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Validating a tool to predict switch to open surgery in laparoscopic treatment for acute gallbladder inflammation: insights from multiple centers

Submission date
10/05/2024

Recruitment status
No longer recruiting

Registration date
17/05/2024

Overall study status
Completed

Last Edited
17/05/2024

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study investigates risk factors associated with conversion from early laparoscopic cholecystectomy (ELC) to open cholecystectomy in patients diagnosed with acute calculous cholecystitis (ACC). The primary objective is to develop and externally validate a predictive model based on the study research data.

Who can participate?
Adult patients with a first-time diagnosis of ACC undergoing early laparoscopic cholecystectomy within 7 days of illness onset, according to the Tokyo Guidelines 2018 (TG18) criteria, in eight medical centers in China

What does the study involve?
This study involves demographic characteristics, corresponding physical examination findings, serum biomarkers, transabdominal ultrasound measurements, disease severity grading, and surgical data of the acute calculous cholecystitis patients who performed early laparoscopic cholecystectomy. These data will be collected from the medical records of Huadu District People' s Hospital of Guangzhou.

What are the possible benefits and risks of participating?
This study will aid in identifying patients at higher risk of conversion, allowing surgeons to tailor surgical approaches and optimize patient outcomes.

This study is a retrospective research and did not involve intervening in the treatment of patients. The possible risk is the security and confidentiality issues of patient information. During the research process, to protect the patient's privacy rights, all of the patients' personal identity information was removed.

Where is the study run from?
Huadu District People's Hospital of Guangzhou (China)

When is the study starting and how long is it expected to run for?
January 2019 to June 2022

Who is funding the study?
1. The Internal Medicine Research Fund of Huadu District People's Hospital of Guangzhou (China)
2. The Construction of Major Subject of Huadu District People's Hospital of Guangzhou (China)

Who is the main contact?
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Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2019050, 2019A01, YNZDXK202201

Study information

Scientific Title
Multicenter external validation of a nomogram predicting conversion to open cholecystectomy during laparoscopic surgery for acute calculous cholecystitis: a cross-sectional study

Study objectives
Risk factors associated with conversion from early laparoscopic cholecystectomy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/04/2019, Ethics Committee of Huadu District People's Hospital of Guangzhou (48, Xinhua Road, Huadu District, Guangzhou, 510800, China; +86 020-62935386; rykjk@126.com), ref: 35

Primary study design
Observational

Study design
Multicenter cross-sectional study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Acute calculous cholecystitis who underwent early laparoscopic cholecystectomy

Interventions
This is a retrospective observational study, the study does not intentionally intervene in the patient's treatment measures. This study mainly involved the exposure factor - Acute calculous cholecystitis patients who performed early laparoscopic cholecystectomy transfer or without transfer to an open operation. All of the observation indicators were obtained during the same hospitalization period.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Demographic characteristics, such as gender, age, body mass index (BMI), hypertension status, diabetes mellitus, chronic obstructive pulmonary disease (COPD) status, and history of abdominal surgery, measured using data obtained from the Electronic Medical Record System of Huadu District People’s Hospital of Guangzhou at one time point

Key secondary outcome(s)
1. White blood cell (WBC) count, C-reactive protein (CRP), procalcitonin (PCT), platelet count, creatinine, international normalized ratio (INR), alanine aminotransferase (ALT), and aspartate aminotransferase (AST), measured using laboratory examinations of blood and with a biochemical analyzer within 24 hours of the patient's onset of illness
2. Transabdominal ultrasound characteristics included gallbladder wall thickness, length and width, number of calculi (single or multiple), calculus location (gallbladder body or neck), calculus diameter (≥3cm or <3cm), presence of gallbladder polyps, and pericholecystic effusion, measured using imaging examination with ultrasound machine within 24 hours of the patient's onset of illness

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. A first-time diagnosis of acute calculous cholecystitis confirmed by the presence of fever and /or chills, laboratory evidence of inflammation and/or abnormal liver function, and imaging confirmation of gall bladder calculus
2. Patients who underwent early laparoscopic cholecystectomy within 7 days of illness onset, according to the Tokyo Guidelines 2018 (TG18) criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
3191

Key exclusion criteria
1. Patients with chronic cholecystitis
2. Acute calculous cholecystitis complicated by acute pancreatitis
3. Non-calculous acute cholecystitis, or choledocholithiasis requiring simultaneous choledocholithotomy and T-tube drainage during laparoscopic cholecystectomy

Date of first enrolment
01/10/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
China

Study participating centre
Huadu District People’s Hospital of Guangzhou
-
-
China
-

Sponsor information

Organisation
Huadu District People’s Hospital of Guangzhou

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Internal Medicine Research Fund from Huadu District People's Hospital of Guangzhou

Funder Name
Construction of Major Subject of Huadu District People's Hospital of Guangzhou

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Hongsheng Wu, crazywu2007@126.com (China). The datasets and the analysis R code of this study are available.

IPD sharing plan summary

Available on request