strong>Days of Enteral Feeds</strong></td>
<td>Indicate days of enteral feeds</td>
</tr>
<tr>
<td><strong>Intravenous nutrition</strong></td>
<td>Indicate yes or no whether the patient received intravenous nutrition (TPN, CPN, PPN etc)</td>
</tr>
<tr>
<td><strong>Days of IV Nutrition</strong></td>
<td>Indicate days of IV nutrition</td>
</tr>
<tr>
<td><strong>Number of Days until eating a regular diet by mouth</strong></td>
<td>Number of days until the patient tolerated a regular diet by mouth</td>
</tr>
</tbody>
</table>

**OUTCOMES:**

<table>
<thead>
<tr>
<th><strong>Hospital LOS (days)</strong></th>
<th>Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1) LOS = Length of Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICU LOS (days)</strong></td>
<td>Free text entry of number of consecutive days patient required ICU admission (ICU = Intensive Care Unit, LOS = Length of Stay - Day of admission = hospital day #1)</td>
</tr>
<tr>
<td><strong>Duration of Mechanical Ventilation (days)</strong></td>
<td>Free text entry for total number of days patient required mechanical ventilation</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td>Indicate yes if the patient died during this hospitalization</td>
</tr>
<tr>
<td><strong>Discharge Disposition</strong></td>
<td>Select one of the following discharge dispositions: home, rehab (acute or subacute), skilled nursing facility (SNF), long term acute care facility (LTAC), Hospice, or other</td>
</tr>
<tr>
<td><strong>30 Day Readmission</strong></td>
<td>Readmission to the hospital within 30 days of discharge</td>
</tr>
<tr>
<td><strong>Number of ED visits or readmissions Within 1 year after discharge</strong></td>
<td>Number of ED visits and readmissions to the hospital for a duodenal related complication up to 1 year after initial discharge</td>
</tr>
<tr>
<td><strong>Number of outpatient office visits</strong></td>
<td>Number of outpatient office visits related to duodenal injury</td>
</tr>
<tr>
<td><strong>Was a patient reported outcomes Survey administered as an outpatient</strong></td>
<td>Indicate whether a patient reported outcomes survey was utilized to improve patient care after the patient was discharged from the hospital</td>
</tr>
</tbody>
</table>
DHHS Federal Wide Assurance Identifier: FWA00003913

IRB Chair Person: Cheryl Kennedy
IRB Assistant Director: Swapnali Chaudhari

Effective Date: 9/7/2021
Approval Date: 9/5/2021
Expiration Date: 9/4/2023

**eIRB Notice of Approval for Initial Submission # Pro2021001620**

**STUDY PROFILE**

**Study ID:** Pro2021001620  
**Title:** Outcomes Among Trauma Patients with Duodenal Leak Following Primary vs Complex Repair of Duodenal Injuries

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Rachel Choron</th>
<th>Study Coordinator:</th>
<th>Susette Coyle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-Investigator(s):</td>
<td>Susette Coyle</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Marie Macor</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amanda Teichman</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sponsor:</td>
<td>Department Funded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Determination:</td>
<td>Minimal Risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Review Type:</td>
<td>Expedited</td>
<td>Expedited Category:</td>
<td>(5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Records:</td>
<td>248</td>
</tr>
</tbody>
</table>

**CURRENT SUBMISSION STATUS**
*Retrospective Chart Review:* If applicable, records may be accessed to review information dating:

From: 1/1/2010 To: 12/31/2020

*Study Performance Sites:*

Robert Wood Johnson Medical School (RWJMS)  
125 Paterson Street, CAB 6300  
New Brunswick, NJ 08901

Robert Wood Johnson University Hospital  
1 Robert Wood Johnson Place  
New Brunswick, NJ 08901

ALL APPROVED INVESTIGATOR(S) MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.

3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue.** (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.

4. **Amendments/Modifications/Revisions:** If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements,
the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.

5. **Unanticipated Problems**: Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: [https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hbpp-guidance-topics](https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hbpp-guidance-topics)

6. **Protocol Deviations and Violations**: Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: [https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hbpp-guidance-topics](https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hbpp-guidance-topics)

7. **Consent/Assent**: The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

8. **Completion of Study**: Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

**CONFIDENTIALITY NOTICE**: This email communication may contain private, confidential, or legally privileged information intended for the sole use of the designated and/or duly authorized recipients(s). If you are not the intended recipient or have received this email in error, please notify the sender immediately by email and permanently delete all copies of this email including all attachments without reading them. If you are the intended recipient, secure the contents in a manner that conforms to all applicable state and/or federal requirements related to privacy and confidentiality of such information.

___

Study.PI Name:
Study.Co-Investigators:
1.0 Research Design

1.1 Purpose/Specific Aims

Our primary aim is to evaluate the management of traumatic duodenal injuries requiring surgical repair and to compare mortality in patients who subsequently develop duodenal leaks who were managed initially by primary repair vs complex repair with protective measures.

A. Objectives:
   a. Describe outcomes of traumatically injured patients who required surgical repair of duodenal injuries.
   b. Describe outcomes of traumatically injured patients who required surgical repair of duodenal injuries complicated by post-operative leak.
   c. Compare duodenal-related mortality among patients who had post-operative duodenal leaks following primary surgical repair vs complex surgical repair.
   d. Evaluate secondary outcomes of post-operative trauma patients with duodenal leaks that underwent complex repair with protective measures vs primary repair alone of duodenal injuries.
   e. Better characterize this patient population as a whole and provide insight into their post-operative course to better inform expectations for the clinical teams, patients, and families.

B. Hypotheses / Research Question(s):
   a. We hypothesize patients with duodenal leaks that underwent complex repairs with protective measures have improved mortality as compared to patients who underwent primary repair alone.
   b. We hypothesize patients with duodenal leaks that underwent complex repairs with protective measures have improved secondary outcomes
compared to patients who underwent primary repair alone; these secondary outcomes include: less days with periduodenal drains, less days NPO, less days requiring intravenous nutrition, less time to fistula closure, and less hospital/office visits.

1.2 Research Significance
Duodenal trauma is relatively rare and operative management strategies remain controversial. Historically operative approaches have involved more complex repairs with protective measures (CRPM) including duodenal repair with pyloric exclusion and gastrojejunostomy diversion, duodenal diverticulization, duodudodenectomy with enteric anastomosis, and retrograde duodenostomy drainage tubes with distal feeding tube placement. More recently there has been a trend in literature and clinical practice favoring primary repair alone (PR) of duodenal injuries without additional protective measures. While reports suggest primary repair is safe and possibly the preferred approach as it does not result in a higher leak rate, once a leak develops, it is unclear whether index complex repair with protective measures provide subsequent protection and better outcomes compared to patients who underwent primary repair alone.

Because duodenal injuries requiring operative management are relatively rare, with high volume penetrating trauma centers reporting only 25-90 patients over 5-10 years in published case series, optimal surgical management is difficult to study and almost all reports are small in sample size and retrospective by necessity. More so, patients who develop duodenal leaks after index surgical repairs are an even less studied population.

In 2019 a retrospective multicenter trial from the Panamerican Trauma Society by Ferrada et al. examined outcomes after the surgical management of duodenal injuries in 372 trauma patients. While this study is the first larger multi-center trial analyzing patients requiring operative management for duodenal injuries, questions remain regarding patients complicated by duodenal leak after repair. While primary repair was concluded to be common and safe, the literature has yet to address whether patients who have duodenal leaks have better outcomes when managed with complex or primary repair initially.

We plan to perform a retrospective multicenter trial in which we are recording and controlling the data over the past 11 years from January 1, 2010 to December 31, 2020 to compare outcomes among patients with duodenal leaks after primary vs complex repair with protective measures to determine whether one repair offers improved outcomes in patients who develop subsequent duodenal leaks. We hypothesize patients with duodenal leaks that underwent complex repairs with protective measures have improved mortality as compared to patients who underwent primary repair alone. Additionally, we hypothesize patients with duodenal leaks that underwent complex repairs with protective measures have improved quality of life compared to patients who...
underwent primary repair alone; quality of life would be defined by our secondary outcomes including less days with periduodenal drains, less days NPO, less days requiring intravenous nutrition, less time to fistula closure, and less hospital/office visits.

1.3 Research Design and Methods

A. Study Duration: This will take approximately 2 years to complete.

1.4 Secondary Data Collection

- Study investigators (listed on eIRB) will query the RWJUH Decisions Support Department and Operating Room upon IRB approval to identify eligible charts.
- Study staff (listed on eIRB) will collect data from the patients’ medical record via RWJUH’s SCM system and enter into the study database.
- Data will be collected in a retrospective manner.
- Identifiers will be removed when data collection is complete and verified.
- Subjects will not be followed prospectively.
- Deidentified data collection from other sites adhering to the above protocol will be included as this is a multicenter trial with RWJUH being the primary site. RWJUH study investigators will be controlling the data.

A. Source and Context of Original Primary Collection:

a. Database Location:
   i. RWJUH: SCM

b. Prior Consent Considerations: N/A

B. Format and Number of Records: We anticipate retrospectively reviewing 50 RWJUH charts along with deidentified data contributions from 1000 charts from secondary sites.

C. Date Range: 1/1/2010-12/31/2020

D. Inclusion/Exclusion Criteria: Adult patients 15 years of age or greater who underwent laparotomy for trauma with duodenal injury requiring primary or complex operative repair.

