

DIGESTIVO CHN-VBP

EVALUATION OF THE APPLICABILITY AND
EFFECTIVENESS OF A PROTOCOL FOR THE
MULTIDISCIPLINARY MANAGEMENT OF ACUTE
CHOLECYSTITIS

v.1.0 - 28.09.2020

BRIEF SUMMARY

Acute cholecystitis is a complex disease and its management is sometimes controversial. Two main factors contribute to its complexity: the patient's surgical risk and the possibility of concomitant choledocholithiasis. The design of a multidisciplinary protocol between the services of Gastroenterology and Surgery aims to harmonize its management and to adapt it to the most recent guidelines. As it concerns more than one department, it is crucial to analyze its compliance and effectiveness.

Adult patients attending the emergency department and diagnosed with acute cholecystitis will be asked to participate. Those considered not suitable for surgery will be admitted in a medical department and assigned to conservative treatment or cholecystostomy, according to their acute cholecystitis severity. In patients suitable for surgery, risk of concomitant choledocholithiasis will be assessed and patients will be assigned to low risk or intermediate-high risk. The latter will be admitted in a medical department, and choledocholithiasis will be ruled out and treated if present. The former will be offered cholecystectomy or cholecystostomy according to their surgical risk and acute cholecystitis severity. A flowchart with extended information is attached.

PRIMARY OBJECTIVES

- To harmonize the management of acute cholecystitis with a multidisciplinary protocol based on the most recent guidelines.

SECONDARY OBJECTIVES

- To analyze the compliance with this protocol.
- To evaluate the validity of the criteria used in the decision-making process.
- To assess the morbidity and mortality of different groups of patients according to the selected treatment, severity of cholecystitis and baseline characteristics of the patient.
- To estimate the resource use in each group of patients.
- To compare current data with a previous period.
- To adapt and modify the protocol according the study results.

INCLUSION CRITERIA

- Patients aged 18 or older who agree to participate (an informed consent signature is required)
- Patients attended in the emergency department of our hospital and diagnosed with acute cholecystitis according to the Tokyo criteria.

EXCLUSION CRITERIA

- Patients under 18 years or patients who refuse to participate in the study
- Patients diagnosed with acute cholangitis during admission for other causes.

STUDY DESIGN

Observational , prospective study

Enrollment: 600

Number of Groups/Cohorts: 4

Groups and Interventions

Groups/Cohorts Interventions

All patients attended in the Emergency Department of our Hospital with possible acute cholecystitis (AC) will be evaluated by the surgical team. Once the diagnosis is confirmed, they must establish whether the patient is suitable or not for surgery (based on the presence of serious comorbidities).

- Patients unfit for Surgery: check the AC severity according to the Tokyo Guidelines. Admission in a Medical Department (Gastroenterology or Geriatric Medicine)
 - Mild-moderate acute cholecystitis: conservative treatment (antibiotics, etc). Endoscopic Ultrasound (EUS)-guided gallbladder drainage will be considered in recurrent acute cholecystitis and in patients with no improvement in 48-72h after admission.
 - Severe acute cholecystitis: percutaneous cholecystostomy or EUS-guided cholecystostomy (the latter is not 24/7 available). Palliative care may also be considered in patients with very serious conditions and low life expectancy.
- Patients suitable for Surgery: assess the risk of concomitant choledocholithiasis with laboratory and abdominal ultrasound (see below).
 - High and intermediate risk: admission in Gastroenterology Department. Antibiotic treatment. Close follow-up of possible AC complications. Once choledocholithiasis is solved or ruled out, the patient will be considered for same-admission cholecystectomy or programmed cholecystectomy.
 - High risk: Endoscopic Retrograde Cholangiopancreatography (ERCP) will be performed.
 - Intermediate risk: EUS or Magnetic Resonance Cholangiopancreatography prior to consider ERCP.

- Low risk: admission in Surgery Department. According to the AC severity:
 - Mild-moderate AC: check de ASA/ Charlson comorbidity index.
 - ASA I-II/Charlson <6: laparoscopic cholecystectomy
 - ASA ≥III/Charlson ≥6: close follow-up 24-48h. Consider laparoscopic cholecystectomy (first choice) or percutaneous cholecystostomy (if no improvement is achieved).
 - Severe AC: consider Intensive Care Unit admission. Percutaneous cholecystectomy.

Concomitant choledocholithiasis risk assessment:

- High and moderate risk is defined as the presence of at least one of these conditions:
 - Acute cholangitis
 - Choledocholithiasis seen on abdominal ultrasound
 - Total Bilirubin level ≥4 mg/dL
 - Common bile duct diameter >6 mm
- Low risk: none of them.

OUTCOME MEASURES

Primary Outcome Measure:

1. Inclusion rate: Rate of patients with AC diagnosis registered in the study.
2. Protocol compliance: rate of patients with complete protocol compliance.
3. Morbidity and mortality in the different subtypes of patients: length of hospital stay, need for unplanned readmissions, recurrent cholecystitis, 90-day disease-specific mortality

Secondary Outcome Measure:

4. Identify causes of protocol compliance failure.
5. Evaluate the technical success, clinical success, and adverse events of the different treatments.
6. Evaluate the accuracy of Magnetic Resonance Cholangiopancreatography (MRCP) and EUS in the diagnosis of concomitant choledocholithiasis.

ELIGIBILITY

Inclusion Criteria:

- Patients aged 18 or older who agree to participate (an informed consent signature is required)
- Patients attended in the emergency department of our hospital and diagnosed with acute cholecystitis according to the Tokyo criteria.

