# Feasibility of Predicting Incidental Gallbladder Cancer:
# An Interim Analysis of Feasibility Outcomes of a Trainee-Led, Multi-Centre Diagnostic Modelling Study

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## AT A GLANCE

The primary aim of this study (fP-iGBC) was to assess the feasibility of conducting a diagnostic modelling study for incidental gallbladder cancer in cholecystectomy.

fP-iGBC shows that a high-quality, prospective dataset for adult cholecystectomy can be collected using a trainee-led collaborative.

Post-operative histology will unexpectedly diagnose incidental gallbladder cancer (iGBC) in around 1:500 benign cholecystectomies.

UK guidance recommends that all gallbladders should be sent for histopathology, as cancer and dysplasia are often flat, and invisible to the naked eye.

P-iGBC aims to develop a diagnostic tool to risk-stratify gallbladders for iGBC. 30,000 patients are needed. fP-iGBC assesses study processes.

## Screening and Recruitment

**551** screened → **508** recruited → **505** operated

- Combined, sites were open for 594 days
- Recruitment closed early

Each month, the average site:
- Screened 27.8 patients
- Recruited 25.7 patients

6 out of 8 sites reached minimum recruitment (10.5 patients/ month)

## Data Quality

All case record forms were signed off as complete.

Data completeness for core variables was 98.7%

Data concordance rated as “good” or “excellent” for all core values. Absolute agreement 91.4%

**DESIGN**

Multicentre, trainee collaborative

Internal pilot of main study

Prospective, consecutive identification

Non-consented, de-identified data collected in REDCap

**ELIGIBILITY**

Adult patients undergoing cholecystectomy during the recruitment window

Surgery for benign diseases

- Gallstone complications
- Dyskinesia

**EXCLUSIONS**

Patients with described high-risk for cancers

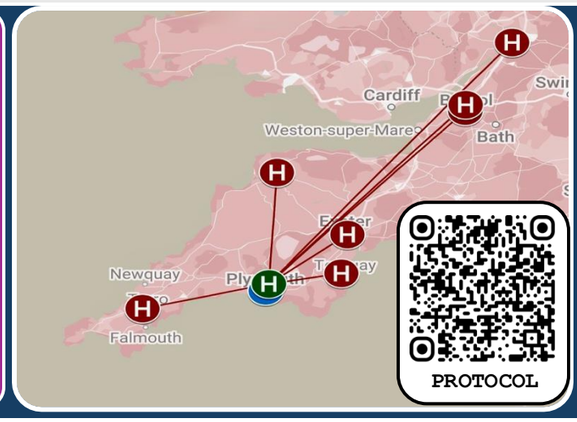
- Polyps >5mm
- Mirizzi III/IV
- Pre-operative history/suspicion of biliary malignancy
- High risk congenital abnormalities

Cholecystectomy as part of another procedure

**VALIDATION**

Double data entry conducted by independent collaborators

Concordance assessed using Kappa and absolute agreement




P-iGBC Predicting Incidental Gallbladder Cancer

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