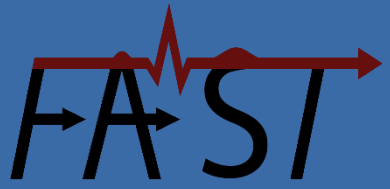

Accelerated cholecystectomy versus standard of care for acute cholecystitis: FAST Pilot RCT

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Background

- Prevalence of gallstones is 10-20% among Canadians.
- 10% of these patients develop acute cholecystitis (AC).
- Surgery is the only definitive treatment for AC
- Recent studies suggest that early surgery may be associated with:
  - Shorter LOS
  - Less cost of care
  - Less complications
- **Controversy remains regarding the optimal timing of cholecystectomy for AC**

Research Question

In patients with acute cholecystitis, is a trial of accelerated surgery (i.e., as soon as possible with a goal of surgery within 6 hours of diagnosis) compared to standard care feasible?

Trial Design

- Multicentre, parallel group, randomized controlled trial
- Randomizing patients with acute cholecystitis to accelerated surgery (within 6 hours of diagnosis) or standard of care
- 60 patients with a recruitment period of 10 months across 3 Hamilton sites

Patient Population

Inclusion Criteria

1. ≥45 years; or ≥18 years and <45 years with at least one co-morbidities: DM or chronic respiratory, cardiovascular, or renal disease;
2. Diagnosis of AC defined by the presence of at least 2 of the following:
    a) Abdominal pain in upper right quadrant,
    b) Murphy's sign,
    c) Leukocytosis >10 × 10^3/µl, or
    d) Oral temperature <36.5°C or >38°C;
3. Cholelithiasis (stones/sludge) and Ultrasound signs of cholecystitis;
4. Ultrasound signs of cholecystitis as interpreted by a surgeon or radiologist
5. AC that requires surgery and is diagnosed during working hours;
6. Expected at least an overnight hospital admission after surgery; and
7. Provide written informed consent to participate in FAST.

Exclusion Criteria

1. Patients requiring emergent surgery or emergent interventions;
2. Patients whose therapeutic anticoagulation is not reversible;
3. Patients with a history of heparin-induced thrombocytopenia and use of warfarin with an INR ≥1.5;
4. Pregnant patients; and
5. Previous participation in the trial.

Primary Outcomes

The primary outcome is the feasibility of a large-scale trial as defined by:

1. Recruitment of 60 patients across the participating sites, we will judge recruitment as feasible if we are able to randomize across all sites the equivalent of 1 patient per site per month; and
2. ≥95% of participants complete the follow-up at 90 days after randomization.

Among patients randomly assigned to accelerated care, we will also evaluate the proportion who receive initiation of surgery within 6 hours of the diagnosis of acute cholecystitis.

Secondary Outcomes

1. A composite of the following complications within 90 days of randomization: all-cause mortality, non-fatal sepsis, surgical site infection, pneumonia, Clostridium difficile-associated diarrhea, intra-abdominal abscess, bile duct injury, cystic duct stump leak, conversion to open surgery, intra-abdominal re-operation, intra-abdominal percutaneous or endoscopic re-intervention including placement of drain, embolization or ERCP, cholangitis, pancreatitis, myocardial injury, myocardial infarction, stroke, symptomatic proximal VTE, new atrial fibrillation, acute congestive heart failure, new acute renal injury requiring dialysis and major bleeding.
2. Individual components of the composite outcome
3. Cumulative length of hospital stay
4. Length of surgical procedure
5. Subtotal cholecystectomy rate
6. Postoperative ileus
7. AKI
8. Admission to ICU within 90 days of randomization
9. Hospital readmissions within 90 days of randomization
10. Peripheral arterial thrombosis within 90 days of randomization
11. Intra-operative cholangiogram rate
12. Postoperative delirium according to the 3D-CAM assessment

Patient follow-up