Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST 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: _____	Liver: _____ I / II / III / IV / V	Spleen: _____ I / II / III / IV / V
Kidney: _____ I / II / III / IV / V	Adrenal: _____	Esophagus: _____
Stomach: _____	Jejunum or Ileum: _____	Colon: _____
Rectum: _____	Gallbladder: _____	Bladder: _____
Ureter: _____	Urethra: _____	Diaphragm: _____

Intra-abdominal Vascular Injury: _____ I / II / III / IV / V
Intra-thoracic Vascular Injury: _____
Extremity Vascular Injury: _____

Cardiac: _____	Lung: _____	Rib/Sternal: _____
Spine: _____	Orthopedic: _____	TBI: _____

Other: _____

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
_____Duoduodenectomy 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

_____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

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

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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:

Entry space	Definition / Instructions
Site ID	Each site's assigned number
Patient ID	5-digit number starting with your Site ID, ie 12-001, 12-002, 12-003, etc
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	Yes or No if comorbidities exist
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)

ADMISSION DATA

Trauma Mechanism Blunt	Blunt, Penetrating, or Both Options include: MVC (Motor Vehicle Collision) MCC (Motorcycle Collision / Crash) Motor Vehicle vs. Pedestrian (Pedestrian Struck) Fall Assault Crush Injury Other
Penetrating	Options include: GSW (Gunshot wound) Stab (Stab Wound) Other
Admission Heart Rate	Admission Heart Rate
Admission Blood Pressure	Admission Blood Pressure
Admission GCS	Admission Glasgow Coma Scale
Hemoglobin	Admission Hemoglobin value (g/dL)
pH	Admission pH value (arterial preferred, but venous venous value acceptable if no arterial value available)
Lactate	Admission lactate (mmol/L)
Base Deficit	Admission Base Deficit (mmol/L)
ISS	Numerical value for calculated ISS (ISS = Injury Severity Score)
AIS Head	Numerical Value for AIS body region = Head (AIS = Abbreviated Injury Score)
AIS Chest	Numerical Value for AIS body region = Chest (AIS = Abbreviated Injury Score)
AIS Abdomen	Numerical Value for AIS body region = Abdomen (AIS = Abbreviated Injury Score)
Massive Transfusion Protocol	Yes or No whether the institution's massive transfusion protocol was instituted on admission
Intra-operative blood loss (mL)	Recorded intra-operative blood loss for the index procedure in mL
PRBC in 24 hours	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)
FFP in 24 hours	Total fresh frozen plasma product given in first 24 hours of admission (to be recorded in mL) (of note 1 unit is about 200mL)

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 (1^{st}, 2^{nd}, 3^{rd}, or 4^{th} 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

Damage Control Laparotomy	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)
Operative management of duo injury	Options include: Primary repair alone Pyloric exclusion with gastrojejunostomy Duoduodenectomy 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
Total number of operations	Total number of operations during hospitalization
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 Extremity 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 duo 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:

