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Effects of cholecystectomy on recurrent biliary complications after endoscopic treatment of common bile duct stone: a population-based cohort study

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Abstract

Background The aim of this study was to evaluate the benefits of cholecystectomy on mitigating recurrent biliary complications following endoscopic treatment of common bile duct stone.

Methods We used the data from the Taiwan National Health Insurance Research Database to conduct a population-based cohort study. Among 925 patients who received endoscopic treatment for choledocholithiasis at the first admission from 2005 to 2012, 422 received subsequent cholecystectomy and 503 had gallbladder (GB) left in situ. After propensity score matching with 1:1 ratio, the cumulative incidence of recurrent biliary complication and overall survival was analyzed with Cox's proportional hazards model. The primary endpoint of this study is recurrent biliary complications, which require intervention.

Results After matching, 378 pairs of patients were identified with a median follow-up time of 53 (1–108) months. The recurrent rate of biliary complications was 8.20% in the cholecystectomy group and 24.87% in the GB in situ group ($p < 0.001$). In the multivariate Cox regression analysis, the only independent risk factor for recurrent biliary complications was GB left in situ (hazard ratio [HR] 3.55, 95% CI 2.36–5.33).

Conclusions Cholecystectomy after endoscopic treatment of common bile duct stone reduced the prevalence of recurrent biliary complications.

Keywords Common bile duct stone · Endoscopic retrograde cholangiopancreatogram · Cholecystectomy · Recurrence

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Gallstone is a common disease all over the world, though its prevalence and etiology differ among countries. Compared with a higher incidence of around 15% in the American population, for example, the incidence of the disease is slightly lower in Taiwan, ranging from 5.0 to 13.2% in different population subgroups [1–3]. In this population, common bile duct (CBD) stone accounted for 10–15%. However, some had primary bile duct stone not associated with GB stone, which occurs especially in Asian populations [4].

First developed in 1974, endoscopic treatment has become the treatment of choice for CBD stone [5, 6] and gallstone-related cholangitis [7]. The performance of cholecystectomy was advocated for following endoscopic treatment for common bile duct stone in a previous meta-analysis, which included several heterogeneous randomized trials [8]. Most western guideline recommended cholecystectomy after endoscopic clearance of CBD [9–11]. However, some studies have recently shown controversial results regarding its use in Asian populations, especially for the treatment of recurrent CBD stone and cholangitis [12–16]. Although cholecystectomy was recommended for this population, some patients still take the wait-and-see policy in clinical settings in Taiwan [17]. However, recurrent biliary complications may lead to possible severe complications, requiring the use of invasive treatments such as surgical, endoscopic, or percutaneous biliary procedures, and may cause excessive medical costs [18]. No previous population-based study for this topic has ever been conducted, to our knowledge. Thus, in this study, we designed a cohort study in Taiwan to understand the effects of cholecystectomy on recurrent biliary complications after endoscopic treatment for CBD stone using information from a research database.

Methods

Data source

The National Health Insurance program in Taiwan was launched on March 1, 1995. This program is compulsory and covers more than 99% of Taiwan's population. Taiwan's National Health Insurance research database (NHIRD) contains registration files and original claims data for reimbursement purposes from the program [19]. The dataset was released for scientific research purposes after de-identification and anonymization to protect subject privacy. Most interestingly, the dataset received had complete records of NHI procedure codes. The NHI procedure codes are the foundations of the institute claims for government reimbursement. There is an independent peer review evaluation system for the indication of the procedure based on the medical records from the hospital. If there are no enough reasons for the procedure, the institute will not be paid, and may even incur a severe penalty from the Bureau of National Health Insurance (BNHI). This study was approved by the Ethics Institution Review Board of Chang Gung Memorial Hospital.

The Longitudinal Health Insurance Database 2005 (LHID 2005) is a subset of the NHIRD that contains data of 1,000,000 beneficiaries enrolled in year 2005. The Registry for Beneficiaries (ID) of the NHIRD contains data from the year 1996 to 2013 (http://www.nhi.gov.tw/english/index.aspx).

