

DATE: Friday, January 26, 2024  
 TO: [Vanessa Nomellini](#), [Vanessa Nomellini](#),  
 CC:  
 FROM: HRPP Designated Reviewer  
 PROTOCOL NUMBER: [STU-2023-1113](#)  
 TITLE: Defining Outcomes of Early vs. Delayed Cholecystectomy for Perforated Cholecystitis  
 FUNDING: Internal - Departmental

Agency	Grant Number
There are no items to display	

REVIEW: New Exempt Study Review – **Activated**

REVIEW TYPE: Exempt

Documents: FormB-Personnel.docx, FormA-Protocol.docm, FormJ-DataCollection.docx, FormC-Population.doc, FormH-HIPAAWaiver-Full-Signed.pdf, FormH-HIPAAWaiver-Full.docx

Dear Principal Investigator,

Your new study was reviewed and ACCEPTED by the IRB on Thursday, January 25, 2024.

Your submission was reviewed and determined to meet Exempt criteria under 45 CFR 46.104(d). The Designated Reviewer made regulatory determinations for this study which may be found in eIRB in the Determinations tab.

As of Friday, January 26, 2024, the study met all the required approvals and may begin at the performance sites below with a status of "Approved." **For those performance sites listed as "Pending," you may not begin research activities until approval has been issued.**

Approval Component	Component Name	Status
Performance Site	UTSW	Approved
Performance Site	Children's	Not Applicable
Performance Site	Parkland	Pending
Performance Site	THR	Not Applicable
Coverage Analysis	Coverage Analysis	Not Required
Contract	Clinical Trial Agreement	CTA Not Required

If the study is sponsored, sponsor activation may be required before study activities may begin.

This exempt determination does not expire.

If changes are made to this research which may affect this determination, submit those changes to HRPP for review.

*Warning: This is a private message for authorized UT Southwestern employees only. If the reader of this message is not the intended recipient you are hereby notified that any dissemination, distribution or copying of this information is STRICTLY PROHIBITED.*

University of Texas Southwestern Medical Center  
 Institutional Review Board

5323 Harry Hines Boulevard  
 Dallas, Texas 75390-8843  
 phone: 214-648-3060  
 fax: 214-648-2171

# Early vs. Delayed Cholecystectomy for Perforated Cholecystitis

Please complete the survey below.

Thank you!

---

Enrolling Center

---

**Demographics**

Age \_\_\_\_\_

Sex  Male  
 Female

Height (cm) \_\_\_\_\_

Weight (kg) \_\_\_\_\_

BMI \_\_\_\_\_

Date of admission \_\_\_\_\_

Date of discharge \_\_\_\_\_

## Pre-existing Health Conditions Variables

Functional status	<input type="radio"/> Independent <input type="radio"/> Partially dependent <input type="radio"/> Totally dependent <input type="radio"/> Unknown
ASA Class	<input type="radio"/> ASA I - healthy patient <input type="radio"/> ASA II - mild systemic disease <input type="radio"/> ASA III - severe systemic disease <input type="radio"/> ASA IV - severe systemic disease/constant threat to life <input type="radio"/> ASA V - moribund/not expected to survive surgery
Pre-operative immunosuppressive use	<input type="radio"/> Yes <input type="radio"/> No
Ascites within 30 days prior to surgery	<input type="radio"/> Yes <input type="radio"/> No
Systemic sepsis within 48hr prior to surgery	<input type="radio"/> None <input type="radio"/> SIRS, sepsis, septic shock
Ventilator dependence	<input type="radio"/> Yes <input type="radio"/> No
Disseminated cancer	<input type="radio"/> Yes <input type="radio"/> No
DM	<input type="radio"/> None <input type="radio"/> Yes without insulin <input type="radio"/> Yes with insulin
HTN requiring medications	<input type="radio"/> Yes <input type="radio"/> No
CHF within 30 days prior to surgery	<input type="radio"/> Yes <input type="radio"/> No
Dyspnea	<input type="radio"/> None <input type="radio"/> With moderate exertion <input type="radio"/> At rest
Current smoker within 1 year	<input type="radio"/> Yes <input type="radio"/> No
Severe COPD	<input type="radio"/> Yes <input type="radio"/> No
Dialysis	<input type="radio"/> Yes <input type="radio"/> No
Acute renal failure	<input type="radio"/> Yes <input type="radio"/> No
Liver failure	<input type="radio"/> Yes <input type="radio"/> No

