

# JOURNAL CLUB

“Early Versus Delayed Cholecystectomy for Acute Cholecystitis, Are the 72 hours Still the Rule? A Randomized Trial”

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# Background

- ▶ This study aims to compare the outcome of patients with acute cholecystitis (AC) undergoing early laparoscopic cholecystectomy (ELC) versus delayed laparoscopic cholecystectomy (DLC) after 72 hours of symptoms.
- ▶ At the time of publish (2016), LC was proposed for patients with symptoms less than 72 hours and no prospective data was available for patients with symptoms >72 hours. Long standing understanding of pathophysiology; edema 2-4 days followed by necrosis and subsequently suppurative cholecystitis.
- ▶ Tokyo guideline (TG13) propose ELC within 72 hours for grade 1 and selected grade 2 (experienced surgeon, advance laparoscopic system). >72 hours patients, LC was delayed.
- ▶ ELC is defined as LC as soon as diagnosis is made within the same admission. DLC is defined as 6 weeks after diagnosis is made.

# ABSTRACT

This is a structured abstract of an original article comparing between the clinical outcomes of ELC versus DLC for patients diagnosed with AC with symptoms of more than 72 hours.

86 patient was recruited and evenly randomized into 2 groups which undergone ELC or DLC. Primary outcome (PO) was morbidity. Secondary outcome (SO) was hospital length of stay, duration of abx, hospital costs and surgical outcome.

Conclusion of this study shows that:

- ELC is **safe** compared to DLC ( $P = 0.015$ ) with concomitant benefit of **shorter hospital stay** ( $P = 0.001$ ), **lower overall cost** ( $P = 0.0018$ ), **less morbidity** and **shorter duration of antibiotics** ( $P = 0.001$ ).

**Objective:** The aim of this study was to compare clinical outcomes of early versus delayed laparoscopic cholecystectomy (LC) in acute cholecystitis with more than 72 hours of symptoms.

**Background:** LC is the treatment of acute cholecystitis, with consensus recommendation that patients should be operated within 72 hours of evolution. Data however remain weak with no prospective study focusing on patients beyond 72 hours of symptoms.

**Methods:** Patients with acute cholecystitis and more than 72 hours of symptoms were randomly assigned to early LC (ELC) or delayed LC (DLC). ELC was performed following hospital admission. DLC was planned at least 6 weeks after initial antibiotic treatment. Primary outcome was overall morbidity following initial diagnosis. Secondary outcomes were total length of stay, duration of antibiotic therapy, hospital costs, and surgical outcome.

**Results:** Eighty-six patients were randomized (42 in ELC and 44 in DLC group). Overall morbidity was lower in ELC [6 (14%) vs 17 (39%) patients,  $P = 0.015$ ]. Median total length of stay (4 vs 7 days,  $P < 0.001$ ) and duration of antibiotic therapy (2 vs 10 days,  $P < 0.001$ ) were shorter in the ELC group. Total hospital costs were lower in ELC (9349€ vs 12,361 €,  $P = 0.018$ ). Operative time and postoperative complications were similar (91 vs 88 min;  $P = 0.910$ ) and (15% vs 17%;  $P = 1.000$ ), respectively.

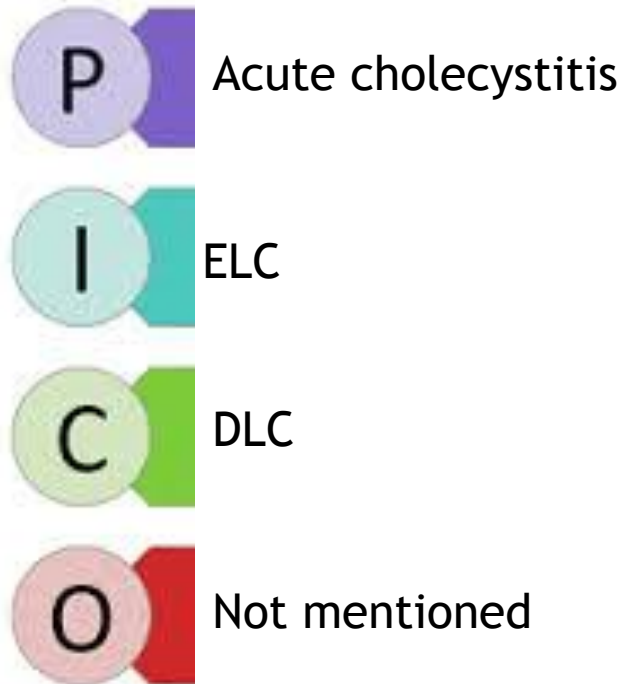
**Conclusions:** ELC for acute cholecystitis even beyond 72 hours of symptoms is safe and associated with less overall morbidity, shorter total hospital stay, and duration of antibiotic therapy, as well as reduced cost compared with delayed cholecystectomy (NCT01548339).

