

## STROBE Statement—checklist of items that should be included in reports of observational studies

Section/item	Item No	Recommendation	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract	1	(a) Retrospective, observational, and comparative study: "Is elective cholecystectomy effective in geriatric patients to prevent new biliopancreatic events following ERCP for benign biliopancreatic pathology?"	Page 1 Line 1-2	Title page Paragraph 1
		(b) This is a retrospective, observational, and comparative study that included 164 patients aged over 80 years who underwent ERCP-ES. They were divided into two groups: Group A, consisting of 89 patients who had undergone cholecystectomy before ERCP, and Group B, comprising 75 patients who had not undergone cholecystectomy. Epidemiological, clinical, and procedure-related variables were collected. The groups were homogeneous in terms of age, sex, and associated comorbidities. Complications were analyzed 6 months after ERCP-ES in both groups over an average follow-up period of 82 months.  In patients over 80 years old, laparoscopic cholecystectomy performed either before or after ERCP-ES for benign biliopancreatic pathology prevents the occurrence of subsequent episodes of acute cholecystitis but is associated with a higher incidence of post-ERCP choledocholithiasis and acute cholangitis.	Page 2 Line 41-47  Page 3 Line 64-67	Abstract Paragraph 3  Paragraph 7
<b>Introduction</b>				
Background/ rationale	2	ERCP is the preferred therapeutic approach for benign biliary tract pathology, but complications may arise, particularly in cholelithiasis patients. Once the diagnosis is confirmed, preoperative ERCP-ES followed by laparoscopic cholecystectomy (LC) is the most utilized method in clinical practice. Elective cholecystectomy is recommended for the treatment of recurrent biliary colic, acute cholecystitis, prevention of pancreatitis, or choledocholithiasis. However, there is controversy regarding its efficacy in preventing long-term biliary events after ERCP with sphincterotomy. It is known that sphincterotomy does not alter gallbladder function. Moreover, the absence of the gallbladder may hinder effective bile clearance from the bile duct, leading to bile stasis and the formation of larger de novo stones. Coupled with the fact that elderly patients develop acute cholecystitis less frequently and the increased risk of lethal events associated with surgery in this age group, there is a need to consider elective cholecystectomy after resolving benign biliary pathology through ERCP-ES in geriatric patients.	Page 4 Line 89-96 Line 112-121	Introduction Paragraph 1-2 Paragraph 6

Objectives	3	The aim of this study is to establish the relationship between undergoing ERCP-ES in elderly patients, whether they have had a cholecystectomy or not, and the development of medium to long-term biliopancreatic pathology.	Page 5 Line 123-124	Introduction Paragraph 8
<b>Methods</b>				
Study design	4	Cohort retrospective study.	Page 6 Line 135	Methods Paragraph 1
Setting	5	A retrospective study was conducted, analyzing the medical records and imaging studies of aged patients who underwent endoscopic retrograde cholangiopancreatography with sphincterotomy (index ERCP) between January 1995 and December 2017.	Page 6 Line 135	Methods Paragraph 1
Participants	6	(a) Out of a total of 576 ERCP procedures indicated for benign biliopancreatic pathology, those performed on patients aged 80 years and older with a minimum follow-up of more than two years were selected, resulting in a cohort of 164 patients. These patients were divided into two groups based on a history of prior cholecystectomy before the initial ERCP (index ERCP): Group A - cholecystectomized (89 patients) and Group B - noncholecystectomized (75 patients). All patients were included with a binomial test to ensure that the groups originated from the same sample in the same proportion (0.5) with a p value of 0.301.	Page 6 Line 137-144	Methods Paragraph 1
Variables	7	Demographic parameters, medical history, comorbidities, and history of upper digestive tract surgery that could complicate the endoscopic procedure were studied. Parameters related to ERCP were also recorded: indications for ERCP, diagnosis after the procedure, biliary epithelium cytology, stent placement, performance of duodenal precut, diversion from the digestive tube to the bile duct, repetition of ERCP, and reason for repetition.  The only complications studied in this research were the ones that occurred more than 6 months after the index ERCP to avoid including residual choledocholithiasis	Page 6 Line 145-149	Methods Paragraph 2
Data sources/ measurement	8*	Medical records and imaging studies of patients who underwent endoscopic retrograde cholangiopancreatography with sphincterotomy (index ERCP) between January 1995 and December 2017.	Page 6 Line 137-138	Methods Paragraph 1