**Admission Lab Values**

Hgb \_\_\_\_\_

WBC \_\_\_\_\_

Platelet \_\_\_\_\_

INR \_\_\_\_\_

PTT \_\_\_\_\_

T-bili \_\_\_\_\_

Albumin \_\_\_\_\_

Na \_\_\_\_\_

Lactate \_\_\_\_\_

Cr \_\_\_\_\_

BUN \_\_\_\_\_

**US findings**

	Yes	No
Gallstones	<input type="radio"/>	<input type="radio"/>
Gallbladder wall thickening	<input type="radio"/>	<input type="radio"/>
Pericholecystic fluid	<input type="radio"/>	<input type="radio"/>
Gallbladder wall emphysema	<input type="radio"/>	<input type="radio"/>
CBD dilation	<input type="radio"/>	<input type="radio"/>

US Diagnosis of gallbladder perforation  Yes  
 No

**CT findings**

	Yes	No
Gallstones	<input type="radio"/>	<input type="radio"/>
Gallbladder wall thickening	<input type="radio"/>	<input type="radio"/>
Pericholecystic fluid	<input type="radio"/>	<input type="radio"/>
Gallbladder wall emphysema	<input type="radio"/>	<input type="radio"/>
CBD dilation	<input type="radio"/>	<input type="radio"/>

CT diagnosis of gallbladder perforation

- Yes
- No

**Management variables**

Cholecystectomy during index admission?  Yes  
 No

Procedures aside from cholecystectomy during index admission?  None  
 Cholecystostomy tube  
 Image guided percutaneous drain placement  
 ERCP  
 Others

Please specify the procedure if you selected "Others" above \_\_\_\_\_

Date of the operation or procedure \_\_\_\_\_

Number of days from admission to operation (please enter "N/A" if patient did not undergo cholecystectomy during the initial hospitalization): \_\_\_\_\_

Date of interval cholecystectomy, if performed \_\_\_\_\_



**Operative variables**

All operative procedures performed

---

Presence of free perforation during the operation?

- Yes
- No

Presence of contained perforation during the operation?

- Yes
- No

Presence of cholecystoenteric fistula during the operation?

- Yes
- No

Operative time (minutes)

---

Estimated blood loss (ml)

---

**Post-operative complications**

Length of total hospital stay

\_\_\_\_\_

Mortality

- Yes
- No

Date of death

\_\_\_\_\_

Unplanned operation?

- Yes
- No

Number of days from index operation or procedure to unplanned operation

\_\_\_\_\_

Diagnosis for unplanned operation

\_\_\_\_\_

All procedures performed during unplanned operation

\_\_\_\_\_

Post-operative procedure(s) excluding unplanned operations

- None
- Image guided percutaneous drain placement
- ERCP
- Cholecystostomy tube placement
- Others

Please specify the procedure if you selected "Others" above

\_\_\_\_\_

Complications Yes/No POD

Superficial wound infection \_\_\_\_\_

Deep wound infection \_\_\_\_\_

Organ space wound infection \_\_\_\_\_

Wound dehiscence \_\_\_\_\_

Pneumonia \_\_\_\_\_

Re-intubation \_\_\_\_\_

Fail to wean from the ventilator for > 48hr \_\_\_\_\_

Pulmonary embolism \_\_\_\_\_

DVT \_\_\_\_\_

Acute renal failure \_\_\_\_\_

UTI \_\_\_\_\_

CVA \_\_\_\_\_

Cardiac arrest \_\_\_\_\_

MI \_\_\_\_\_

Bleeding requiring intra-operative and/or post-operative transfusion within 48hours of operation \_\_\_\_\_

