

Early EUS in Acute Biliary Pancreatitis

This study has been completed.

Sponsor:	Istituto Clinico Humanitas
Collaborators:	
Information provided by (Responsible Party):	Michele Tedeschi, Istituto Clinico Humanitas
ClinicalTrials.gov Identifier:	

Purpose

Acute biliary pancreatitis (ABP) is a potentially life-threatening condition caused by common bile duct (CBD) stones or sludge, which requires prompt diagnosis and treatment by endoscopic removal of the material. Accurate detection of CBD stones is warranted to select patients for early therapeutic endoscopic retrograde cholangiopancreatography (ERCP).

In clinical practice the decision to perform an ERCP is often based on biochemical and radiological criteria despite they already have been shown to be unreliable predictors of CBD stone presence.

EUS is not currently a worldwide standard diagnostic procedure early in the course of acute biliary pancreatitis, but it has been shown to be accurate, safe and cost effective in diagnosing biliary obstructions compared with MRCP and ERCP and therefore in preventing unnecessary ERCP and its related complications.

We aim to investigate the clinical usefulness of early EUS in the management of ABP.

All consecutive patients entering the emergency department due to acute abdominal pain and showing biochemical and/or radiological findings consistent with possible ABP will be prospectively enrolled. Patients will be classified as having a low, moderate, or high probability of CBD stones, according to established risk stratification. All enrolled patients will undergo EUS within 48 h of their admission. ERCP will be performed immediately after EUS only in those cases with proven CBD stones or sludge.

The following parameters will be investigated: (1) clinical: age, sex, fever; (2) radiological: dilated CBD, (3) biochemical: bilirubin, AST, ALT, gGT, ALP, amylase, lipasis, PCR. Association between presence of CBD stone at EUS and the individual predictors were assessed by univariate logistic regression. Predictors significantly associated with CBD stones ($p < 0.05$) will enter in a multivariate logistic regression model.

Condition	Intervention	Phase
Acute Biliary Pancreatitis	Device: Endoscopic Ultrasound	N/A

Study Type: Interventional

Study Design: Diagnostic, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study

Official Title: Early EUS in Acute Biliary Pancreatitis: a Prospective Pilot Study.

Further study details as provided by Michele Tedeschi, Istituto Clinico Humanitas:

Primary Outcome Measure:

- Reliability of early EUS [Time Frame: Two years] [Designated as safety issue: Yes]
reliability of EUS, as an early approach in patients with ABP, to correctly identify the presence of CBD stones and consequent need of early ERCP with respect to the risk stratification based on clinical criteria
- Feasibility of early EUS-ERCP [Time Frame: Two years] [Designated as safety issue: Yes]
feasibility of the early sequential approach EUS/ERCP in diagnosis and treatment of CBD stones in the setting of ABP.

Enrollment: 181

Study Start Date: January 2010

Primary Completion Date: July 2012

Study Completion Date: June 2013

Arms	Assigned Interventions
<p>Early EUS</p> <p>Early EUS: all consecutive patients entering the emergency department due to acute abdominal pain and showing biochemical and/or radiological findings consistent with possible acute biliary pancreatitis.</p>	<p>Device: Endoscopic Ultrasound</p> <p>Early EUS</p>

► Eligibility

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- All consecutive patients entering the emergency department for possible acute biliary pancreatitis

Exclusion Criteria:

- gastrectomy
- patient in whom the cause of biliary obstruction was already identified by US

► Contacts and Locations

Locations

Italy

Endoscopy Unit, Gastroenterology Department, Humanitas Research Hospital
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Investigators

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► More Information

Publications:

Fabbri C, Polifemo AM, Luigiano C, Cennamo V, Fuccio L, Billi P, Maimone A, Ghersi S, Macchia S, Mwangemi C, Consolo P, Zirilli A, Eusebi LH, D'Imperio N. Single session versus separate session endoscopic ultrasonography plus endoscopic retrograde cholangiography in patients with low to

moderate risk for choledocholithiasis. *J Gastroenterol Hepatol*. 2009 Jun;24(6):1107-12. doi: 10.1111/j.1440-1746.2009.05828.x.

ASGE Standards of Practice Committee, Maple JT, Ben-Menachem T, Anderson MA, Appalaneni V, Banerjee S, Cash BD, Fisher L, Harrison ME, Fanelli RD, Fukami N, Ikenberry SO, Jain R, Khan K, Krinsky ML, Strohmeyer L, Dominitz JA. The role of endoscopy in the evaluation of suspected choledocholithiasis. *Gastrointest Endosc*. 2010 Jan;71(1):1-9. doi: 10.1016/j.gie.2009.09.041.

De Lisi S, Leandro G, Buscarini E. Endoscopic ultrasonography versus endoscopic retrograde cholangiopancreatography in acute biliary pancreatitis: a systematic review. *Eur J Gastroenterol Hepatol*. 2011 May;23(5):367-74. doi: 10.1097/MEG.0b013e3283460129. Review.

Responsible Party: Michele Tedeschi, Chief of Clinical Research, Istituto Clinico Humanitas

Study ID Numbers: EARLY-EUS

Health Authority: Italy: Ethics Committee

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