**Keywords:** 72 hours symptoms, acute cholecystitis, early versus delayed laparoscopic cholecystectomy, randomized trial

# ABSTRACT - title

Early Versus Delayed Cholecystectomy for Acute Cholecystitis,  
Are the 72 hours Still the Rule?

*A Randomized Trial*



## Summary:

1. Randomized study but blinding is not mentioned.
2. Title is inadequate - no outcome measures.
3. Unclear whether comparison is made for <72 vs >72 hrs or not.



**P**

PATIENT,  
POPULATION  
or  
PROBLEM

What are the  
characteristics  
of the Patient?

**I**

INTERVENTION  
or  
EXPOSURE

What do you  
want to do with  
this Patient?

**C**

COMPARISON

Other  
intervention  
Treatment,  
No Treatment etc.

**O**

OUTCOME

What are you  
trying to  
accomplish,  
measure,  
improve or affect?

## ▶ Study Design

- **Design:** Single-center randomized controlled trial (RCT)
- **Setting:** University Hospital CHUV, Switzerland
- **Registration:** NCT01548339
- **Randomization:** 1:1 allocation (sealed opaque envelopes)
- **Blinding:** None
- **Study period:** 2009-2014
- **Sample size:** 86 patients (after interim analysis recalculation)

## □ Author and journal Quality

- Annals of Surgery : Impact factor 6.4
- Author H index : 27.
- Authors are from surgical department. Lead corresponding author has **several thousand citations across surgical research**, including hepatobiliary and emergency surgery topics.

Career Stage	Approx. H-Index	Interpretation
Early Career (≤5 years post-training)	~5–10	Building publication record
Mid-Career (5–15 years)	~10–20	Moderate influence; growing citations
Established/Senior (>15 years)	~20–40	High productivity and impact
Very High Impact / Thought Leader	>40	Frequently cited research across many studies

