



**EAST MULTICENTER STUDY  
DATA DICTIONARY**

Current Management of Suspected Retained Common Bile Duct Stones in  
Gallstone Pancreatitis and Choledocholithiasis

Data Entry Points and appropriate definitions / clarifications:

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Entry space	Definition / Instructions
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**Demographics:**

Admit Date	Admission date of the patient enrolled
Admit Time	Admission time of the patient enrolled
Discharge Date	Discharge date of the patient enrolled
Age	Age of patient enrolled
Gender	Gender of Patient enrolled
Preoperative Diagnosis	Diagnosis of the patient at time of admission (Select single best choice for description of diagnosis: CDL = choledocholithiasis; GSP = Gallstone pancreatitis)

**Pre-hospital comorbidities (check all that apply):**

Hypertension	Abnormally high blood pressure
Diabetes mellitus	A long-term metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin
Peripheral vascular disease	A circulation disorder characterized by narrowing or blockage of blood vessels
Coronary artery disease	An impedance or blockage of one or more blood vessels that supplies blood to the heart
Current smoker	If patient is an active smoker at the time of initial presentation, check yes
Alcohol abuse	A pattern of drinking that results in harm to one's health, interpersonal relationships, or ability to work
Substance abuse	The harmful or hazardous use of psychoactive

substances, including illicit drugs

### **Admission Physiology**

Temperature

Temperature at the time of presentation

Initial HR

Heart rate at the time of presentation

Initial SBP

Systolic blood pressure at the time of presentation

### **Admission Lab Values**

WBC

Indicate date and time admission labs were collected:

Admission White Blood Cell Count (K/mcL)

HGB

Admission Hemoglobin (g/dL)

T. Bili

Admission Total Serum Bilirubin (mg/dL)

D. Bili

Admission Direct Serum Bilirubin (mg/dL)

AST (SGOT)

Admission Aspartate transaminase (U/L)

ALT (SGPT)

Admission Alanine transaminase (U/L)

ALP

Admission Alkaline Phosphatase (U/L)

### **Repeat Lab values:**

Indicate date and time first set of **repeat** labs were collected:

WBC

Repeat White Blood Cell Count (K/mcL)

HGB

Repeat Hemoglobin (g/dL)

T. Bili

Repeat Total Serum Bilirubin (mg/dL)

D. Bili

Repeat Direct Serum Bilirubin (mg/dL)

AST (SGOT)

Repeat Aspartate transaminase (U/L)

ALT (SGPT)

Repeat Alanine transaminase (U/L)

ALP

Repeat Alkaline Phosphatase (U/L)

### **Management Variables**

#### **Preoperative Procedures:**

Preoperative Ultrasound

Check if right upper quadrant ultrasound was performed preoperatively. Indicate date and time procedure was performed. Check off ultrasound findings such as presence of gallstones, pericholecystic fluid, gallbladder wall thickening. Indicate the diameter of the CBD in millimeters. Indicate whether stones were visualized in the common bile duct. Free text other findings

Preoperative ERCP

Check if Endoscopic Retrograde Cholangiopancreatography (endoscopic cannulation of the common bile duct with a side-viewing endoscope and a retrograde contrast injection) was performed prior to cholecystectomy. Indicate date and time procedure was performed. Indicate whether CBD stones were seen. Free text other findings ONLY if preoperative ERCP was performed. Leave blank if none performed

Preoperative MRCP

Check if Magnetic Resonance Cholangiopancreatography (non-invasive medical imaging technique) was performed prior to cholecystectomy. Indicate the date and time the procedure was performed. Indicate whether CBD stones were seen. Free text other findings ONLY if preoperative MRCP was performed, otherwise leave blank

Preoperative EUS

Check here if Endoscopic ultrasound was done prior to cholecystectomy. Include the date and time that it was performed. Indicate if stones were

visualized in the CBD. Free text any other findings ONLY if preoperative endoscopic ultrasound was performed, otherwise leave blank

Operative Procedures

Check off type of cholecystectomy that was performed (i.e. laparoscopic, open, laparoscopic converted to open, partial cholecystectomy)