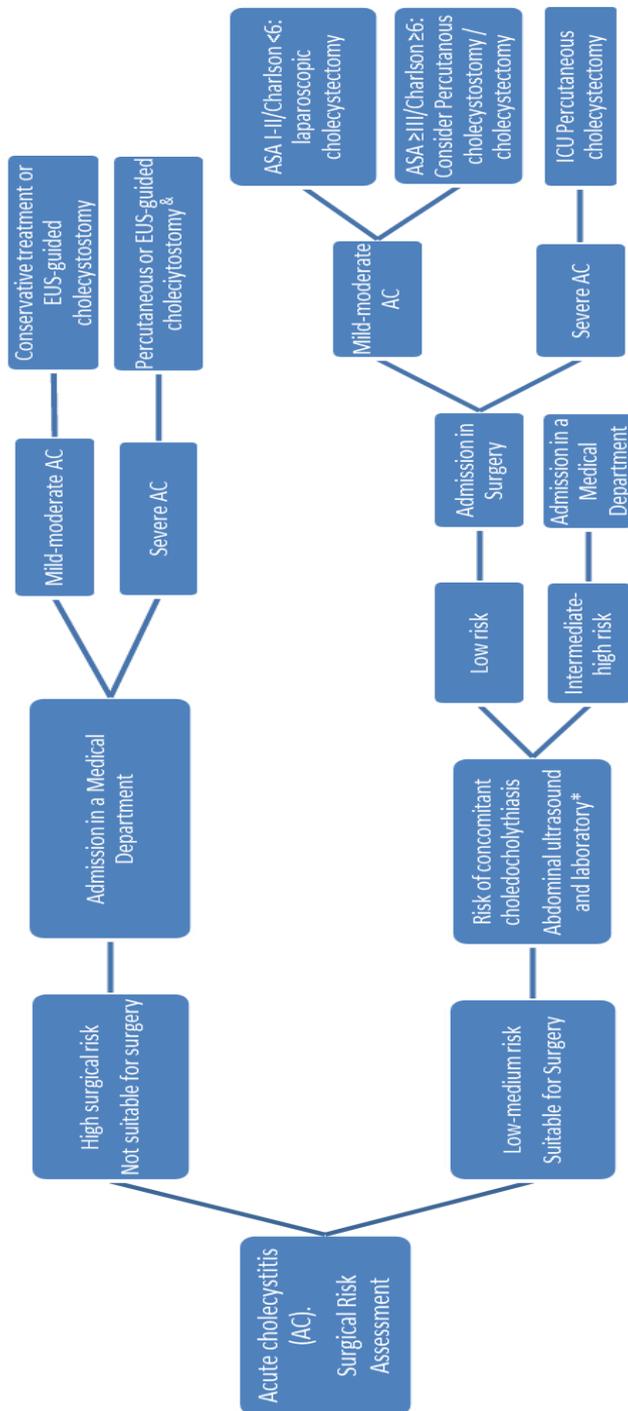
Exclusion Criteria:

- Patients under 18 years or patients who refuse to participate in the study
- Patients diagnosed with acute cholecystitis during admission for other causes.

REFERENCES

Citations:

1. Montoro Huguet Miguel GPJC. Manual de emergencias en Gastroenterología y Hepatología – Emergencias en Gastroenterología y Hepatología. 3a. 2019 [cited in september 2019]. Available in: <https://cursodeemergencias.com/manual-de-emergencias-en-gastroenterologia-y-hepatologia/>
2. Yokoe M, Hata J, Takada T, Strasberg SM, Asbun HJ, Wakabayashi G, et al. Tokyo Guidelines 2018: diagnostic criteria and severity grading of acute cholecystitis (with videos). J Hepato-Biliary-Pancreatic Sci. 2018;25(1):41-54.
3. Ansaloni L, Pisano M, Coccolini F, Peitzmann AB, Fingerhut A, Catena F, et al. 2016 WSES guidelines on acute calculous cholecystitis. World J Emerg Surg WJES. 2016;11:25.
4. Chisholm PR, Patel AH, Law RJ, Schulman AR, Bedi AO, Kwon RS, et al. Preoperative predictors of choledocholithiasis in patients presenting with acute calculous cholecystitis. Gastrointest Endosc. 2019;89(5):977-983.e2.
5. Maple JT, Ben-Menachem T, Anderson MA, Appalaneni V, Banerjee S, Cash BD, et al. The role of endoscopy in the evaluation of suspected choledocholithiasis. Gastrointest Endosc. 2010;71(1):1-9.
6. Buxbaum JL, Fehmi SMA, Sultan S, Fishman DS, Qumseya BJ, Cortessis VK, et al. ASGE guideline on the role of endoscopy in the evaluation and management of choledocholithiasis. Gastrointest Endosc. 2019;89(6):1075-1105.e15.
7. Manes G, Paspatis G, Aabakken L, Anderloni A, Arvanitakis M, Ah-Soune P, et al. Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy. 2019;51(5):472-91.
8. Luk SW-Y, Irani S, Krishnamoorthi R, Wong Lau JY, Wai Ng EK, Teoh AY-B. Endoscopic ultrasound-guided gallbladder drainage versus percutaneous cholecystostomy for high risk surgical patients with acute cholecystitis: a systematic review and meta-analysis. Endoscopy. 2019;51(8):722-32.



*** Intermediate-high risk:**

- Cholecholelithiasis, or
- Bil ≥ 4 mg/dL, or
- Common bile duct diameter > 6 mm, or
- Acute cholangitis

*** Low risk: none of these**

⁸ Palliative care may be also considered in some cases
[#] Endoscopic cholecystostomy is not available 24/7

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