# Method

## Inclusion criteria

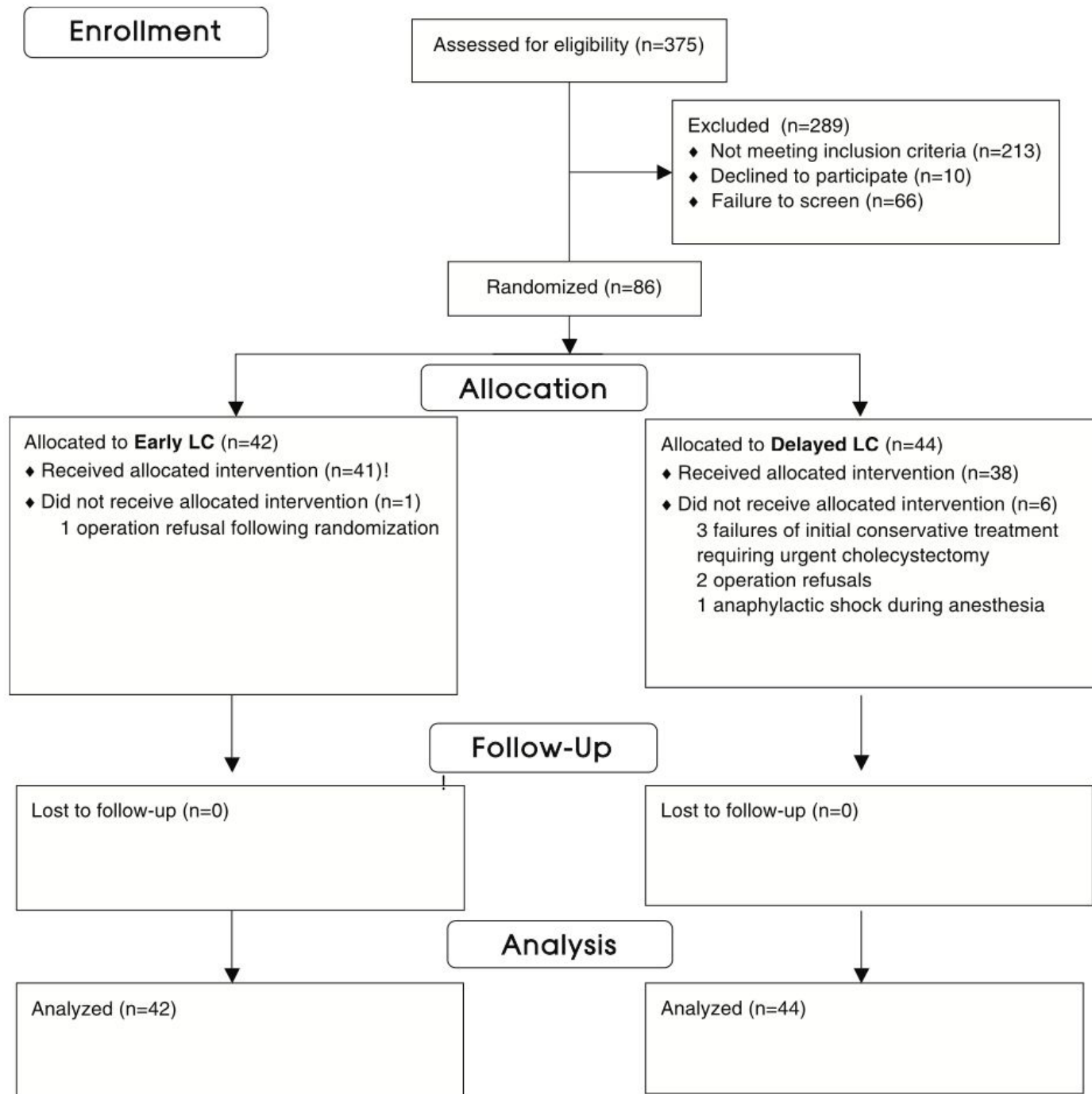
- Age >16 years
- Acute cholecystitis (Tokyo diagnostic criteria)
- Symptoms >72 hours
- No upper limit of symptom duration

## Exclusion criteria

- Severe sepsis
- Perforation
- Cholangitis
- Pancreatitis
- Pregnancy
- Immunosuppression

ELC: 42

DLC: 44



# Method

- ▶ **Early LC (ELC)**
  - Surgery performed during index admission
  - Antibiotics stopped post-op unless indicated
- ▶ **Delayed LC (DLC)**
  - Initial conservative treatment (10-14 days antibiotics)
  - Planned LC  $\geq 6$  weeks later

# Analysis

**TABLE 1.** Baseline Characteristics Comparing Patients With Early Versus Delayed Laparoscopic Cholecystectomy

	<b>ELC</b> <b>(n = 42)</b>	<b>DLC</b> <b>(n = 44)</b>	<b>P</b>
Age, mean (SD), yr	55.8 (16.8)	57.9 (16.6)	0.564
Male gender, n (%)	24 (57)	25 (57)	1.000
Body mass index, mean (SD), kg/m <sup>2</sup>	28.2 (5.5)	27.6 (4.3)	0.596
Hypertension, n (%)	15 (36)	12 (27)	0.488
Diabetes, n (%)	4 (10)	4 (9)	1.000
Cardiac disease*, n (%)	7 (17)	9 (20)	0.784
Pulmonary disease†, n (%)	5 (12)	2 (5)	0.260
Chronic renal insufficiency, n (%)	0	2 (5)	0.236
Cerebrovascular attack, n (%)	2 (5)	0	0.494
Charlson comorbidity index, median (IQR)	0 (0–1)	0 (0–1)	0.413
ASA grade I–II, n (%)	40 (95)	42 (95)	1.000
Previous intrabdominal operation, n(%)	7 (17)	9 (20)	0.784
Length of symptoms, median (IQR), d	4 (3–7)	4 (3–5)	0.385

\*Rhythmic, valvular, or ischemic cardiopathy.

†Asthma, chronic obstructive pulmonary disease, obstructive sleep apnea.

ASA indicates American Society of Anesthesiologists.