		The results were expressed as median with SD.	Page 6 Line 153	Methods Paragraph 3
Bias	9	The only complications studied in this research were the ones that occurred more than 6 months after the index ERCP to avoid including residual choledocholithiasis.	Page 6 Line 150-152	Methods Paragraph 3
Study size	10	The study collected retrospectively the data from patients with inclusion criteria over a period of 20 years.	Page 6 Line 137	Methods Paragraph 1
Quantitative variables	11	Statistical significance was defined as $p < 0.05$ . The mean, standard deviation (SD), minimum (Min), and maximum (Max) were calculated for all quantitative parameters.  These patients were divided into two groups based on a history of prior cholecystectomy before the initial ERCP (index ERCP): Group A - cholecystectomized (89 patients) and Group B - noncholecystectomized (75 patients). All patients were included with a binomial test to ensure that the groups originated from the same sample in the same proportion (0.5) with a p value of 0.301.	Page 6 Line 152-153 Line 140-144	Methods Paragraph 3 Paragraph 1
Statistical methods	12	Statistical analysis was performed using IBM SPSS version 23 software. Statistical significance was defined as $p < 0.05$ . The mean, standard deviation (SD), minimum (Min), and maximum (Max) were calculated for all quantitative parameters, while frequency and percentage were used for qualitative parameters. Nonparametric Mann–Whitney U tests were employed to compare the groups, and chi-square and Spearman tests were used for the analysis of the associations among nominal data variables.  The Kaplan–Meier curve was used to describe the cumulative incidences of choledocholithiasis and cholangitis in the sample. Potential risk factors and benign complications were evaluated through bivariate correlation tests, and Cox logistic regression was applied to explain the hazard ratio (HR) with a p value $< 0.05$ and 95% confidence intervals (95% CI) using the forward stepwise method of Wald.	Page 6 Line 151-157	Methods Paragraph 3
		(b) Not applicable: there is no subgroups.		
		(c) The study includes only data that met the follow-up criteria during the study time.	Page 6 Line 139	Methods Paragraph 1

		(d) Loss to follow-up was carried out by validating the content of the clinical history.		
		(e) An independent samples t test was conducted to analyze the means and correlation of variables of normally distributed data (Kolmogorov–Smirnov normality test - sample size > 50) assuming equal variances with Levene's test for homogeneity of variance.	Page 6 Line 157-160	Methods Paragraph 3
<b>Results</b>				
Participants	13*	(a) An observational and retrospective study was conducted, analyzing the medical records and imaging studies of patients who underwent endoscopic retrograde cholangiopancreatography with sphincterotomy (index ERCP) between January 1995 and December 2017. Out of a total of 576 ERCP procedures indicated for benign biliopancreatic pathology, those performed on patients aged 80 years and older with a minimum follow-up of more than two years were selected, resulting in a cohort of 164 patients.	Page 6 Line 135-140	Methods Paragraph 1
		(b) Loss to follow-up during the study period.		
		(c) Consider use of a flow diagram: The description of the groups made in Methods makes it unnecessary.		
Descriptive data	14*	(a) This is a retrospective, clinical, and cohort study. No potential confounders are detected.	Page 6 Line 135-136	Methods Paragraph 1
		(b) Participants with missing data were not included.		
		(c) <b>Cohort study</b> — Mean follow-up was of 75 months (range 21-2170) for group A and 89 months (range 24- 235) for group B ( p>0.005).	Page 8 Line 181-183	Results Paragraph 3
Outcome data	15*	The indications for the index ERCP were quite similar in both groups, except for acute cholangitis, with 20 patients in Group A (22.47%) compared to 12 patients in Group B (16%) (p=0.005). Overall, the most common indication was cholestatic syndrome.	Page 8 Line 184-187	Results Paragraph 4-5
		Regarding the most common pathology found in the index ERCP, choledocholithiasis topped the list, with 53 patients in Group A (59.9%) compared to 39 patients in Group B (52%), showing significant differences (p=0.008).	Line 188-191	Paragraph 188-191