Exclusion Criteria
Patients who die within 24 hours of presentation would be excluded as we are interested in examining patients who develop duodenal leak complications.
E. **Data Abstraction Form(s):** Data Collection Sheet uploaded. Identifiers will be removed when data collection complete and verified.

F. **Sample Size Justification:** We conducted a power analysis and have estimated the required sample size to compare mortality outcomes among patients who had a duodenal leak after complex repair with protective measures vs. primary repair alone of traumatic duodenal injuries. Recent literature reveals high volume trauma centers report about 25-50 operative duodenal injuries over 10 years with about a 3-to-1 ratio of patients managed with primary repair vs complex repairs respectively. Of those patients who undergo operative management of duodenal injuries, about 8-33% have duodenal leak complications with literature reporting mortality of 8-28% among those with duodenal leaks.

Assuming a 3-to-1 ratio of primary repairs to complex repair and conservatively assuming a 10% mortality among patients with duodenal leaks, a total sample of 248 patients will be required to detect a 15-percentage point difference in mortality at the 0.05 alpha level with 80% power. Assuming that each site will contribute an average of 8 patients with duodenal leaks, we anticipate recruiting approximately 31 sites to participate.

G. **Data Analysis:** Standardized data will be collected for each patient. Continuous variables will be compared using Student’s t-test and the Mann-Whitney U test for parametric and non-parametric data, respectively. Categorical variables will be compared by the Chi-squared tests or Fisher’s exact test. Univariate and multivariate logistic regression will be used to determine factors associated with mortality.

H. **Data Management:** Describe how data will be handled study-wide:

   a. **Access**
      i. Study Staff listed on eIRB will have access to data

   b. **Storage**
      i. Where, how and for how long data will be stored? De-identified data will be stored for 6 years after study is closed.
      ii. How will you transport, manage and store the data? All data will be collected and entered into a secure web-based application (Research Electronic Data Capture (REDCap™)).
      iii. Describe the steps you will take to secure the data – Data will only be accessible to study personnel listed on eIRB, via REDCap.
I. Disposition: Identifiers/links will be destroyed as soon as data collection is complete and verified by the PI.

J. Intent to Contact, Identify, Re-Identify or Generate Identifiable Information: N/A

1.5 Secondary Use of Biospecimens: N/A

2.0 Project Management

2.1 Research Staff Qualifications & Training
Research investigators and staff listed on eIRB are CITI trained.

2.2 Resources Available
REDCap, a secure platform for data storage, will be utilized for collection, storage, and analysis.

2.3 Research Sites
Rutgers Robert Wood Johnson Medical School (RWJMS) & Robert Wood Johnson University Hospital (RWJUH)

3.0 Multi-Center Research
This is a retrospective observational multicenter study with the primary site being Rutgers Robert Wood Johnson University Hospital. Our research investigators and staff listed on the eIRB will be controlling the data. The protocol will be amended each time a new site provides their IRB approval.

4.0 Subject Considerations

4.1 Consent Process (Is Not Applicable to Secondary Research)

4.2 Waiver or Alteration of Consent Process
We request a waiver of consent - As a chart review, this study will collect data already recorded for non-research purposes, and therefore comprises minimal risk.

4.3 Risks of Harm/Potential for Benefits to Subjects

   A. Risks of Harm to Subjects: As a minimal risk study, the only risk is loss of confidentiality.

   B. Risks of Harm to Non-Subjects: N/A
C. **Minimizing Risks of Harm:** Every effort will be made to maintain confidentiality including keeping the ID link in a password-protected file stored on OneDrive, which will only be accessible to designated study investigators. Furthermore, links to identifiers will be destroyed/removed once data collection is completed and verified.

D. **Potential Benefits to Subjects:** There are no direct benefits to subjects.

E. **Certificate of Confidentiality (CoC):** N/A

### 5.0 Special Considerations

5.1 **Health Insurance Portability and Accountability Act (HIPAA)**  
Request waiver - As a retrospective chart review, this study will collect data already recorded for non-research purposes, and therefore comprises minimal risk.

5.2 **Family Educational Rights and Privacy Act (FERPA)**  
N/A

5.3 **General Data Protection Regulation (GDPR)**  
N/A

### 6.0 Reporting Results

6.1 **Reporting Results Details**

A. **Individual Subjects' Results:** N/A.

B. **Professional Reporting:** Data will be submitted for presentation and/or publication at scientific, medical and surgical conferences and in peer-reviewed journals.

6.2 **Further Secondary Uses of the Data or Biospecimens**  
Data will only be used for this study by investigators listed on eIRB

### 7.0 Research Repositories – Data or Biospecimens

N/A.

### 8.0 Approvals/Authorizations

N/A.
9.0 Bibliography


