Validation of a predictive model to determine the need for repeat ERCP after endoscopic treatment of iatrogenic biliary leaks – multicentric study

Background

Iatrogenic biliary leaks are a significant complication of hepatobiliary procedures. Endoscopic retrograde cholangiopancreatography (ERCP) is the first-line therapeutic approach. Various forms of endoscopic treatment are highly effective to treat biliary leaks.

Currently, ESGE recommends endoscopic placement of plastic stent(s) to treat bile duct leaks that are not due to transection of the common bile duct or common hepatic duct. According to several studies, removal is indicated 4-8 weeks after stent placement.

After this period, the re-evaluation ERCP diagnoses leak persistence or other pathologies (lithiasis, stricture, other) in some patients. How could we predict leak persistence or other pathology? Due to difficulty in predicting a normal cholangiogram, ERCP is nowadays considered the standard method for stent removal. The main question is: Which patients would have a normal cholangiogram, in order to use upper endoscopy for stent removal?

It is important to identify patients who will have a normal cholangiogram on repeat ERCP (without any pathology), in whom stents could be removed with upper endoscopy. In a Portuguese cohort, a **model using specific criteria** (total bilirubin, elective iatrogenic procedure, therapeutic ERCP in ≤ 7 days, stent removal in ≤ 12 weeks) allowed the selection, with high degree of specificity, of 43% of patients in which repeat ERCP would not be necessary and biliary stents could be removed with upper endoscopy.

Aim

The aim of this study is to validate a model (using the same criteria) in a multicentric scenario with a higher sample size.

Methods

Study population

Inclusion criteria:

- ≥ 18 year-old;
- Iatrogenic biliary leak (surgical and non-surgical);
- Submitted to ERCP with sphincterotomy and successful insertion of plastic biliary stent(s)
- Stent removal with ERCP and reevaluation cholangiogram.

Exclusion criteria: Patients with a biliary leak due to the transection of the common bile duct or common hepatic duct (Amsterdam Classification Type D).

Primary outcome: normal cholangiogram on repeat ERCP (complete resolution of the biliary leak and absence of additional pathology).

Data (ver base de dados SPSS)

- Age, sex

- Iatrogenic procedure responsible for the biliary leak (ver as varias opções na base de dados)
- Elective procedure (yes/no)
- Total billirubin (mg/dl)
- Alanine transaminase (AST)
- Aspartate transaminase (ALT)
- Gamma Glutamyl Transpeptidase (GGT)
- Alkaline phosphatase (FA)
- Leucocitosis
- C reactive protein (CRP)
- Timing of therapeutic ERCP (≤7 days; 8-14 days; >14 days)
- Leak location (ver as opções na base de dados)
- Amsterdam classification (type A - cystic bile duct leakage; type B - CBD leakage; type C - bile duct stricture)
- Stent type; stent length; stent size
- Complications after 1st ERCP (pancreatitis, cholangitis, bleeding, perforation, others)
- Timing of reevaluation ERCP (≤ 8 weeks; 9-12 weeks; >12 weeks)
- Biliary leak resolution (yes/no)
- Lithiasis on reevaluation ERCP (yes/no)
- Stricture on reevaluation ERCP (yes/no)
- Primary outcome (normal cholangiogram) (yes/no)
- Complications after 1st ERCP (pancreatitis, cholangitis, bleeding, perforation, others)
- Death after 2nd ERCP

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