Post-operative sepsis/SIRS/septic shock \_\_\_\_\_

Post-operative ICU admission \_\_\_\_\_

ED visit within 30 days of initial hospitalization

- Yes
- No

Number of ED visits

\_\_\_\_\_

---

Diagnosis for ED visit

---

---

Re-admission within 30 days of initial hospitalization

- Yes
- No

---

Number of readmissions

---

---

Diagnosis for readmissions

---



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

**EAST MULTICENTER STUDY  
 DATA DICTIONARY**

**Multicenter Study:** Defining Outcomes of Early vs. Delayed Cholecystectomy for Perforated Cholecystitis

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
<b><u>Demographics:</u></b>	
Age	Age of the patient in years
Sex	Biological sex of the patient
Height	Height of the patient in centimeters
Weight	Weight of the patient in kilograms
BMI	Body mass index of the patient
Date of admission	Date on which the patient was admitted to the hospital in the format of mm/dd/yy
Date of discharge	Date on which the patient was discharged from the hospital in the format mm/dd/yy
<b><u>Pre-existing Health Conditions Variables:</u></b>	
Functional status	Functional health status prior to surgery, categorized as independent, partially dependent, totally dependent, or unknown
ASA class	The American Society of Anesthesiology Physical Status Classification, categorized as the following: <ul style="list-style-type: none"> <li>• ASA I - healthy patient</li> <li>• ASA II - mild systemic disease</li> <li>• ASA III - severe systemic disease</li> <li>• ASA IV - severe systemic disease/constant threat to life</li> <li>• ASA V - moribund/not expected to survive surgery</li> </ul>
Pre-operative immunosuppressive use	Immunosuppressive therapy use for chronic conditions prior to surgery
Systemic sepsis within 48 hr prior to surgery	Systemic inflammatory response syndrome, sepsis, or septic shock within 48 hours prior to surgery
Ascites within 30 days prior to surgery	History of ascites within 30 days prior to surgery noted on physical examination, abdominal ultrasound, or abdominal CT/MRI
Ventilator dependence	Patient requiring ventilator-assisted respiration at any time during 48 hours prior to surgery, excluding the treatment of sleep apnea with CPAP
Disseminated cancer	Diagnosis of primary cancer that has metastasized to a major organ with at least one of the following: <ul style="list-style-type: none"> <li>• Active treatment for the cancer within one year of the surgery date</li> </ul>

	<ul style="list-style-type: none"> <li>• Patient elected not to receive treatment for the metastatic disease</li> <li>• Patient's metastatic cancer has been deemed untreatable</li> </ul>
DM	Diagnosis of diabetes mellitus prior to surgery managed with daily oral hypoglycemic agents or exogenous insulin; enter "no" for diabetes controlled by diet alone
HTN requiring medication	Diagnosis of hypertension requiring antihypertensive medications within 30 days prior to surgery
CHF within 30 days prior to surgery	New diagnosis of congestive heart failure within 30 days prior to surgery or a diagnosis of chronic congestive heart failure with signs or symptoms in the 30 days prior to surgery
Dyspnea	The patient's dyspnea status when they were in their usual state of health, categorized as with moderate exertion or at rest
Current smoker within 1 year	The patient has smoked cigarettes in the year prior to admission for surgery, excluding those who smoke cigars, pipes or use chewing tobacco
Severe COPD	Diagnosis of severe chronic obstructive pulmonary disease resulting in one of the following: <ul style="list-style-type: none"> <li>• Functional disability from COPD (for example, dyspnea, inability to perform ADLs)</li> <li>• Hospitalization in the past for treatment of COPD</li> <li>• Chronic bronchodilator therapy with oral or inhaled agents</li> <li>• FEV1 of &lt;75% of predicted</li> </ul>
Dialysis	Requiring peritoneal dialysis, hemodialysis, hemofiltration, hemodiafiltration, or ultrafiltration within 2 weeks prior to surgery; enter "yes" if the patient requires dialysis but refuses it
Acute renal failure	Rapid decline of kidney function with at least one of the following: <ul style="list-style-type: none"> <li>• Increased BUN on two measurements AND two Cr results &gt; 3mg/dl</li> <li>• Surgeon or physician has documented Acute Renal Failure AND one of the following: <ul style="list-style-type: none"> <li>○ Increased BUN on two measurements</li> <li>○ Two Cr results &gt; 3mg/dl</li> </ul> </li> </ul>
Liver failure	Surgeon or physician documented liver failure or documented Child-Pugh class B or C
<b><u>Admission Lab Values:</u></b>	
Hgb	Hemoglobin (g/dL)
WBC	White blood cell (x 10 <sup>9</sup> /L)
Platelet	Platelet (x 10 <sup>9</sup> /L)
INR	International normalized ratio
PTT	Partial thromboplastin time (seconds)
Tbili	Total bilirubin (mg/dL)
Albumin	Albumin (g/dL)
Na	Sodium (mEq/L)
Lactate	Lactate (mmol/L)
Cr	Creatinine (mg/dL)
BUN	Blood urea nitrogen (mg/dL)
<b><u>Imaging Findings:</u></b>	
US diagnosis of gallbladder perforation	Identification gallbladder perforation and associated signs, such as pericholecystic complex fluid collections or abscess, gallbladder wall disruption or discontinuity on ultrasound