		There were also significant differences in the time to onset of the initial complication (47 months in Group A vs. 31 months in Group B (p=0.001)), with recurrent choledocholithiasis occurring at 50 months in Group A versus 31 months in Group B (p=0.003). Similarly, in the cholecystectomized group, more ERCPs were repeated (31.4% vs. 9.3% (p=0.001).	Page 9 Line 202-206	Results Paragraph 1
Main results	16	(a) Overall, medium- to long-term biliary events were more frequent in the cholecystectomized group, with 28 (31.46%) compared to 13 (17.33%) in Group B. Except for the incidence of acute pancreatitis, all other complications showed statistically significant differences between the two groups.  (b) Not applicable: no continuous variables were included.  (c) Not applicable.	Page 8 Line 196-199	Results Paragraph
Other analyses	17	The survival hazard ratios (HR) found with the model for the study sample (n=164) are distributed as follows: A. HR < 1 Number of patients: 29; B. HR > 1 Number of patients: 8, and C. HR = 1 Number of patients: 127. According to the above results, overall, repetition of ERCP does not affect survival after choledocholithiasis events.  The model is suitable with a global chi-square = 77.96 and a p value = 0.000. This ensures that the model fits the data perfectly as the likelihood differs from 1. The model predicts a large percentage of events in the sample (n=164).	Page 9 Line 217-220  Line 221-223	Methods Paragraph 5  Paragraph 6
<b>Discussion</b>				
Key results	18	Patients over 80 years old who have undergone cholecystectomy present higher benign biliary complications after an initial episode requiring ERCP with associated sphincterotomy than those who have not undergone cholecystectomy.	Page 12 Line 289-292	Conclusions Paragraph 1
Limitations	19	A limitation of our study is its retrospective nature, so the cholecystectomy group after ERCP was not randomized, and for this reason, there may be selection and analysis biases. Additionally, data were	Page 11-12	Discussion

		collected from the patients who survived, and the follow-up was continued for at least 2 years after ERCP, so any serious complications after surgery may not be fully reflected.	283-287	Paragraph 12
Interpretation	20	Cholecystectomy is effective in reducing the incidence of acute cholecystitis after ERCP.  In aged patients, the indication for prophylactic cholecystectomy should not be performed systematically after a benign biliary event requiring ERCP with sphincterotomy, except in cases of previous episodes of acute cholecystitis	Page 10 Line 230-232 Page 12 Line 292-295	Discussion Paragraph 1 Conclusios Paragraph 1
Generalisability	21	In general, prophylactic cholecystectomy following ERCP + ES for benign biliopancreatic pathology is considered to reduce the subsequent incidence of biliary and pancreatic events. However, this therapeutic approach in elderly patients remains a topic of ongoing debate. Additionally, it has been observed that cholecystectomy in patients with a history of choledocholithiasis treated by ERCP with ES is associated with higher complexity, conversion rates, morbidity, and associated complications.  Prophylactic cholecystectomy in this group of patients may be a good therapeutic strategy in the case of a history of acute cholecystitis or biliary dyspepsia, but it should be indicated more restrictively in the absence of such data.	Page 10 Line 230-235 Page 12 Line 294-296	Discussion Paragraph 1 Conclusios Paragraph 1
<b>Other information</b>				
Funding	22	None.		

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

Article information: <https://dx.doi.org/10.21037/ls-23-19>

\*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