Intra-abdominal abscess	Intra-abdominal abscess identified on imaging
GI bleed	GI bleed (upper or lower) diagnosed clinically
Marginal Ulcer	New ulceration at the gastrojejunal anastomosis
Ileus	Clinical or image identified ileus resulting in diet restriction
Abdominal Compartment Syndrome	Abdominal compartment hypertension causing end organ dysfunction and operative intervention for decompression
Enteric Fistula	Enteric fistula (NOT including duodenal leak or fistula)
Anastomotic Leak	Enteric anastomotic leak (NOT including duodenal leak)
Deep Vein Thrombosis (DVT)	Radiographic proven DVT (ultrasound, Computed tomography, venography, etc)
Pulmonary Embolism (PE)	Radiographic proven PE (ultrasound, computed tomography, venography etc)
Acute Kidney Injury (AKI)	AKI as defined by the KDIGO criteria
Renal Replacement Therapy (RRT)	The patient required dialysis newly initiated during this hospitalization.
Liver Dysfunction	Elevated transaminases 15 times greater than normal
Sepsis:	Sepsis: Has a confirmed infectious process AND two or more of the following: 1. Body temperature < 36 degrees Celsius (97 F) or > 38 C (100 F) 2. Heart rate > 100 bpm 3. Respiratory rate > 20 breaths per minute or, on blood gas, PaCO2 of less than 32 mm Hg 4. White blood cell count > 4,000 cells/mm^3 or > 12,000 cells/mm^3 or greater than 10% and forms (immature wbc)
Pneumonia	Hospital Acquired Pneumonia: Confirmed by the presence of the following after 48 hours of hospitalization: 1. purulent sputum 2. associated systemic evidence of infection: a. WBC > 11,000 or < 4,000 b. Fever > 100.4 degrees F / 38 degrees Celsius 3. Two or more serial chest radiographs with new or progressive and persistent infiltrate, consolidation or cavitation. 4. BAL, mini-BAL or sterile endotracheal specimen with: a. Limited number of epithelial cells b. WBC (2-3+) c. Dominant organism(s) identified on gram stain or culture with quantitative culture > 100,000 cfu/mL
Bacteremia	Defined as positive blood cultures
Urinary Tract Infection	Defined as positive urinary cultures

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 And/or IR drains	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

Post-operative day that nutrition Was first started	Post-operative day from index surgery that nutrition was first started
Enteral feeds given	Indicate yes or no whether the patient received enteral feeds (Tube feeds)
Days of Enteral Feeds	Indicate days of enteral feeds
Intravenous nutrition	Indicate yes or no whether the patient received intravenous nutrition (TPN, CPN, PPN etc)
Days of IV Nutrition	Indicate days of IV nutrition
Number of Days until eating a regular diet by mouth	Number of days until the patient tolerated a regular diet by mouth

OUTCOMES:

Hospital LOS (days)	Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1) LOS = Length of Stay
ICU LOS (days)	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
Duration of Mechanical Ventilation (days)	Free text entry for total number of days patient required mechanical ventilation
Mortality	Indicate yes if the patient died during this hospitalization
Discharge Disposition	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
30 Day Readmission	Readmission to the hospital within 30 days of discharge
Number of ED visits or readmissions Within 1 year after discharge	Number of ED visits and readmissions to the hospital for a duodenal related complication up to 1 year after initial discharge
Number of outpatient office visits	Number of outpatient office visits related to duodenal injury
Was a patient reported outcomes Survey administered as an outpatient	Indicate whether a patient reported outcomes survey was utilized to improve patient care after the patient was discharged from the hospital

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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

Principal Investigator:	Rachel Choron	**Study Coordinator:**	Susette Coyle
Co-Investigator(s):	Susette Coyle Marie Macor Amanda Teichman		
Sponsor:	Department Funded	**Approval Cycle:**	24 months
Risk Determination:	Minimal Risk		

Review Type:	Expedited	**Expedited Category:**	(5)	**Records:**	248

CURRENT SUBMISSION STATUS

Submission Type:	Research Protocol/Study	**Submission Status:**	Approved
Approval Date:	9/5/2021	**Expiration Date:**	9/4/2023

Vulnerable Population Codes:	
Children	No Children As Subjects
Pregnant Women	No Pregnant Women as Subjects
Prisoners	No Prisoners As Subjects

Protocol:	Protocol August 22, 2021	**Other Materials:**	Data Sheet August 19, 2021

*** 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
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/hspp-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/hspp-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.

—

Study.PI Name:
Study.Co-Investigators:

SECONDARY RESEARCH WITH DATA OR BIOSPECIMENS
RESEARCH PROTOCOL TEMPLATE
(HRP-503c)

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

Principal Investigator:

Rachel L. Choron, MD
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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, duoduodenectomy 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

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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

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