CT diagnosis of gallbladder perforation	Identification gallbladder perforation and associated signs, such as pericholecystic complex fluid collections or abscess, gallbladder wall disruption or discontinuity on computed tomography
Gallstones	Identification of the presence of gallstones on imaging
Gallbladder wall thickening	Identification of gallbladder wall thickening on imaging defined as by > 3mm
Pericholecystic fluid	Identification of fluid that surrounds the gallbladder on imaging
Gallbladder wall emphysema	Identification of gas in the lumen or in the wall of the gallbladder on imaging
CBD dilation	Identification of common bile duct dilation with a diameter of > 6mm on imaging
<b><u>Management Variables:</u></b>	
Cholecystectomy during index admission	Patient underwent laparoscopic, robotic-assisted-laparoscopic, or open cholecystectomy during the same admission, during which they were diagnosed with gallbladder perforation
Procedures aside from cholecystectomy during index admission	Patient underwent procedures that did not require general anesthesia, including but not limited to cholecystostomy tube placement, percutaneous drain placement, ERCP, during the same admission, during which they were diagnosed with gallbladder perforation
Cholecystostomy tube	Percutaneous cholecystostomy tube placement
Image guided percutaneous drain placement	Image guided percutaneous drain placement for intra-abdominal fluid collections other than cholecystostomy tube
ERCP	Endoscopic retrograde cholangiopancreatography
Date of operation or procedure	Date on which the patient underwent laparoscopic, robotic-assisted-laparoscopic, or open cholecystectomy, or other procedures; enter "N/A" if the patient did not undergo cholecystectomy or any other procedures during the initial hospitalization
Number of days from admission to operation	Number of days from admission to operation; enter "0" if the patient underwent an operation the same day as admission; enter "N/A" if the patient did not undergo cholecystectomy during the initial hospitalization
Date of interval cholecystectomy	Date of laparoscopic, robotic-assisted-laparoscopic or open cholecystectomy performed during an admission later than the admission during which the patient was diagnosed with gallbladder perforation (mm/dd/yy), enter "N/A" if the patient did not undergo an operation during an admission later than the index admission
<b><u>Operative variables:</u></b>	
All operative procedures performed	All operative procedures associated with a CPT code that were performed during the definitive operation for gallbladder perforation, including both index and interval operations; enter "N/A" if none
Free perforation	Intraoperative finding of free intraperitoneal fluid corresponding to bile
Contained perforation	Intraoperative finding of pericholecystic abscess or fluid collection walled off by adhesions from the general peritoneal cavity
Fistula	Intraoperative finding of a fistulous communication between the gallbladder and other viscus organ
Operative time	Total length of time for the operation (minutes)
<b><u>Post-operative complications:</u></b>	

