

Long-term risks after endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy.

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STUDY PROTOCOL

1. Background and current status of the issue:

The treatment of benign biliary pathology have changed over the years after the development of endoscopic retrograde cholangiopancreatography (ERCP) , especially in the non-surgical management of choledocholithiasis, by endoscopic cleaning of the bile duct after performing sphincteroplasty or sphincterotomy of the papilla of Vater. However, we have to keep on mind the long-term complications of this endoscopy technique.

2. Study justification:

There are proven long-term complications after sphincterotomy such as ascending cholangitis. However, the risks of malignancy after ERCP is not well established.

3. Goals:

To analyze the long-term complications of ERCP, both benign and malignant, and the factors related to their development.

4. General objectives:

To analyze the long-term complications of ERCP with sphincterotomy.

5. Specific objectives:

a. To study the characteristics of patients who develop complications after endoscopic sphincterotomy.

b. Demonstrate causality between ERCP with sphincterotomy and the development of neoplasms in the bile duct.

6. Hypothesis:

The presence of post-ERCP chronic ascending cholangitis can produce benign and malignant complications in the biliary system.

7. Methodology:

This is a single center retrospective study.

8. Reference and study population: All patients undergoing ERCP with sphincterotomy for benign diseases between 1995 and 2015.

9. Inclusion criteria:

a. Patients undergoing ERCP with sphincterotomy for benign biliopancreatic disease.

b. Survival or follow-up at less two years after ERCP.

c. No malignant biliary disease development at less two years after ERCP.

10. Exclusion criteria:

a. Patients undergoing ERCP for malignant biliary diseases.

b. Loss of follow-up within two years after ERCP.

c. Death of the patient within two years after ERCP for any reason.

11. Sample size: 450-500 cases

12. Study variables: age, sex, comorbidities, ERCP indications, ERCP sphincterotomy or precut, biliary stent insertion and type of stent, post-ERCP diagnosis, abnormal diameter of biliary tree, ERCP repetition and causes, the presence of benign complications and their number after more than two months, and malignant complications after more than two years.

13. Data collection and information sources: The data were treated confidentially and anonymously according to the provisions of Spanish Organic Law 15/1999 of December 13 of the Personal Data Protection (LOPD). Ethical approval from the Clinical Trials and Ethics Committee of Valladolid University was granted.

14. Analysis of data: The statistical program IBM SPSS Statistics 25.0 will be used. A descriptive analysis of the collected data will be carried out.