IOC  
Intraoperative ERCP  
Intraoperative EUS

Check off if IOC (Intraoperative cholangiogram), intraoperative ERCP or intraoperative EUS were performed. Indicate whether CBD stones were visualized. Free text any other findings

Postoperative Procedures:

Check off any postoperative procedures that were performed (ERCP or MRCP). Indicate the date and time that they were performed. Indicate whether CBD stones were visualized. Free text any other findings ONLY if that postoperative procedure was performed, otherwise leave blank

Antibiotic use:

Type of antibiotics

Free text entry for specific type of antibiotic initiated  
Generic or trade-name acceptable

Duration of antibiotic

Number of days antibiotic was used

**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 (Day of admission = hospital day #1)

Mortality

Indicated if patient expired during initial hospitalization

Complications (check all that apply):

Superficial Incisional SSI

Check if applies. SSI = Surgical Site infection. Indicate location of infection and date it was discovered. Definition below

Superficial Incisional SSI: Infection occurs within 30 days after the operation and infection involves only skin and subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage with or without laboratory confirmation, from the superficial incision
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative
4. Diagnosis of superficial incisional SSI made by a surgeon or attending physician



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

ARDS Check if applies. ARDS = Acute respiratory distress syndrome. Indicate date diagnosed  
Definition below

ARDS: Berlin definition will be utilized

- Mild ARDS: 201 - 300 mmHg ( $\leq$  39.9 kPa)
- Moderate ARDS: 101 - 200 mmHg ( $\leq$  26.6 kPa)
- Severe ARDS:  $\leq$  100 mmHg ( $\leq$  13.3 kPa)
- New onset of bilateral infiltrates (patchy, diffuse, or homogenous) consistent with pulmonary edema
- No clinical evidence of left atrial hypertension

AKI Check if applies. AKI = Acute kidney injury; indicate date diagnosed. Defined for the purpose of this study as elevation of serum creatinine greater or equal to 2.0 mg/dL during hospitalization in patient without antecedent renal dysfunction

DVT/PE: Check if applies. DVT/PE = Deep vein thrombosis/Pulmonary embolus; indicate date diagnosed

Myocardial infarction (MI) Check if applies. Indicate date diagnosed. Definition below.

Myocardial infarction: detection of 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

Congestive heart failure (CHF) Check if applies. Indicate date diagnosed. Heart failure in which the heart is unable to maintain adequate circulation of blood in the bodily tissues or to pump out the venous blood returned

Readmission within 30 days Check if applies. Indicate date and reason for readmission.

Reoperation within 30 days Check if applies. Indicate date and reason for reoperation. Free text type of reoperation performed

Other secondary intervention Free text any other interventions performed related to CDL or GSP



**EAST MULTICENTER STUDY  
DATA COLLECTION TOOL**

**Multicenter Study:** Current Management of Retained Common Bile Duct Stones in Gallstone Pancreatitis and Cholelithiasis

Enrolling Center: \_\_\_\_\_  
Enrolling Co-investigator: \_\_\_\_\_

**Demographic Information:**

Admit Date: \_\_\_\_\_ Admit Time: \_\_\_\_\_ Discharge Date: \_\_\_\_\_

Age: \_\_\_\_\_ Gender: \_\_\_\_\_

Preoperative Diagnosis (circle one): CDL vs. GSP

Pre-hospital comorbidities (check all that apply):

Hypertension: \_\_\_\_\_  
Diabetes mellitus: \_\_\_\_\_  
Peripheral vascular disease: \_\_\_\_\_  
Coronary artery disease: \_\_\_\_\_  
Current smoker: \_\_\_\_\_  
Alcohol abuse: \_\_\_\_\_  
Substance abuse: \_\_\_\_\_

**Admission Physiology:**

Temperature: \_\_\_\_\_ HR: \_\_\_\_\_ BP: \_\_\_\_\_

Admission Lab values: Date/Time Collected: \_\_\_\_\_

WBC: \_\_\_\_\_  
Hgb: \_\_\_\_\_  
Tbili: \_\_\_\_\_  
Dbili: \_\_\_\_\_  
ALP: \_\_\_\_\_  
AST: \_\_\_\_\_  
ALT: \_\_\_\_\_