Demographic of patient is similar in both subgroup

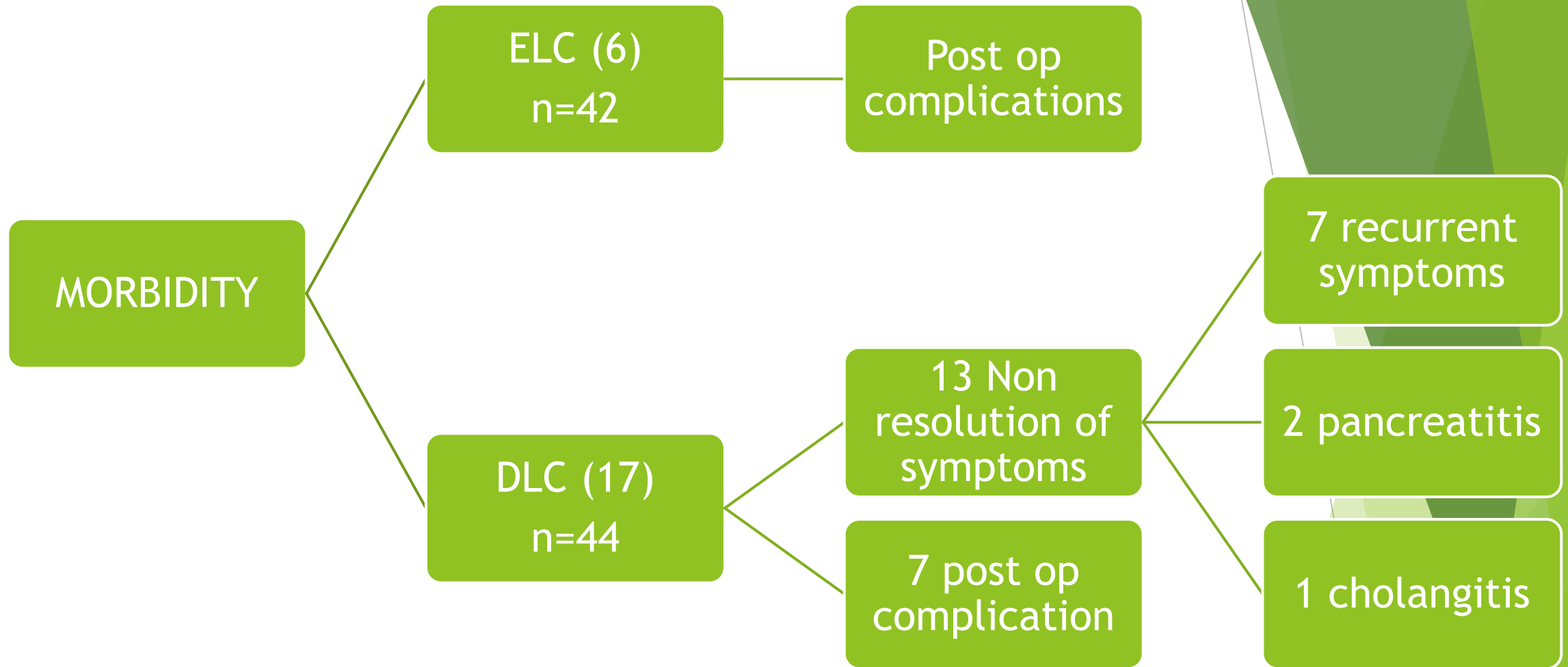
# Analysis - PO and SO

**TABLE 2.** Overall Morbidity, Total Duration of Antibiotic Therapy, Length of Stay, and Hospital Costs

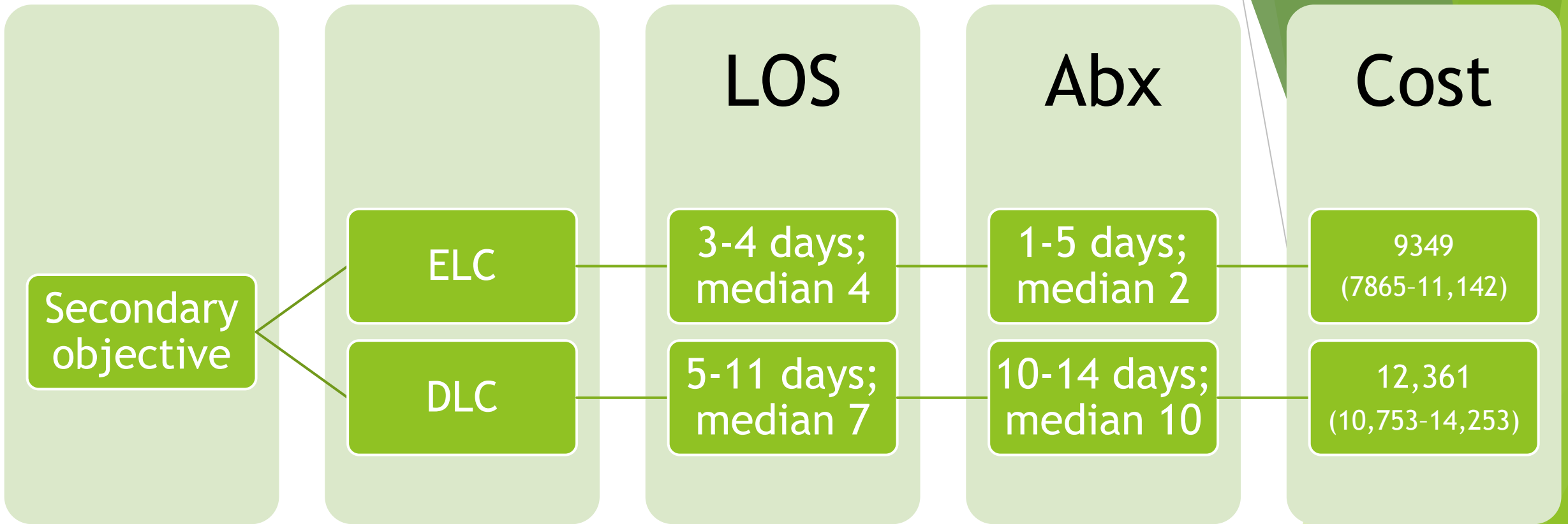
Outcomes	ELC (n = 42)	DLC (n = 44)	OR (95% CI)	P
Overall morbidity, n (%)	6 (14.3)	17 (38.6)*	0.26 (0.0–0.76)	0.015
Failure of initial treatment	0 (0)	3 (6.8)	0.14 (0–2.79)	0.242
Unplanned readmission/emergency consultation awaiting delayed cholecystectomy	0 (0)	10 (22.7)	0.04 (0–0.68)	0.001
Posoperative complications	6 (14.3)	7 (15.9)	0.88 (0.27–2.88)	1.000
Total antibiotic duration, median (IQR), d	2 (1–5)	10 (10–14)	—	<0.001
Total hospital length of stay, median (IQR), d	4 (3–4)	7 (5–11)	—	<0.001
Total hospital costs, mean cost per patient (95% CI), €	9349 (7865–11,142)	12,361 (10,753–14,253)	—	0.018

\*Three patients with unplanned readmission while awaiting DLC also presented with postoperative complications.  
CI indicates confidence interval; OR, odds ratio.

DLC : 17 MORBIDITY



