Original Article

Is elective cholecystectomy effective in geriatric patients to prevent new biliopancreatic events following endoscopic retrograde cholangiopancreatography for benign biliopancreatic pathology?

Juan Carlos Martín-del Olmo[1]^, Juan Ramón Gómez-López[1]^, Pilar Concejo-Cutoli[1], Jean Carlo Trujillo-Díaz[1], Carlos Vaquero-Puerta[2]^, Mercedes Ibáñez-García[3]

[1]Department of General Surgery, Hospital de Medina del Campo, Valladolid, Spain; [2]Department of Surgery, Universidad de Valladolid, Valladolid, Spain; [3]Department of Gastroenterology, Hospital de Medina del Campo, Valladolid, Spain

Contributions: (I) Conception and design: JC Martín-del Olmo; (II) Administrative support: C Vaquero-Puerta; (III) Provision of study materials or patients: M Ibáñez-García; (IV) Collection and assembly of data: P Concejo-Cutoli, M Ibáñez-García, JR Gómez-López, JC Trujillo-Díaz; (V) Data analysis and interpretation: M Ibáñez-García; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Juan Carlos Martín-del Olmo, MD, PhD. Department of General Surgery, Hospital de Medina del Campo, Ctra. Peñaranda, 24, 47400 Medina del Campo, Valladolid, Spain. Email: jcmolmo@gmail.com.

Background: Endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy (ES) is the preferred technique for the management of benign biliary tract pathology. The initial ES performance can lead to long-term complications due to duodenal reflux into the biliary tract. In patients with cholelithiasis, elective cholecystectomy following ERCP is performed to prevent new biliary events and acute cholecystitis. There is no consensus on the indication for cholecystectomy in all cases in elderly patients. The aim of this study is to determine whether cholecystectomy is effective in preventing medium- to long-term biliopancreatic complications in elderly patients who have undergone ERCP-ES for benign conditions.

Methods: 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, 89 patients who had undergone cholecystectomy before ERCP, and Group B, 75 patients without previous cholecystectomy. Epidemiological, clinical, and procedure-related variables were collected. Complications were analyzed 6 months after ERCP-ES with an average follow-up period of 82 months. The Mann-Whitney U test was applied for an independent group comparison. Cox logistic regression was used to identify a model explaining the cause-effect relationships between biliary stone recurrence, benign complications, and predictor variables. Additionally, a Kaplan-Meier survival model was employed to predict survival times in patients with choledocholithiasis and cholangitis and for repeat ERCP.

Results: After ERCP, were registered a total of 22 cases of recurrent choledocholithiasis (13.41%), 8 of acute cholangitis (4.9%), 10 of acute cholecystitis (13.33%), and 1 of acute pancreatitis (0.69%). When comparing both groups, in Group A repeat ERCPs were performed in 28 patients (31.46%), as opposed to 7 patients (9.33%) in Group B, with P=0.001. There were more cases of recurrent choledocholithiasis in Group A, with 20 cases (22.47%) compared to 2 cases (2.67%) in Group B, with P=0.008. The incidence of ascending cholangitis was higher in group A (7.87% *vs.* 1.33%, P=0.03).

Conclusions: In patients over 80 years old, laparoscopic cholecystectomy performed before ERCP-ES prevents the occurrence of subsequent episodes of acute cholecystitis but is associated with a higher incidence of post-ERCP choledocholithiasis and acute cholangitis.

^ ORCID: Juan Carlos Martín-del Olmo, 0000-0001-9056-7630; Juan Ramón Gómez-López, 0000-0002-2659-1473; Carlos Vaquero-Puerta, 0000-0002-2195-1679.

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a well-established diagnostic and therapeutic endoscopic technique commonly employed for various conditions, and choledocholithiasis is the most frequent benign pathology it addresses (1).

Choledocholithiasis can manifest with a diverse range of symptoms, and ERCP with sphincterotomy (ES) has demonstrated favorable outcomes, even in elderly patients (2-4). Despite the widespread use of this technique and its positive results, studies have linked the performance of ES associated with ERCP to late complications such as cholangitis and pancreatitis, with a variable but typically approximately 10% incidence (5,6).

Biliary duct stones may originate from the gallbladder through the migration of gallstones into the bile duct or can form *de novo* on the biliary epithelium (7). Recurrent choledocholithiasis is defined as stones reappearing at least 6 months after their prior extraction via ERCP, mostly due to the formation of new stones in the biliary tract caused by duodenal reflux following sphincterotomy (8).

While most patients with gallstones remain asymptomatic throughout their lives, 10% to 25% of them will experience complications, with an annual risk of 2–3% (9). Between 10% and 18% of patients requiring cholecystectomy concurrently have stones in the bile duct (10). The diagnostic confirmation is primarily through imaging studies, and the American Society for Gastrointestinal Endoscopy and the Society of American Gastrointestinal and Endoscopic Surgeons (ASGE-SAGES) has established a probability score for suspected choledocholithiasis: very strong [common bile duct (CBD) stone on ultrasound, bilirubin >4 mg/dL]; strong (CBD >6 mm, bilirubin 1.8–4 mg/dL); and moderate (abnormal liver function tests other than bilirubin, age >55 years, previous acute biliary pancreatitis) (11).

Once the diagnosis is confirmed, preoperative ERCP-ES followed by laparoscopic cholecystectomy (LC) is the most utilized method in clinical practice (9,12).

Elective cholecystectomy is recommended for the treatment of recurrent biliary colic, acute cholecystitis, prevention of pancreatitis, or choledocholithiasis (13). However, there is controversy regarding its efficacy in preventing long-term biliary events after ERCP with sphincterotomy (14). 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 (15). 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 (16).

The aim of this study is to establish the relationship between undergoing ERCP-ES in elderly patients, whether they have had a previous cholecystectomy or not, and the development of medium to long-term biliopancreatic

Highlight box

Key findings

- In aged patients, cholecystectomy is effective in reducing the incidence of acute cholecystitis after endoscopic retrograde cholangiopancreatography (ERCP) procedure for benign biliopancreatic pathology.
- But is associated with a higher risk of post-ERCP choledocholithiasis and acute cholangitis.

What is known and what is new?

- 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.

What is the implication, and what should change now?

- In aged and frails patients, prophylactic cholecystectomy should not be indicated systematically.

pathology. We present this article in accordance with the STROBE reporting checklist (available at https://ls.amegroups.com/article/view/10.21037/ls-23-19/rc).

Methods

A retrospective study was conducted, analyzing the medical records and imaging studies of patients who underwent ERCP 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 were selected, resulting in a cohort of 164 patients. All of them had a minimum follow-up of more than two years, with the aim of avoiding cases with undiagnosed biliopancreatic malignant pathology.

These patients were divided into two groups based on a history of prior cholecystectomy, performed for symptomatic cholelithiasis, before the initial ERCP (index ERCP): Group A [pre-ERCP 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.

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.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Clinical Trials and Ethics Board of Valladolid University (No. PI 18-889) and individual consent for this retrospective analysis was waived.

Statistical analysis

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. 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.

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% CIs) using the forward stepwise method of Wald.

Results

The demographic characteristics of the study patients are presented in *Table 1*.

Both groups were homogeneous in terms of mean age, sex, and associated comorbidities, with the most frequent comorbidities being hypertension, diabetes mellitus, and smoking habit. The only variable with a statistically significant value was a history of foregut surgery, with 11 procedures in Group A compared to none in Group B (P=0.002) (*Table 1*).

The mean follow-up was 75 months (range, 21–170 months) for Group A and 89 months (range, 24–235 months) for Group B (without statistically significant). A total of 199 ERCPs were analyzed (164 index, 35 subsequent).

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 (16.00%) (P=0.005) (*Table 2*).

Overall, the most common indication was cholestatic syndrome (50 cases, 30.48%), with 21 patients in Group A (23.60%) *vs.* 29 patients in Group B (38.67%). Regarding the most common pathology found in the index ERCP, choledocholithiasis topped the list, with 53 patients in Group A (59.55%) compared to 39 patients in Group B (52.00%), showing significant differences (P=0.008) (*Table 2*).

Biliary duct dilation was documented in 71 patients in Group A (79.78%) *vs.* 50 patients in Group B (66.67%). Concerning variables related to the procedure, there were no significant differences in stent placement, precut performance, cytology collection, or endoscopic diversion

Table 1 Characteristics of patients

Characteristics	Group A (N=89)	Group B (N=75)	P value
Sex (men/women)	29/60	31/44	0.24
Age, years, median ± SD	84±3.28	86±4.20	>0.99
Advanced liver disease, n (%)	1 (1.12)	4 (5.33)	0.11
Hypertension, n (%)	63 (70.79)	54 (72.00)	0.86
Diabetes mellitus, n (%)	16 (17.98)	18 (24.00)	0.34
Obesity, n (%)	11 (12.36)	7 (9.33)	0.53
Abuse alcohol intake, n (%)	5 (5.62)	5 (6.67)	0.78
Smoking habit, n (%)	12 (13.48)	8 (10.67)	0.58
Previous foregut surgery, n (%)	11 (12.36)	0	0.002
Peptic ulcer, n (%)	14 (15.73)	10 (13.33)	0.66
Inflammatory bowel disease, n (%)	1 (1.12)	0	0.35
Chronic pancreatitis, n (%)	1 (1.12)	2 (2.67)	0.46
Biliary duct dilation, n (%)	71 (79.78)	50 (66.67)	0.058

Group A: pre-ERCP cholecystectomy. Group B: without previous cholecystectomy. ERCP, endoscopic retrograde cholangiopancreatography.

Table 2 ERCP variables

Variables	Group A (N=89)	Group B (N=75)	P value
ERCP indication, n (%)			
Acute pancreatitis	17 (19.10)	15 (20.00)	0.47
Choledocholithiasis	27 (30.34)	12 (16.00)	0.001
Cholestasis/jaundice	21 (23.60)	29 (38.67)	0.02
Cholangitis	20 (22.47)	12 (16.00)	0.005
Biliary leak	1 (1.12)	0	0.35
Cholecystopancreatitis	0	4 (5.33)	0.53
Biliary colic	1 (1.12)	3 (4.00)	0.23
Hydatic cyst	1 (1.12)	0	>0.99
others	1 (1.12)	0	0.35
ERCP diagnosis, n (%)			
Normal biliary duct	1 (1.12)	2 (2.67)	0.85
Choledocholithiasis	53 (59.55)	39 (52.00)	0.008
Biliary sludge	17 (19.10)	16 (21.33)	0.54
Benign stricture	14 (15.73)	17 (22.67)	0.45
Biliary leak	2 (2.25)	0	0.01
Others	2 (2.25)	1 (1.33)	0.62
Successive ERCP, n (%)	28 (31.46)	7 (9.33)	0.001

Group A: pre-ERCP cholecystectomy. Group B: without previous cholecystectomy. ERCP, endoscopic retrograde cholangiopancreatography.

Table 3 Long-term benign post-ERCP complications

Variables	Group A (N=89)	Group B (N=75)	P value
Overall complications, n (%)	28 (31.46)	13 (17.33)	0.001
Acute cholecystitis, n (%)	0	10 (13.33)	0.09
Acute pancreatitis, n (%)	1 (1.12)	0	0.60
Choledocholithiasis, n (%)	15 (16.85)	2 (2.67)	0.008
Choledocholithiasis successive episodes, n (%)	5 (5.62)	0	
Cholangitis, n (%)	5 (5.62)	1 (1.33)	0.03
Cholangitis successive episodes, n (%)	2 (2.25)	–	
Median complications time (months)	47	31	0.001
Median choledocholithiasis time (months)	50	31	0.003

Group A: pre-ERCP cholecystectomy. Group B: without previous cholecystectomy. ERCP, endoscopic retrograde cholangiopancreatography.

from the bile duct to the digestive tube.

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 (*Table 3*).

Among them, choledocholithiasis was the most common, with a total of 22 cases, 20 in Group A (22.47%) *vs.* 2 in Group B (2.67%) (P=0.008).

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 *vs.* 31 months in Group B (P=0.003).

Similarly, in the cholecystectomized group, more ERCPs were repeated [31.46% *vs.* 9.33% (P=0.001)] (*Table 2*).

There were 10 cases of acute cholecystitis in group B (13.33%), undergoing surgery. The average time between ERCP and surgery was 8 months.

Kaplan-Meier curves were used to illustrate the survival of patients in the sample (N=164) according to the complications they developed (choledocholithiasis and cholangitis) (*Figures 1*,*2*).

The Cox logistic regression method was employed to find a model that predicts or estimates complications in elderly patients regarding the history of cholecystectomy to provide causal-effect relationships and enable individualized decision-making for each patient.

The variables that were included in the predictive model with Wald >6.32, with statistical significance P value <0.012, and that predicted the time of event occurrence (recurrent choledocholithiasis) are as follows: repetition of ERCP, post-ERCP pancreatitis, and ascending cholangitis.

The survival HRs found with the model for the study sample (n=164) are distributed as follows: (I) HR <1, number of patients: 29; (II) HR >1, number of patients: 8; and (III) 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 P<0.001. 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).

Discussion

In general, prophylactic cholecystectomy following ERCP-ES for benign biliopancreatic pathology is considered to reduce the subsequent incidence of biliary and pancreatic events (17-19). However, this therapeutic approach in elderly patients remains a topic of ongoing debate (17). 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 (20,21).

Furthermore, the prevalence of cholecystectomy after ERCP for choledocholithiasis is only 22% and 8% in patients aged ≥75 years and ≥85 years, respectively. The main reason for this could be the comorbidity burden or frailty of elderly patients, likely due to the comorbidities

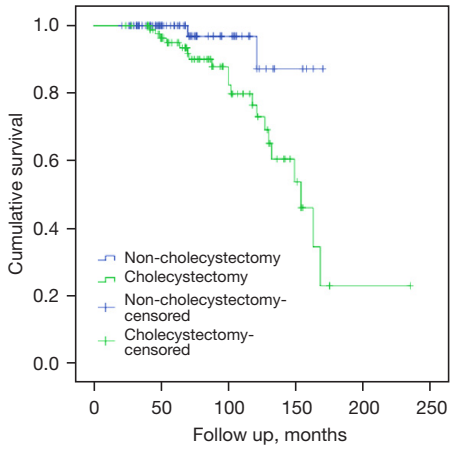

Figure 1 The cumulative risk, as determined by Kaplan-Meier analysis, for the occurrence of choledocholithiasis is 154 months in group A, with a 95% CI of 131.69–176.98. In group B, the cumulative risk is 162 months, with a 95% CI of 151.6–172.6. Group A: pre-ERCP cholecystectomy. Group B: without previous cholecystectomy. CI, confidence interval; ERCP, endoscopic retrograde cholangiopancreatography.

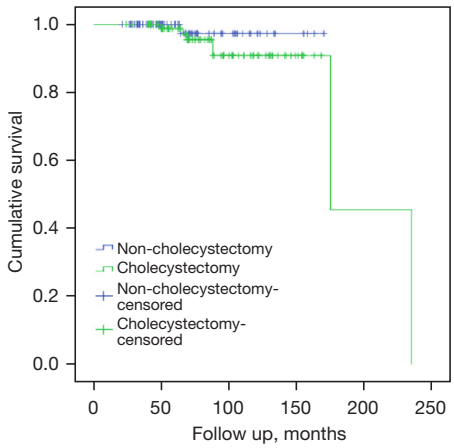

Figure 2 The cumulative risk determined using Kaplan-Meier analysis, for the occurrence of cholangitis is 193 months in group A, with a mean time and a 95% CI of 150.81–235.31. In group B, the mean time is 167 months, with a 95% CI of 161.59–172.67. Group A: pre-ERCP cholecystectomy. Group B: without previous cholecystectomy. CI, confidence interval; ERCP, endoscopic retrograde cholangiopancreatography.

and frailty associated with advanced age (22).

Nevertheless, based on the risk of complications when deferring post-ERCP cholecystectomy, some authors recommend an active approach even in this patient population if there are no absolute contraindications to anesthesia or surgery (17). This study, a meta-analysis with a large number of cases, finds that prophylactic cholecystectomy reduces the incidence of acute cholecystitis, cholangitis, pancreatitis and biliary events after ERCP. However, the average age of the included data series ranges between 48–85 years and only one of them has an average age greater than 80 years.