Study population

This was an observational retrospective cohort study. Its main goal was to identify patients with first episodes of common bile duct stone who were treated with endoscopic treatment and who never received cholecystectomy. We identified all patients who were admitted with the diagnosis of cholelithiasis (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9CM] codes 574) and who underwent an endoscopic biliary procedure during the same admission between January 1, 2005 and December 31, 2013. We identified inpatient order records with specific NHI procedure codes to pinpoint the endoscopic biliary procedures, which included endoscopic retrograde cholangiopancreatography (ERCP), endoscopic retrograde biliary drainage (ERBD), endoscopic nasobiliary drainage (ENBD), endoscopic sphincterotomy, endoscopic balloon sphincteroplasty, and endoscopic papillotomy with or without stone removal (Supplementary Table S1). The first day of the index admission is defined as the index date. Patients with previously diagnosed malignant disease (ICD-9-CM codes 140-208) were excluded. Furthermore, to reduce the influence of other underlying biliary conditions, patients who had records of any benign biliary disease (ICD-9-CM codes 574,575,576) or who received any type of cholecystectomy were excluded from this study (Supplementary Table S2). Patients who were younger than 18 years of age were also excluded, as were those with a follow-up period of less than 1 year after the index day.

Outcome and comorbidities

The primary endpoint of this study was recurrent biliary complications that required intervention. The recurrent date was defined as the first day the patient admitted with the diagnosis of cholelithiasis (ICD code 574) and received an endoscopic, percutaneous, or surgical intervention, other than cholecystectomy. The relevant procedures were detected based on NHI procedure code. Cholecystitis is

excluded from the outcome measurement because there would be bias in the cholecystectomy group if it was included. After index day, any patients who received any type of cholecystectomy before recurrence of biliary complications were assigned to the cholecystectomy group. Otherwise, patients were assigned to the GB in situ group. Both groups were followed up until the date of recurrent biliary complication, death, or the end of 2013.

Death was defined as any patients who demonstrated documented death in inpatient expenditures, by admission and emergency visit with major disease, or those who dropped out from the NHI program within 28 days. Comorbidities and known risk factors of cholelithiasis were defined as more than one outpatient record or any inpatient records that included hypertension (ICD-9-CM codes 401–405), diabetes mellitus(DM) (ICD-9 code 250), hyperlipidemia (ICD-9-CM codes 272), hepatitis B (ICD-9-CM codes V02.61,070.20, 070.22, 070.30, and 070.32), hepatitis C (ICD-9-CM codes V02.62,070.41, 070.44, 070.51, and 070.54), menopause status (ICD-9-CM codes V49.81,627.2, 627.8, and 627.9), chronic liver disease (ICD-9-CM codes 571) or chronic kidney disease necessitating chronic dialysis (confirmed by Registry for Catastrophic Illness Patient Database, a subpart of the NHIRD).

Statistical analysis

All analyses were performed using R (v3.3.1). The association between cholecystectomy and demographic factors, comorbidities, and risk factors were analyzed by Chi-square test for categorical variables and by Student's *t* test for continuous variables. To eliminate the channeling bias for cholecystectomy, we used propensity score matching with nearest neighbor and a 1:1 ratio between the two groups with R package "MatchIt" [20]. The parameters used for matching include age, gender, hypertension, diabetes mellitus, hyperlipidemia, hepatitis B, hepatitis C, menopause status, chronic liver disease, chronic kidney disease necessitating chronic dialysis use, and year of index admission. The cumulative incidence of recurrent biliary complication was analyzed with the Kaplan–Meier method and log-rank test for differences between the two groups, and plotted using R package "survminer." Univariate and multivariate analyses were analyzed with a Cox proportional hazard model to estimate the hazard ration (HR) with 95% confidence interval (CI) for recurrent biliary complication. The time to date of cholecystectomy was treated as a time-dependent covariate from index date in the Cox model. All statistical tests were two-sided, and *p*-values <0.05 were considered statistically significant.

Results

Between January 2005 and December 2013, we identified a total of 2629 patients who were admitted to hospitals with the diagnosis of cholelithiasis and who received endoscopic biliary procedures. A total of 1592 patients were excluded, including 441 patients who had malignant disease, 1150 patients who had benign biliary disease and/or cholecystectomy before the index date, and one patient was younger than 18 years old. An additional 112 patients were excluded because of having less than 1 year of follow-up (Fig. 1).