Repeat Lab values: Date/Time Collected: \_\_\_\_\_

WBC: \_\_\_\_\_  
Hgb: \_\_\_\_\_  
Tbili: \_\_\_\_\_  
Dbili: \_\_\_\_\_

ALP: \_\_\_\_\_  
AST: \_\_\_\_\_  
ALT: \_\_\_\_\_

**Management Variables:**

Preoperative Procedures (Check all that apply):

Preoperative Ultrasound (Y/N): \_\_\_\_\_ Date/Time: \_\_\_\_\_  
Cholelithiasis (Y/N): \_\_\_\_\_  
Pericholecystic  
Fluid (Y/N): \_\_\_\_\_  
Wall thickening (Y/N): \_\_\_\_\_  
CBD Diameter: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Preoperative ERCP: \_\_\_\_\_ Date/Time: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Preoperative MRCP: \_\_\_\_\_ Date/Time: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Preoperative EUS: \_\_\_\_\_ Date/Time: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Operative Procedures (Check all that apply):

Date/Time of Operation: \_\_\_\_\_  
Laparoscopic cholecystectomy: \_\_\_\_\_  
Open cholecystectomy: \_\_\_\_\_  
Lap converted to open: \_\_\_\_\_  
Partial cholecystectomy: \_\_\_\_\_

IOC: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Intraoperative ERCP: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Intraoperative EUS: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Postoperative Procedures (Check all that apply):

Postoperative ERCP: \_\_\_\_\_ Date/Time: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_  
Other findings: \_\_\_\_\_

Postoperative MRCP: \_\_\_\_\_ Date/Time: \_\_\_\_\_  
CBD stones (Y/N): \_\_\_\_\_

Other findings: \_\_\_\_\_

**Antibiotic use:**

Type: \_\_\_\_\_ Duration: \_\_\_\_\_  
Type: \_\_\_\_\_ Duration: \_\_\_\_\_  
Type: \_\_\_\_\_ Duration: \_\_\_\_\_  
Type: \_\_\_\_\_ Duration: \_\_\_\_\_

**Outcomes:**

Hospital LOS: \_\_\_\_\_ ICU LOS: \_\_\_\_\_  
Ventilator Days: \_\_\_\_\_ Mortality (circle one): YES / NO  
Disposition: \_\_\_\_\_

**Complications (check all that apply):**

Superficial SSI: \_\_\_\_\_ Date: \_\_\_\_\_  
    Location: \_\_\_\_\_  
Deep SSI: \_\_\_\_\_ Date: \_\_\_\_\_  
    Type: \_\_\_\_\_  
    Location: \_\_\_\_\_  
Bleeding: \_\_\_\_\_ Date: \_\_\_\_\_  
Bile leak: \_\_\_\_\_ Date: \_\_\_\_\_  
Retained stones: \_\_\_\_\_ Date: \_\_\_\_\_  
Shock: \_\_\_\_\_ Date: \_\_\_\_\_  
HAP: \_\_\_\_\_ Date: \_\_\_\_\_  
ARDS: \_\_\_\_\_ Date: \_\_\_\_\_  
AKI: \_\_\_\_\_ Date: \_\_\_\_\_  
DVT/PE: \_\_\_\_\_ Date: \_\_\_\_\_  
Myocardial Infarction: \_\_\_\_\_ Date: \_\_\_\_\_  
Congestive heart failure: \_\_\_\_\_ Date: \_\_\_\_\_  
Readmission within 30 days: \_\_\_\_\_ Date: \_\_\_\_\_  
    Reason for readmission: \_\_\_\_\_  
Reoperation within 30 days: \_\_\_\_\_ Date: \_\_\_\_\_  
    Reason for reoperation: \_\_\_\_\_  
Other secondary intervention: \_\_\_\_\_ Date: \_\_\_\_\_  
    Type: \_\_\_\_\_  
    Reason: \_\_\_\_\_