- Overall morbidity P = 0.015
- Unplanned readmission/emergency consultation awaiting delayed cholecystectomy P = 0.001
- Postop complication P = 1.0



- LOS P = 0.001
- Abx P = 0.001
- Cost P = 0.018

**TABLE 3. Surgical Characteristics and Surgery-related Outcomes**

	<b>ELC (n = 41)</b>	<b>DLC (n = 41)</b>	<b>OR (95% CI)</b>	<b>P</b>
Operative time, median (IQR), min	91 (70–114)	88 (71–118)	—	0.910
Peroperative cholangiography, n (%)	7 (17)	2 (4.9)	4.02 (0.8–20.7)	0.155
Pathological diagnosis			—	<0.001
Acute cholecystitis, n (%)	22 (53.7)	10 (24.4)		
Acute on chronic cholecystitis, n (%)	15 (36.6)	0		
Chronic cholecystitis, n (%)	4 (9.8)	31 (75.6)		
Conversion to laparotomy, n (%)	1 (2.4)	0 (0)	3.07 (0.1–77.8)	1.000
Bile duct injury/leak, n (%)	0 (0)	1 (2.4)	0.33 (0–8.2)	1.000
Postoperative complications, n (%)	6 (14.6)	7 (17)	0.83 (0.3–2.7)	1.000
Grade I	2	3		
Grade II	2	1		
Grade III a/b	1	2		
Grade IV a/b	1	1		
Grade V	0	0		
Postoperative length of stay, median (IQR), d	4 (3–4)	2 (2–3)	—	<0.001
Postoperative readmission, n (%)	0 (0)	2 (4.8)	0.19 (0–4.1)	0.494

Postoperative complications graded by severity according to the Clavien classification.<sup>11</sup>

Postoperative complications, n (%)	6 (14.6)	7 (17)	0.83 (0.3–2.7)	1.000
Grade I	2	3		
Grade II	2	1		
Grade III a/b	1	2		
Grade IV a/b	1	1		
Grade V	0	0		
Postoperative length of stay, median (IQR), d	4 (3–4)	2 (2–3)	—	<0.001
Postoperative readmission, n (%)	0 (0)	2 (4.8)	0.19 (0–4.1)	0.494

Postoperative complications graded by severity according to the Clavien classification.<sup>11</sup>

Degree	Definition
I	Any deviation from the normal postoperative course without need of intervention beyond the administration of anti-emetics, antipyretics, analgesics, diuretics, electrolytes, and psychical therapy <sup>a</sup>
II	Complication requiring pharmacological treatment with other medicines beyond the ones used for complications of degree I
III	Complications requiring surgical, endoscopic, or radiological intervention
III-a	Intervention without general anesthesia
III-b	Intervention under general anesthesia
IV	Life-threatening complication requiring admission to intensive care unit
IV-a	Uniorgan dysfunction (including dialysis)
IV-b	Multiorgan dysfunction
V	Death

<sup>a</sup> This degree also includes wound infections opened at the bedside.

# Discussion

1. Previous literature at the point of this study publication discusses LC for AC from point of admission until operation without encompassing duration of symptoms of which patient experience.
2. Degree of inflammation does not necessarily time-dependent.
3. ELC for AC beyond 72 hours is safe. Recommendation:
  - Daytime surgery. Nighttime 13-15% conversion rate.

# Study strength and limitation

## ▶ Strengths

- ✓ Randomized controlled design
- ✓ Clearly defined inclusion criteria
- ✓ Intention-to-treat analysis
- ✓ Clinically meaningful composite primary outcome
- ✓ Cost analysis included
- ✓ First RCT specifically >72 hours subgroup

## ▶ Limitations

- ✗ Single center (limited generalizability)
- ✗ Small sample size (n=86)
- ✗ Underpowered for rare complications (e.g., bile duct injury)
- ✗ No blinding
- ✗ Composite outcome may overestimate clinical impact
- ✗ Long recruitment period (6 years)

# Impact

- ▶ Supports **early surgery irrespective of symptom duration**
- ▶ Challenges traditional timing dogma
- ▶ Supports updating practice beyond strict 72-hour window

Change of practice?

# TG18?



## TG18 / TG13 Diagnostic Criteria for Acute Cholangitis

### A. Systemic Inflammation

- A-1. **Fever** and/or shaking chills
- A-2. **Laboratory data: Evidence of inflammatory response**

### B. Cholestasis

- B-1. **Jaundice**
- B-2. **Laboratory data: Abnormal liver function tests**

### C. Imaging

- C-1. **Biliary dilatation**
- C-2. **Evidence of the etiology on imaging (stricture, stone, stent etc)**

### SEVERE (grade III)

It is associated with dysfunction in one of the following organs/systems

1. Cardiovascular: hypotension requiring dopamine  $> 5 \mu\text{g}/\text{kg}/\text{min}$ , or any dose of norepinephrine
2. Neurological: decrease in the level of consciousness
3. Respiratory:  $\text{PaO}_2/\text{FiO}_2$  ratio  $< 300$
4. Renal: oliguria, creatinine  $> 2.0 \text{ mg/dL}$
5. Liver: PT-INR  $> 1.5$
6. Haematological: platelet count  $< 100,000 \text{ mm}^3$

### MODERATE (grade II)

It is associated with one of the following:

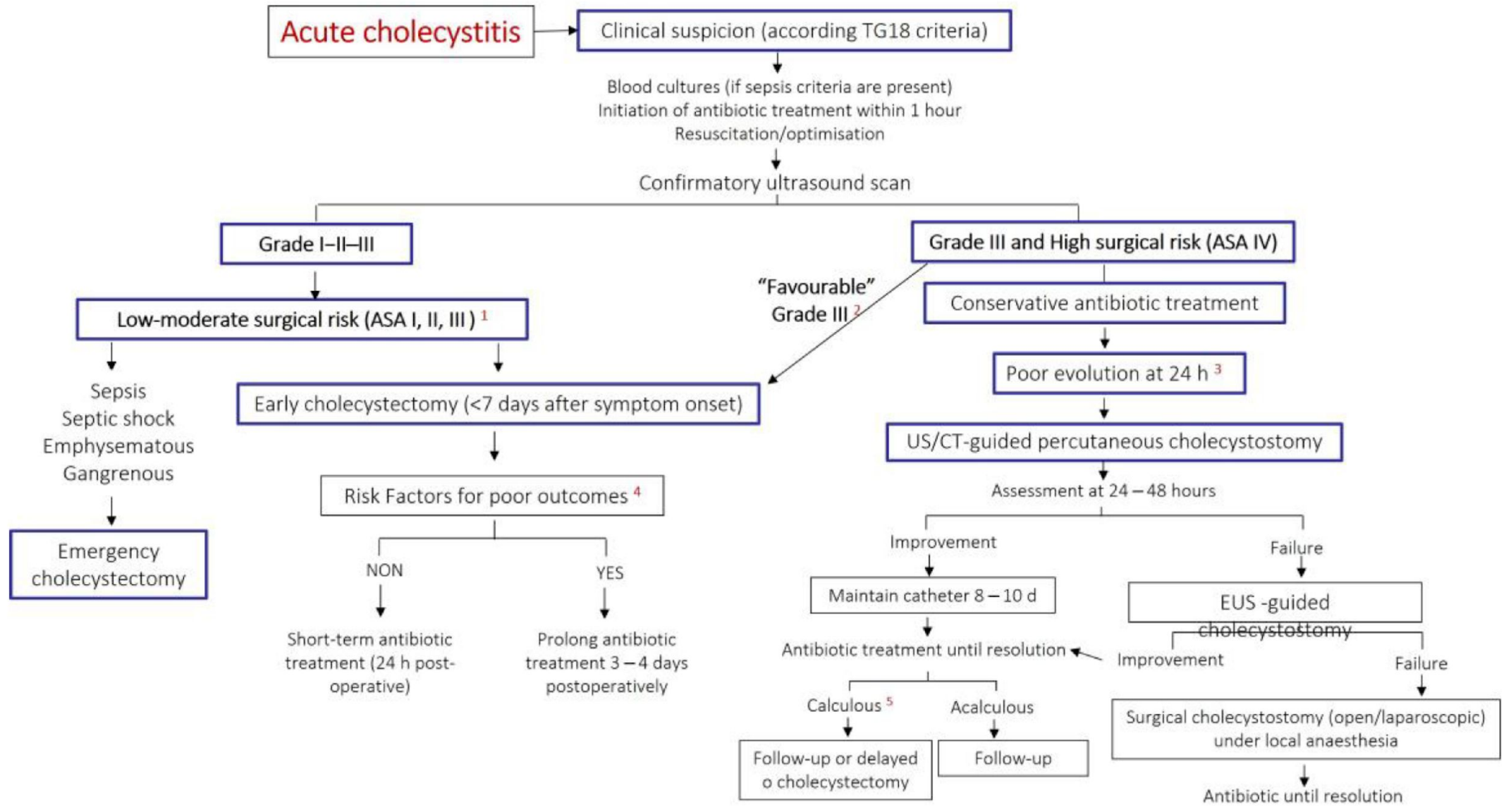
1. Leukocytosis ( $> 18,000/\text{mm}^3$ )
2. Palpable mass with tenderness in upper right quadrant
3. Duration of symptoms  $> 72 \text{ h}$
4. Marked local inflammation (gangrenous cholecystitis, pericholecystic abscess, liver abscess, biliary peritonitis, emphysematous cholecystitis)

### MILD (grade I)

Does not meet criteria for severe or moderate cholecystitis.

