GENERAL INFORMATION

Study Title:
Prospective Multi-Institutional Evaluation of the of Cholecystostomy

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BACKGROUND AND SIGNIFICANCE

Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined:
Biliary diseases are among the most frequently encountered general surgery conditions. The spectrum of
disease is broad. There has been much focus recently on the acute management of patient with biliary colic and
acute cholecystitis and the trend has been toward earlier intervention. Yet, patients who are frail or acutely
critically ill are often managed with cholecystostomy. There are few studies available that describe the indications
and management of patients with cholecystostomy. The published literature is largely retrospective case series of
relatively few patients and largely reflects single institution experience. From these studies it is clear that there is
no standard in management of these complicated patients; some patients initially treated with cholecystostomy
may undergo cholecystectomy during the same admission, while others are managed with cholecystostomy
indefinitely.

The aim of this study is largely descriptive; defining the clinical burden, indications, and management of
cholecystostomy. As there is no standard of care, the information gained will be the foundation upon which to
design future studies.

The specific aims of this multicenter study are:
Primary aim:
Primary aim should be succinctly stated here – single sentence ideal:
Understand common indications for cholecystostomy, and what factors determine management once placed.

Secondary aims:
Any secondary aims should be stated here:
Define a safe, and potentially cost effective treatment algorithm for the management of patients with
cholecystostomy based on indication for placement.
**EXPERIMENTAL DESIGN/METHODS**

**Inclusion Criteria:**
Patients with acute calculous cholecystitis as defined by Tokyo guidelines who are treated with cholecystostomy

**Exclusion Criteria:**
Patients under the age of 18 year old.
Patients with acalculous cholecystitis.
Patients with biliary or pancreatic malignancy.
Patients with biliary tract obstruction.
Patients with pancreatitis

**Therapeutic Interventions:**
This study is a prospective observational study only and will be managed by the treating physician’s discretion

**Outcomes Measures:**

**Primary Outcome:**
(List here)

Indication
Management plan
Time to cholecystostomy tube exchange, removal, or surgery

**Secondary Outcomes:**
Number of interventions
Management related morbidity, and mortality
re-admissions
Outcome at 1 year
Variables:
List the specific variables to be collected and analyzed here. For organization, it is useful to divide these into categories for consideration. Examples of categories might include: Demographics, Admission physiology, Management variables, Surgical variables, Outcomes

Demographics
- Age, gender, race
- Days from admission
- Days of symptoms

Comorbid conditions
- ASA class
- Immunosuppression, CAD, CHF, AKI, CKD, Diabetes, cancer, COPD
- Previous history of biliary complaints
- Previous admissions/ED presentations for biliary disease

Physiology at time of cholecystostomy
- Vital signs (temp, HR, RR, BP)
- Ventilator
- Vasopressor drugs and dose
- Labs (HCT, WBC, Plt, ALT, AST, Total bilirubin, direct bilirubin, Lipase, Cr, Lactate, pH)

Pre-intervention testing
- US
  - Presence of stones, wall thickness, pericholecystic fluid
  - CBD stones
  - CBD dilation
- HIDA
  - Nonfilling of gallbladder
  - Dyskinesia
  - Biliary obstruction
- EUS
  - Choledocolithiasis
- MRCP
- CT

Management variables
- Presence of gallstones
- Cholangiogram
  - Days from cholecystostomy to cholangiogram
  - Impact on management
- Cholecystostomy removal without cholecystectomy
- Cholecystectomy (lap vs open vs lap to open)
- Cholecystostomy exchange

Outcomes
- Mortality at 1 year
- Management at 1 year
- Admissions/ED visits related to biliary disease after cholecystostomy
- Days with cholecystostomy
- Operative morbidity (enterotomy, abscess, leak, bleeding, etc)
- Cholecystostomy morbidity (tube dislodgement, bleeding, abscess, etc)
Data Collection and Statistical Analysis:
Outline the data collection plan and statistical analysis plan succinctly here

An example might include:

- Standardized data will be collected for each patient (see data sheet, Appendix A). Risk factors for failure to achieve primary closure of the open abdomen will be assessed using univariate and multivariate analysis.
- Continuous variables will be compared using Student’s t-test and the Mann Whitney U test. The Chi-squared tests or Fisher’s exact test will be used to compare categorical variables. All variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for failure to achieve primary fascial closure and development of complications. Data will be reported as adjusted odds ratios with 95 % confidence intervals. Statistical significance will be set at a p<0.05.

Data will be collected for each patient
A research coordinator will be responsible for communicating with other sites, and maintaining the database
Statistical analysis will be performed by a statistician
Continuous variables will be compared using the Student’s t-test
Categorical variables will be compared using the Fisher’s exact test

Consent Procedures:
Outline consent procedures here, if applicable. As an example for a prospective study where waiver of consent will be sought, verbiage might include:

“This is a prospective observational study, designed to prospectively record data on patients who are managed according to institutional patient management protocols. Thus, waiver of informed consent is requested. Data will be recorded on a data sheet and transferred to a secured database that is devoid of patient identifiers.”

This is a prospective observational study, designed to define the current practice. Consent will be obtained from the patient or surrogate during the index admission. Data collections sheets will be devoid of patient identifiers.
Risk/ Benefit Analysis:
Succinctly outline a risk / benefit analysis. An example of this might include:

“The incidence and natural history DISEASE PROCESS TO BE STUDIED is unknown. If the optimal timing for and type of intervention can be identified to optimize outcomes in these patients, then significant benefit will result.”

There is no standard indication for the placement, or the management of, cholecystostomy. Defining indications and management algorithms will improve the care of patients with biliary diseases.

Instructions for submitting data collection tools:
All data submissions should be entered through the EAST Multicenter Trial Taskforce website portal. Instructions can be found on the EAST website. The data collection sheet located under the Multicenter Trial Taskforce heading for this study can be utilized to record the data, and then the information transferred to the portal entry system. For any questions regarding this study, please contact the PI.
References:

Include a brief listing of key references here: