

Original Investigation

# Initial Cholecystectomy vs Sequential Common Duct Endoscopic Assessment and Subsequent Cholecystectomy for Suspected Gallstone Migration A Randomized Clinical Trial

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## Introduction

- Right-upper-quadrant pain and elevated liver function tests (LFTs) → suspicion of a stone migration into the common duct
- The best initial strategy for treating common duct stones
  - MRCP, ERCP, EUS, IOC

- According to 2010 American guideline
  - *low-risk patients*: laparoscopic cholecystectomy
  - *high-risk patients*: preoperative ERCP
  - *intermediate-risk patients* (5%-50% risk): no specific guideline for the initial approach
    - increased LFTs, age >55 years, biliary pancreatitis

- Preoperative common duct investigations reduce the need for postoperative ERCP,
  - a number of **unnecessary** procedures

## Method

- Randomized clinical trial with 2 parallel groups
- Study group: cholecystectomy first
  - primary emergency laparoscopic cholecystectomy (<48 hours) with IOC
  - ERCP: either intraoperatively or postoperatively, depending on gastroenterologist availability

- Control group: classical treatment
  - EUS → ERCP → laparoscopic cholecystectomy with IOC
- To avoid randomizing patients with 1 isolated increased LFT
  - a minimal threshold: ALK and AST → twice the normal range in association with at least 1 other modified LFT

Figure 1. Algorithm for Choledocholithiasis Treatment

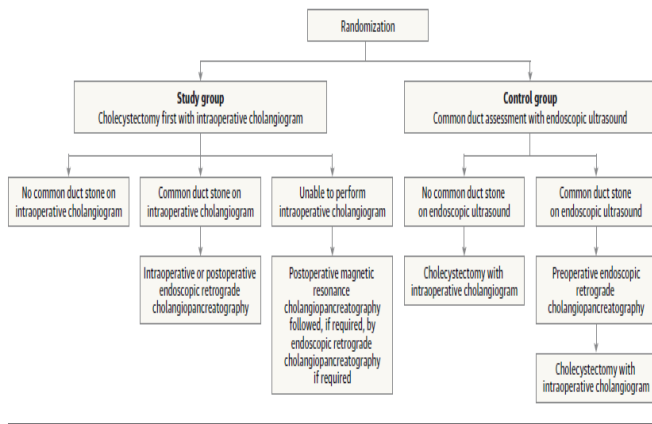


Figure 2. Study Participation for Initial Cholecystectomy vs Sequential Common Duct Endoscopic Assessment, Clearance, and Cholecystectomy

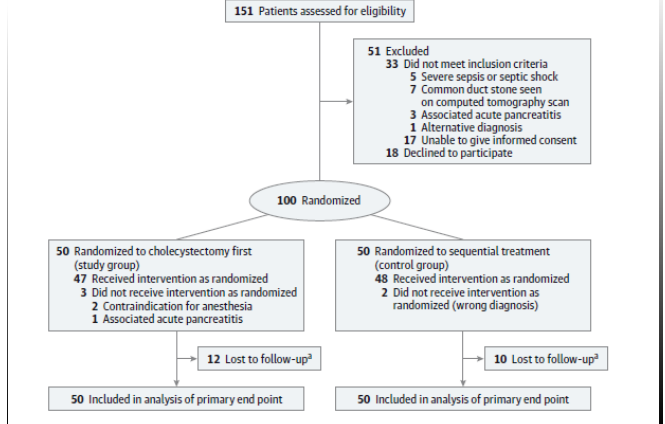


Table 1. Demographic Data, Liver Function Tests, and Common Duct Diameter for All Patients<sup>a</sup>

	Group, Median (IQR) <sup>b</sup>	
	Study (Cholecystectomy First) (n = 50)	Control (Sequential Treatment) (n = 50)
Women to men, ratio (no./no.)	2.1:1 (34:16)	1.9:1 (33:17)
Age, y	46 (33-62)	48 (32-57)
ASA score <sup>c</sup>	1.5 (1-2.5)	1.5 (1-2)
BMI <sup>d</sup>	26 (22-29)	25 (22-28)
Patients with acute cholecystitis, No. (%)	22 (44)	24 (48)
Aspartate aminotransferase, IU/L	134 (99-263)	164 (91-263)
Alanine aminotransferase, IU/L	126 (76-309)	160 (106-324)
Alkaline phosphatase, IU/L	98 (77-153)	109 (84-166)
γ-glutamyl transpeptidase, IU/L	220 (141-375)	250 (121-461)
Bilirubin, mg/dL	1.6 (0.9-2.9)	1.6 (1.1-2.5)
Lipase, IU/L	35 (25-55)	34 (28-43)
Patients with a common duct diameter >6 mm, No. (%)	9 (18)	2 (4)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; IQR, interquartile range.

SI conversion factor: to convert bilirubin to μmol/L, multiply values by 17.1.

<sup>a</sup> There was no statistically significant difference between groups for any item (all P values were > .05).

<sup>b</sup> All values were reported as median (IQR) unless otherwise indicated.

<sup>c</sup> The ASA score evaluates patients' preoperative overall health status and is associated, to a certain extent, with surgical complications and outcomes (range: 1, healthy patient to 5, moribund patient).

<sup>d</sup> BMI is calculated as weight in kilograms divided by height in meters squared.

## Result

Table 2. Outcomes for All Patients<sup>a</sup>

	Group, No. (%)		P Value
	Study (Cholecystectomy First) (n = 50)	Control (Sequential Treatment) (n = 50)	
Length of stay, median (IQR), d	5 (5-8)	8 (6-12)	<.001 <sup>b</sup>
Common duct investigations, No. <sup>c</sup>			
Overall	25	71	<.001 <sup>d</sup>
MRCP	2	5	.44 <sup>d</sup>
EUS <sup>e</sup>	10	54	<.001 <sup>d</sup>
ERCP <sup>f</sup>	13	12	.71 <sup>d</sup>
Same-session EUS and ERCP	3	3	.99 <sup>d</sup>
Patients with confirmed common duct stone	11 (22)	10 (20)	.81 <sup>d</sup>
Failed ERCP	0	0	.99 <sup>d</sup>
Surgical common duct exploration	0	0	.99 <sup>d</sup>
Conversion to laparotomy, No.	1 (2)	2 (4)	.56 <sup>d</sup>
Operating time, median (IQR), min	99 (76-137)	117 (91-136)	.18 <sup>b</sup>
Failed intraoperative cholangiogram	0	3 (6)	.12 <sup>d</sup>
Reoperations	0	3 (6)	.24 <sup>d</sup>
Readmissions	1 (2)	2 (4)	.98 <sup>d</sup>
Interval between admission and first procedure, median (IQR), d <sup>f</sup>	1 (1-2)	1.5 (1-2.75)	.44 <sup>b</sup>

## Complications

Table 3. Perioperative Complications and Grades According to the Clavien-Dindo Classification<sup>a</sup>

Complications	Grade <sup>b</sup>	Associated Acute Cholecystitis
Study group (n = 4)		
Post-ERCP mild pancreatitis (no treatment needed)	I	No
Postoperative bacteremia (treated with antibiotics only)	II	No
Post-ERCP blood clots in distal common duct requiring a second ERCP	III	No
Severe postoperative pancreatitis requiring ICU admission	IV	No
Control group (n = 7)		
Postoperative		
Transitory cardiac arrhythmia (treated with drugs only)	II	No
Bacteremia (treated with antibiotics only)	II	No
Angina pectoris (treated with drugs only)	II	Yes
Preoperative severe pancreatitis requiring radiological drainage		
Wound abscess requiring surgical drainage	III	Yes
Cystic duct bile leak requiring reoperation	III	Yes
Septic shock due to small bowel perforation requiring ICU admission	IV	No

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; ICU, intensive care unit.

<sup>a</sup> Data are based on Dindo et al.<sup>11</sup>

<sup>b</sup> Grade I indicates any complication that does not require any specific treatment; grade II, a complication requiring pharmacological treatment only; grade III, a complication requiring surgical, endoscopic or radiological intervention; grade IV, a life-threatening complication requiring ICU admission; grade V, death of the patient.

## Discussion

- Initial cholecystectomy with IOC for patients at intermediate risk of a common duct stone
- results in shorter lengths of stay
- fewer common duct investigations
- no increased morbidity and a maintained postoperative quality of life

- 60% of patients (30 of 50) in the study group did not need any common duct investigation after the IOC.
- 1- and 6-month follow-ups showed excellent quality of life
  - no statistically significant difference between groups

- Rural US hospitals with limited access to endoscopy → mostly use a cholecystectomy-first approach
- Urban hospitals → investigation-first approach. Both result in similar outcomes
  - ERCP ductal clearance rates are similar prior to and after cholecystectomy (80%- 97%)

- A number of recent reports → single-stage approach
- However, a recent study suggested that intraoperative common duct exploration is less effective than postoperative ERCP
  - in terms of ductal clearance

## Limitations

- The study was not blinded
- Length of stay can potentially be affected by
  - such as inability of older patients to return home
  - surgeons' subjective assessment of a postoperative clinical status
  - absence of blinding of the caregivers

Thank you for your attention!