Various risk factors related to the development of biliary complications after ERCP have been identified, such as the presence of large stones, the use of lithotripsy, and bile duct dilation (23,24). In our cohort, although bile duct dilation was observed in 73.78% of the index ERCPs, this variable was not identified as a risk factor associated with increased complications.

Overall, the incidence of medium/long-term complications after ERCP is approximately 10% (5,25). Sousa *et al.*, in a retrospective study of 131 patients with a mean age of 82 years, found a post-ERCP complication rate of 13%. Fewer biliary events were reported in patients who had a cholecystectomy (7% *vs.* 24%) (22). In our cohort, we found an overall incidence of post-ERCP complications of 18.29%, which was higher in the previously cholecystectomized group (30.33% *vs.* 4%). Therefore, in our model, prior cholecystectomy was associated with a higher incidence of post-ERCP biliary events.

The most frequent complication found was recurrent choledocholithiasis followed by ascending cholangitis. While repetition of ERCP was effective and did not increase the mortality in our series for that reason. Kanamori *et al.* (26) presented a cohort of 250 patients over 80 years old, and they analyzed, among other factors, the performance of cholecystectomy, and concluding that it prevented the recurrence of subsequent complications such as cholangitis, choledocholithiasis, and pancreatitis. However, their analysis was global, and they did not compare age groups. The same is true in the meta-analysis conducted by Mc Geehan (17), where only one of the included series grouped patients over 80 years old.

On the other hand, Heo *et al.* (27) designed a prospective study in patients who underwent ERCP for choledocholithiasis and randomized them for prophylactic cholecystectomy. In their conclusions, cholecystectomy logically reduced the risk of cholecystitis but not the risk of recurrent cholangitis. The same result was found by Song *et al.* for the recurrence of choledocholithiasis in a case-control study (28). Our data confirm these findings.

Yasui *et al.* (15) followed a cohort of 327 patients for

10 years, with 77 over 80 years old, and concluded that they do not recommend intervening after ERCP in patients over 80 years old. The overall biliary complications were significantly lower in cholecystectomized patients than in patients with the gallbladder *in situ* in the young group (7.5% *vs.* 21.7%, P=0.0037), but not different in the elderly group, like the findings in our study, which also has a longer follow-up range.

Cui *et al.*'s study (29) did not differentiate between age groups, presented 164 noncholecystectomized patients, of which only 44 were found to have gallstones. They concluded that prophylactic cholecystectomy should only be recommended in patients with gallstones due to the high risk of developing cholecystitis and that prophylactic cholecystectomy could not be recommended for all patients after ERCP.

Interestingly, in our cohort, although the number of post-ERCP complications are higher in cholecystectomized patients, the complications occurred later in this group of patients than in noncholecystectomized patients.

Limits of the study

A limitation of our study is its retrospective nature, so the pre-ERCP cholecystectomy group was not randomized, and for this reason, there may be selection and analysis biases. Additionally, data were 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.

Our data are based on a cohort of patients treated at our center but reflect the demographics of elderly patients in our setting. Obviously, a larger sample size would allow better generalization of the results.

Conclusions

In conclusion, based on the data from this study, patients over 80 years old who have undergone a previous cholecystectomy present higher benign biliary complication after an initial episode requiring ERCP with associated sphincterotomy than those who have not undergone cholecystectomy. Therefore, we believe that the indication for prophylactic cholecystectomy in this group of patients should not be performed routinely following a benign biliary event requiring ERCP with sphincterotomy. Patients with a history of upper digestive tract surgery and acute cholecystitis may benefit from prophylactic cholecystectomy, while a "watch and wait" approach could be a good option for others.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://ls.amegroups.com/article/view/10.21037/ls-23-19/rc

Data Sharing Statement: Available at https://ls.amegroups.com/article/view/10.21037/ls-23-19/dss

Peer Review File: Available at https://ls.amegroups.com/article/view/10.21037/ls-23-19/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://ls.amegroups.com/article/view/10.21037/ls-23-19/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Clinical Trials and Ethics Board of Valladolid University (No. PI 18-889) and individual consent for this retrospective analysis was waived.

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