Length of total hospital stay	Length of total hospital stay during the initial admission when the patient was diagnosed with gallbladder perforation
Mortality	Death of a patient for any reason within 30 days of either the index or interval cholecystectomy
Unplanned operations	Unplanned return to the operating room for reoperation that is related to a complication of laparoscopic, robotic-assisted-laparoscopic, or open cholecystectomy, or related to a complication of a procedure the patient underwent (e.g., cholecystostomy tube placement, percutaneous drain placement, or ERCP)
Number of days from index operation or procedure to unplanned operation	Number of days from the operation of laparoscopic, robotic-assisted-laparoscopic, or open cholecystectomy, or any procedures to the unplanned operation or re-operation
Diagnosis for unplanned operation	Post-operative diagnosis for unplanned operation or unplanned return to the operating room
All procedures performed during unplanned operation	All procedures performed, associated with a CPT code, during the unplanned operation or unplanned return to the operating room
Post-operative procedure(s) excluding unplanned operation	Unplanned procedures related to a complication of the index operation, that did not require general anesthesia, including but not limited to cholecystostomy tube placement, image guided percutaneous drain placement, ERCP
Superficial wound infection	Infection that occurs within 30 days after the operation involving only the skin or subcutaneous tissue of the incision
Deep wound infection	Infection that occurs within 30 days after the operation involving deep soft tissue (e.g., fascial and muscle layers) of the incision
Organ space wound infection	Infection that occurs within 30 days after the operation involving any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation
Wound dehiscence	Separation of the layers of a surgical wound, which may be partial or complete, with disruption of the fascia within 30 days of the operation
Pneumonia	Inflammation of the lungs caused by bacteria, viruses, and/or chemical irritants within 30 days of the operation; must meet one of the following two criteria: <ul style="list-style-type: none"> <li>• Rales or dullness to percussion on physical examination of chest AND any of the following: a. new onset of purulent sputum or change in character of sputum b. organism isolated from blood culture c. isolation of pathogen from specimen obtained by transtracheal aspirate, bronchial brushing, or biopsy</li> <li>• Chest radiographic examination shows new or progressive infiltrate, consolidation, cavitation, or pleural effusion AND any of the following: a. new onset of purulent sputum or change in character of sputum b. organism isolated from blood culture c. isolation of pathogen from specimen obtained by transtracheal aspirate, bronchial brushing, or biopsy d. isolation of virus or detection of viral antigen in respiratory secretions e. diagnostic single antibody titer (IgM) or fourfold increase in paired serum samples (IgG) for pathogen f. histopathologic evidence of pneumonia</li> </ul>
Re-intubation	Placement of an endotracheal tube and mechanical or assisted ventilation because of the onset of respiratory or cardiac failure within 30 days of the operation after the patient has been extubated after the surgery; In patients who were not intubated during surgery, intubation at any time after their surgery is considered unplanned.
Fail to wean from the ventilator for > 48hr	Total duration of ventilator-assisted respirations during postoperative hospitalization was greater than 48 hours. This can occur at any time

	during the 30-day period postoperatively. Time assessment is cumulative, not consecutive
Pulmonary embolism	Lodging of a blood clot in a pulmonary artery with subsequent obstruction of blood supply to the lung parenchyma within 30 days of the operation
DVT	The identification of a new blood clot or thrombus within the venous system, which may be coupled with inflammation within 30 days of the operation
Acute renal failure	In a patient who did not require dialysis preoperatively, worsening of renal dysfunction postoperatively requiring hemodialysis, peritoneal dialysis, hemofiltration, hemodiafiltration, or ultrafiltration within 30 days of the operation.
UTI	Postoperative symptomatic urinary tract infection must meet one of the following TWO criteria within 30 days of the operation: <ul style="list-style-type: none"> <li>• One of the following: fever, urgency, frequency, dysuria, suprapubic tenderness</li> <li>• Any of the following: dipstick test positive for leukocyte esterase and/or nitrate, pyuria (&gt;10 WBCs/cc or &gt; 3 WBC/hpf of unspun urine), organisms seen on Gram stain of unspun urine, two urine cultures with repeated isolation of the same uropathogen with &gt;102 colonies/ml urine in non-voided specimen</li> </ul>
CVA	Embolic, thrombotic, or hemorrhagic vascular accident or stroke with motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) that persists for 24 or more hours within 30 days of the operation.
Cardiac arrest	The absence of cardiac rhythm or presence of chaotic cardiac rhythm that results in loss of consciousness requiring the initiation of any component of basic and/or advanced cardiac life support within 30 days of the operation.
MI	A new transmural acute myocardial infarction occurring during surgery or within 30 days as manifested by new Q-waves on ECG.
Bleeding requiring intra-operative and/or post-operative transfusion within 48hours of operation	Any transfusion (including autologous) of packed red blood cells or whole blood given from the time the patient leaves the operating room up to and including 72 hours postoperatively
Post-operative sepsis/SIRS/septic shock	Clinical signs and symptoms of SIRS or sepsis, with or without documented organ and/or circulatory dysfunction; with positive blood culture, clinical documentation of purulence or positive culture from any site thought to be causative within 30 days of the operation.
Post-operative ICU admission	Post-operative admission to the ICU within 30 days of the operation for any reason
ED visit	Presentation to the emergency department for any reason within 30 days of the initial admission during which the patient was diagnosed with gallbladder perforation
Re-admission	Unexpected re-admission to the hospital from the clinic or emergency department for any reason within 30 days of the initial admission during which the patient was diagnosed with gallbladder perforation
POD#	Post-operative day, with the day of the operation as day 0