A total of 925 patients who had a first episode of cholelithiasis treated with an endoscopic biliary procedure were enrolled in the study cohort. Among them, 53.5% were male with a mean age of 62.31 years old [standard deviation (SD): 17.58]. The median follow-up time was 53 months (interquartile range, 47.9). There were 422 patients in the cholecystectomy group and 503 patients in the GB in situ group. Following propensity score matching, there were 378 patients allocated in each arm. Table 1 showed the distribution of demographic and comorbidities before and after matching. Before matching, older age, more DM, and hepatitis B were associated with GB in situ group patients. After matching, there were no significant differences in any of the considered factors between the two groups.

During the follow-up period, 125 patients had recurrent biliary complications for an overall recurrence rate of 19.8%. Figure 2 shows the cumulative incidence curve between the cholecystectomy and GB in situ groups. Patients who underwent cholecystectomy showed a significant lower cumulative incidence of biliary recurrence when compared with individuals in the GB in situ ($p < 0.001$). In both groups, we observed a peak of recurrent biliary complications occurring within the first year, with the recurrence rates for the cholecystectomy group and GB in situ group being 4.8 and 18.4%, respectively. The risk of recurrent biliary complications in those patients older than 65 years (hazard ration (HR): 1.53; 95% confidence interval (CI) 1.07–2.18, $p = 0.018$) and in the GB in situ group (HR: 2.62; 95% CI 1.74–3.94, $p < 0.001$) were significantly higher (Table 2). In multivariate analysis, only GB left in situ was the independent risk factor for recurrent biliary complication (HR: 3.55; 95% CI

2.36–5.33, $p < 0.001$) (Table 3). Although cholecystectomy showed an overall survival benefit (log-rank test, $p = 0.023$) (Fig. 3), this was not demonstrated in the Cox regression model (HR: 1.29; 95% CI 0.82–2.04, $p = 0.27$).

Discussion

Controversy still exists regarding whether cholecystectomy should be performed after endoscopic treatment for CBD stone for recurrent biliary complications. Previous studies have shown recurrent rates of biliary complications of 4.1–14.7% in cholecystectomy groups and 8.2–25.6% in GB in situ groups [16, 17, 21–24]. However, all of the studies that considered this issue were restricted to a single institution with a limited number of patients [16, 17, 22, 24]. This current study is based on the Taiwan NHIRD and thus, the patients are randomly selected from medical institutes all over the country, which lowers the physician-related bias. An additional advantage of use of the NHIRD is integrity of follow-up, because of high coverage in Taiwan. As long as the patient receives medical care in an institute covered by the NHI in Taiwan, the data will be collected. We also excluded patients who had history of benign biliary disease; in other words, these patients were all fresh cases of common bile duct stone. By doing this, we were able to identify the patients with records of cholecystectomy or recurrent biliary complications more clearly.

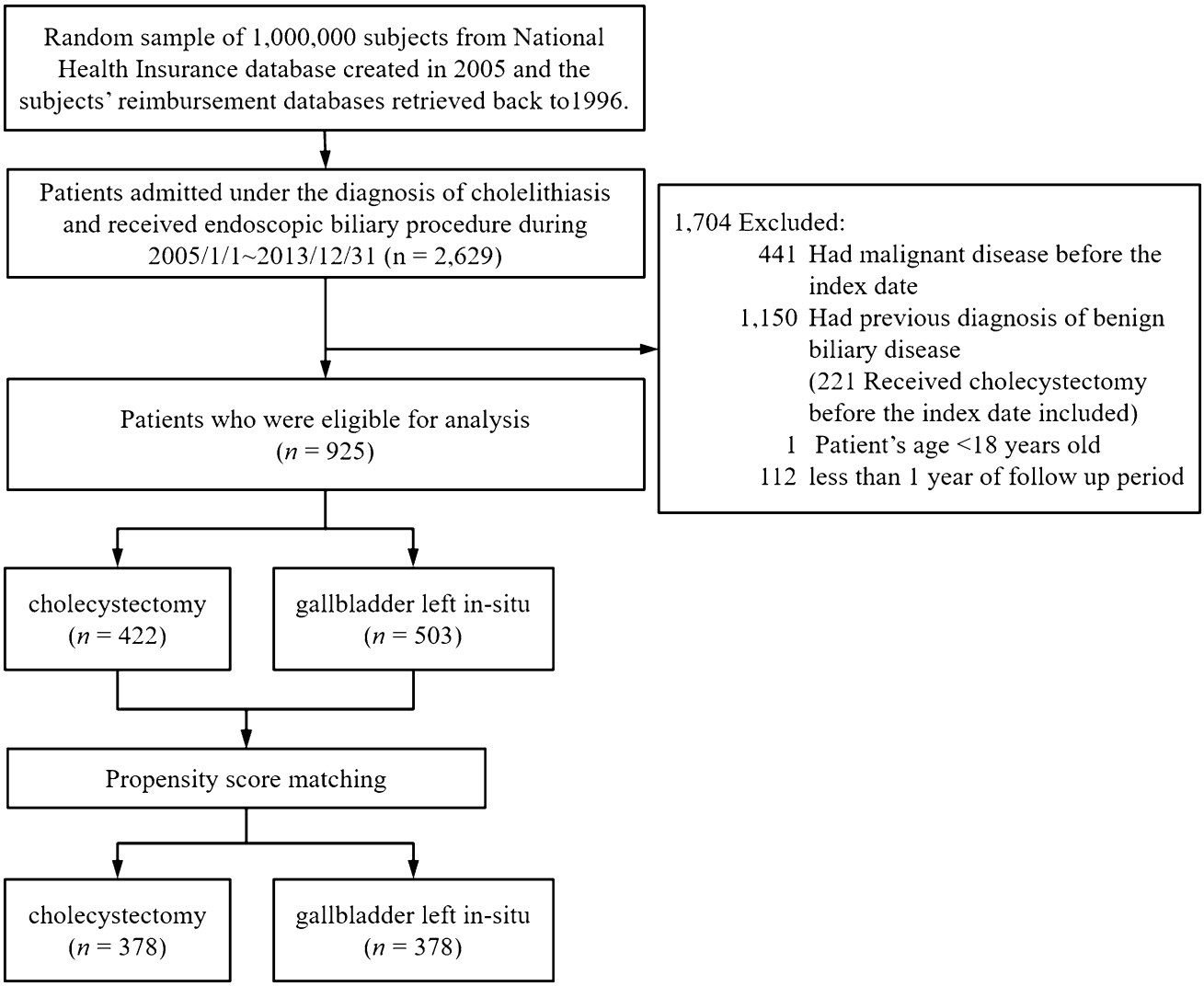

Fig. 1 The flow chart of patient selection and study design

Table 1 Clinical characteristics of patients who received endoscopic treatment for common bile duct stone

Characteristics	Unmatched				*p* value[b]	Propensity score matched[a]				*p* value[b]
	Cholecystectomy group		GB in situ group			Cholecystectomy group		GB in situ group		
	(*N* = 422)		(*N* = 503)			(*N* = 378)		(*N* = 378)		
Age, (mean ± SD)	59.44 ± 17.61		64.72 ± 17.21		*<0.001**	61.02 ± 17.03		61.70 ± 16.97		0.583
Gender (male)	227	53.79%	268	53.28%	0.929	200	52.91%	201	53.17%	1.000
Comorbidity										
HTN	233	55.21%	300	59.64%	0.197	215	56.88%	211	55.82%	0.826
DM	110	26.07%	174	34.59%	*0.006**	106	28.04%	109	28.84%	0.872
Hyperlipidemia	147	34.83%	192	38.17%	0.327	136	35.98%	141	37.30%	0.763
Hepatitis B	11	2.61%	30	5.96%	*0.021**	11	2.91%	9	2.38%	0.821
Hepatitis C	12	2.84%	20	3.98%	0.448	12	3.17%	10	2.65%	0.829
Menopause	46	10.90%	52	10.34%	0.865	42	11.11%	42	11.11%	1.000
Chronic liver disease	146	34.60%	196	38.97%	0.193	138	36.51%	137	36.24%	1.000
ESRD	8	1.90%	12	2.39%	0.777	8	2.12%	9	2.38%	1.000

GB gallbladder, *HTN* hypertension, *DM* diabetes mellitus, *ESRD* end-stage renal disease

* Statistically significant

[a] The factors used for propensity score matching including age, gender, hypertension, diabetes mellitus, hyperlipidemia, hepatitis B, hepatitis C, menopause status, chronic liver disease, chronic kidney disease who need chronic dialysis and year of index admission

[b] The continuous variable was analyzed with t test and categorical variables were analyzed with Chi-square test

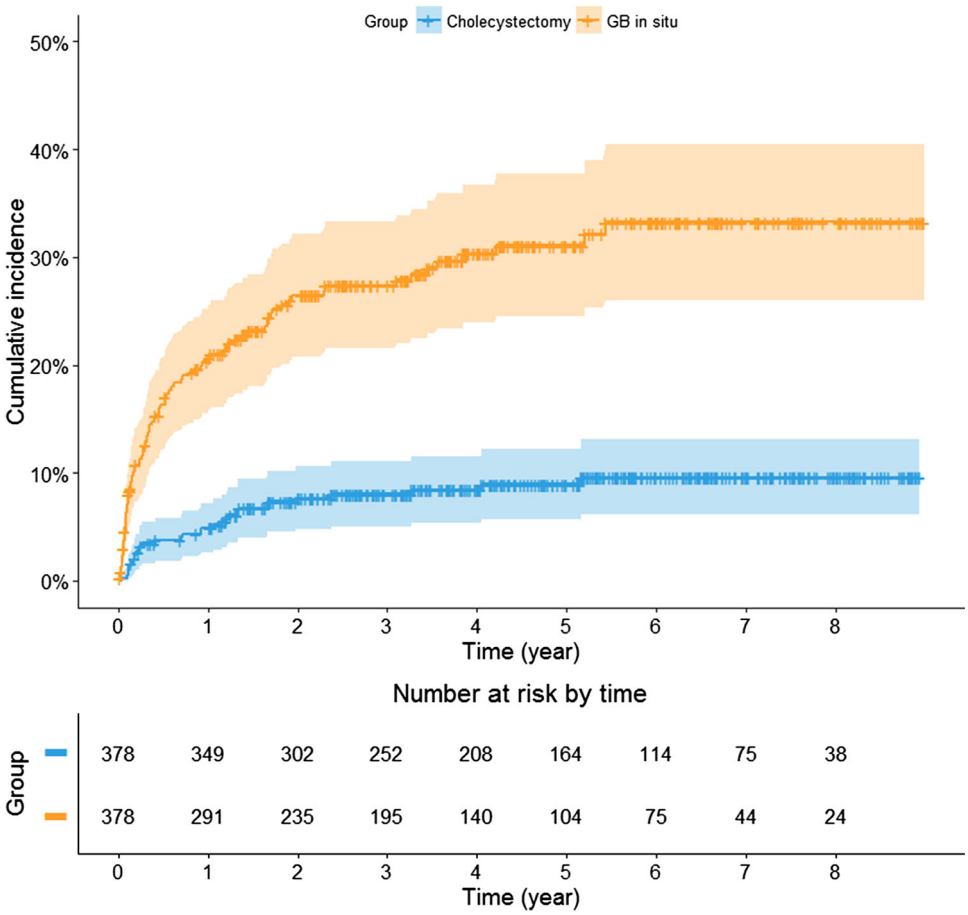

Fig. 2 The cumulative incidence curve with number at risk table of recurrent biliary complication between cholecystectomy group and GB in situ group ($p < 0.001$). *GB* gallbladder

Table 2 Univariate analysis for risk factors of recurrent biliary complication among propensity score matched groups

Variable	Recurrent cholelithiasis need intervention								
	No = 631		Yes = 125		*p* value[a]	Univariate analysis			
	N	%	*N*	%		Hazard ratio	(95% CI)		*p* value[b]
Age					*0.043**				
≤65 y/o	338	86.22	54	13.78		Reference			
>65 y/o	293	80.49	71	19.51		1.53	1.07	2.18	*0.018**
Gender					0.724				
Male	294	82.82	61	17.18		Reference			
Female	337	84.04	64	15.96		0.91	0.64	1.29	0.589
Gallbladder status[c]					*<0.001**				
Cholecystectomy	347	91.80	31	8.20		Reference			
GB in situ	284	75.13	94	24.87		2.62	1.74	3.94	*<0.001**
Comorbidities									
HTN					0.231				
No	282	85.45	48	14.55		Reference			
Yes	349	81.92	77	18.08		1.29	0.90	1.85	0.167
DM					0.081				
No	443	81.89	98	18.11		Reference			
Yes	188	87.44	27	12.56		0.68	0.45	1.05	0.081
Hyperlipidemia					0.281				
No	394	82.25	85	17.75		Reference			
Yes	237	85.56	40	14.44		0.80	0.55	1.17	0.249
Hepatitis B					0.555				
No	613	83.29	123	16.71		Reference			
Yes	18	90.00	2	10.00		0.59	0.15	2.38	0.457
Hepatitis C					0.389				
No	614	83.65	120	16.35		Reference			
Yes	17	77.27	5	22.73		1.41	0.58	3.46	0.449
Menopause					0.665				
No	559	83.18	113	16.82		Reference			
Yes	72	85.71	12	14.29		0.86	0.48	1.57	0.628
Chronic liver disease					0.312				
No	396	82.33	85	17.67		Reference			
Yes	235	85.45	40	14.55		0.80	0.55	1.17	0.248
ESRD					1.000				
No	616	83.36	123	16.64		Reference			
Yes	15	88.24	2	11.76		0.73	0.18	2.97	0.665

* Statistically significant

[a] The categorical variables were analyzed with Chi-square test

[b] The univariate analyses were analyzed with Cox's proportional hazard model

[c] Gallbladder status was analyzed as time-dependent covariate in Cox's proportional hazard model

Several important and interesting issues are discovered in this study.

First, our study found that patients older than 65 years of age demonstrated an increased risk for recurrent biliary complications following endoscopic treatment for CBD stone; but this was not defined as an independent associated factor.

Second, cholecystectomy following endoscopic biliary procedure for CBD stone will markedly decrease the incidence rate of recurrent biliary complications from 24.8

Table 3 Multivariate analysis for risk factors of recurrent biliary complications

Variable	Recurrent cholelithiasis needing intervention			
	Hazard ratio	(95% CI)		*p* value
Age				
≤65 y/o	1			
>65 y/o	1.35	0.88	2.06	0.168
Gender				
Male	1			
Female	0.86	0.59	1.25	0.429
Gallbladder status[a]				
Cholecystectomy	1			
GB in situ	3.55	2.36	5.33	*<0.001**
Comorbidities				
HTN				
No	1			
Yes	1.37	0.88	2.15	0.168
DM				
No	1			
Yes	0.67	0.42	1.07	0.091
Hyperlipidemia				
No	1			
Yes	0.78	0.51	1.19	0.241
Hepatitis B				
No	1			
Yes	0.84	0.20	3.52	0.807
Hepatitis C				
No	1			
Yes	1.53	0.61	3.86	0.367
Menopause				
No	1			
Yes	0.88	0.46	1.67	0.692
Chronic liver disease				
No	1			
Yes	0.87	0.58	1.29	0.483
ESRD				
No	1			
Yes	0.79	0.19	3.26	0.743

* Statistically significant

[a] Gallbladder status was analyzed as time-dependent covariate in Cox's proportional hazard model

to 8.2%. On the contrary, if the patient decided to leave GB in situ, they would have a higher recurrent biliary complication rate of up to 24.8%. However, overall survival is not affected by GB status after the index episode.

Third, although the risk of biliary complications in the cholecystectomy group is significantly decreased, they still can happen. Importantly, our study demonstrated the peak of recurrence is within several months, and seldom occurs after 2 years, with an overall 8.2% recurrence rate. Type 1 or 2 periampullary diverticulum and multiple CBD stones may explain the causes of recurrent biliary complications after combined endoscopic treatment and cholecystectomy [21]. The other possible explanation is that the residual CBD stones after cholecystectomy or in situ stimulate the formation of new stones in the biliary system.

Fourth, the surgical mortality rate for cholecystectomy was as low as 0.22–0.4% [25, 26], with major morbidities being around 5% [27]. In our study, the risk of recurrent biliary complication in those who were older than 65 years of age increased, and the severity of cholangitis is known to increase with age. The mortality of cholangitis in a recent series ranges from 0.5–24.1% [28]. Therefore, to prevent further recurrence in elderly patients, early cholecystectomy after endoscopic treatment for CBD stones may be justified as an effective approach.

Although we suggest that cholecystectomy could decrease the risk of biliary complications, there were still some limitations in this study. First, this study was unable to obtain patient medical records prior to 1995 because the NHI system had been initiated. Second, if any patients had received cholecystectomy more than 10 years ago, and had no related medical problems recorded in the NHIRD until 2005, such would be a source of bias. Third, several studies reported that it is not necessary to perform cholecystectomy in patients without evidence of GB stone to prevent biliary complications [13, 16, 22]. Because of the lack of detailed image reports, we couldn't identify if the patients in the GB in situ group still had gallstone. Finally, this study included only patients randomly selected from the Taiwanese population; thus, further study of population data from Western countries is still needed to provide a more comprehensive picture. Furthermore, a multicenter randomized control trial may still be needed to evaluate the benefit of cholecystectomy for patients with no residual gallstone after endoscopic removal of common bile duct stone.

In conclusion, our study shows that cholecystectomy significantly reduced the incidence of recurrent biliary complications—from 24.8 to 8.2%—in patients who received endoscopic treatment for common bile duct stone. Cholecystectomy should be recommended for these patients with acceptable surgical and anesthesia risk.

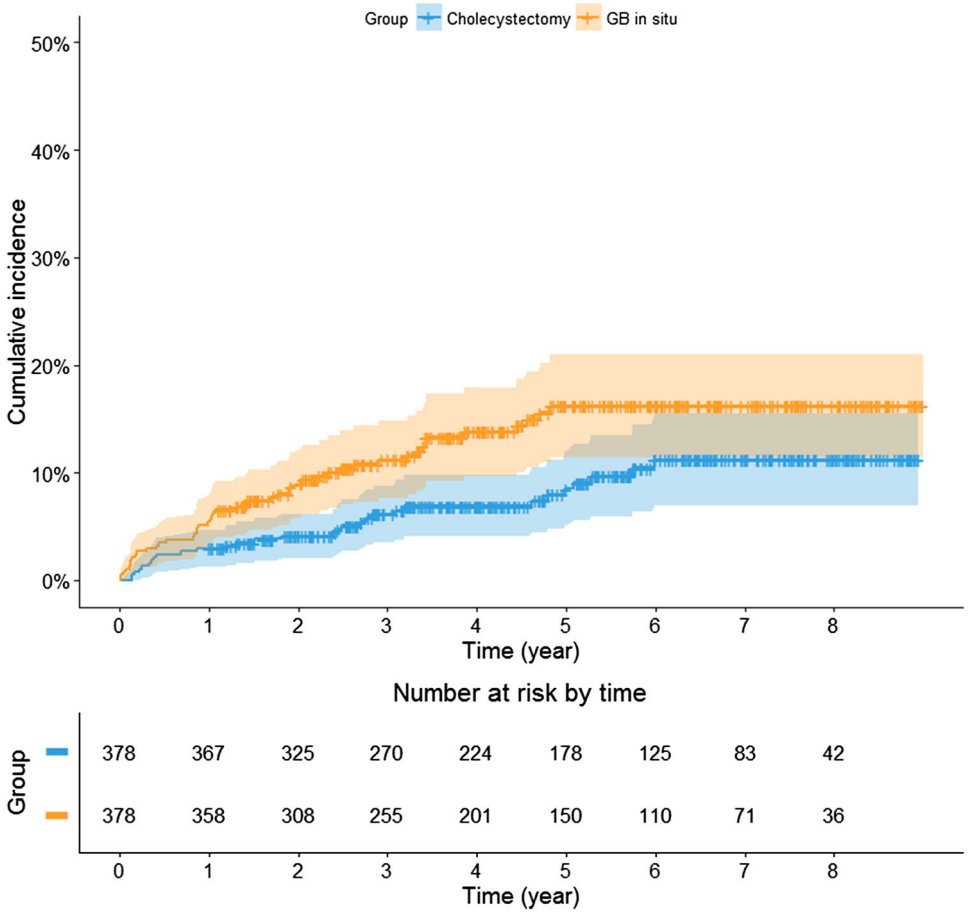

Fig. 3 The cumulative incidence curve with number at risk table of overall survival between cholecystectomy group and GB in situ group ($p = 0.023$). *GB* gallbladder

Compliance with ethical standards

Disclosures Chi-Tung Cheng, Chun-Nan Yeh, Kun-Chun Chiang, Ta-Sen Yeh, Kuan-Fu Chen, Shao-Wei Chen have no conflicts of interest or financial ties to disclose.

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