It can be defined as acute cholecystitis in a healthy patient without organic dysfunction and with mild inflammatory changes in the gallbladder

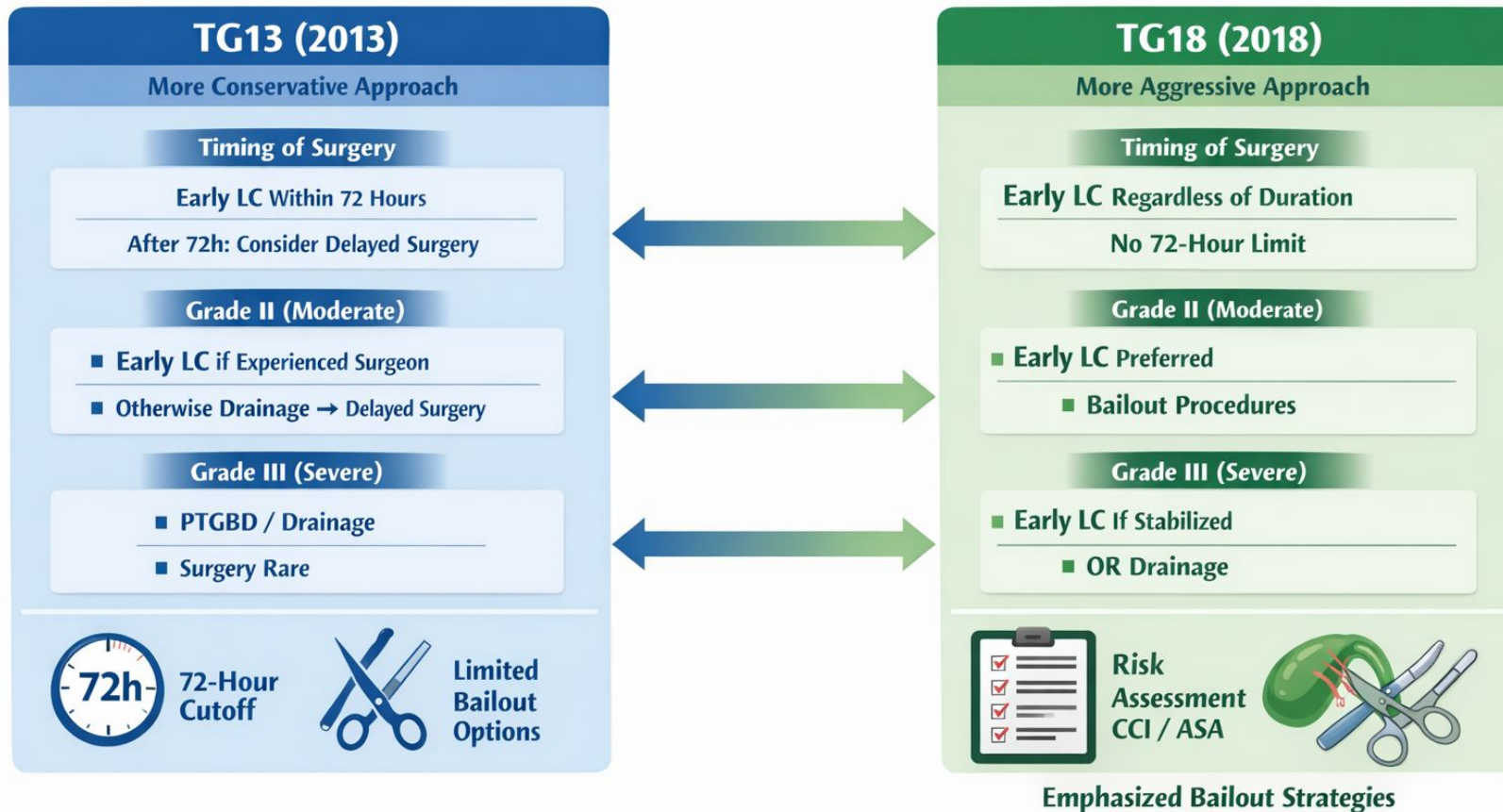
### SEVERITY



# Clinical practice TG13 vs TG18

Tokyo Guidelines

## Acute Cholecystitis Management



# Bailout strategies

A bail-out procedure is chosen when Calot triangle is appropriately exposed but CVS is cannot be achieved.  
- non-dissectible scarring, fibrosis

Tokyo Guidelines  
**TG18 Bailout Strategies for Acute Cholecystitis**  
Alternative Approaches When Standard Laparoscopic Cholecystectomy is Unsafe

