

# Treatment of Common Bile Duct Stones in Sweden 1989–2006: An Observational Nationwide Study of a Paradigm Shift

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### Abstract

*Background* The preferred strategies for treatment of common bile duct stones have changed from choledochotomy with cholecystectomy to sphincterotomy with or without cholecystectomy. The aim of the present study was to compare the effectiveness of these treatment strategies on a nationwide level in Sweden.

*Methods* All patients with hospital care for benign biliary diagnoses 1988–2006 were identified in Swedish registers. Patients with common bile duct stones and a first admission with choledochotomy and or endoscopic sphincterotomy from 1989 through 2006 comprised the study group. These patients were analyzed with respect to readmission for biliary diagnoses and acute pancreatitis.

*Results* Incidence of open and laparoscopic choledochotomy decreased from 19.4 to 5.2, whereas endoscopic sphincterotomy increased from 5.1 to 26.1 per 100,000 inhabitants per year, respectively. Among patients treated for common bile duct stones (n = 26,815), 60.0 % underwent cholecystectomy during the first hospital admission in 1989–1994, compared to 30.1 % in 2001–2006. The treatment strategy that included endoscopic sphincterotomy was associated with more readmissions for biliary diagnoses and increased risk for acute

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pancreatitis than the treatment strategy with choledochotomy. However, patients treated with endoscopic sphincterotomy and concurrent cholecystectomy at the index admission had the lowest risk of readmission.

*Conclusions* Cholecystectomy has been increasingly separated from treatment of bile duct stones, and endoscopic sphincterotomy has superseded choledochotomy as a first alternative for bile duct clearance in Sweden. In patients fit for surgery, clearance of the common bile duct can be combined with cholecystectomy, as it probably reduces the need for biliary related readmissions.

## Introduction

The prevalence of gallstone disease increases with age, and as many as one third of women and one fifth of men over the age of 60 years have gallstones [1, 2]. At cholecystectomy, 10-15 % of patients have common bile duct stones (CBDS) [3]. Recent guidelines for the treatment of CBDS recommend that in patients with symptoms and clinical evaluation suggesting ductal stones as a cause, stones should be extracted if possible [4]. In view of the increasing population age [5], more healthcare resources will be required for the treatment of patients with CBDS in the future. Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) has become an alternative to choledochotomy for treatment of CBDS in the past two decades [6-8]. Although favorable reports with laparoscopic choledochotomy and exploration through the cystic duct have been published [9–13], these techniques are used less extensively than ERCP/ES on a population-based level [8]. Changes in routine practice of CBDS treatment should be scrutinized against available evidence for the effectiveness of the methods, both in the

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short-term and long-term perspective. If possible, such analyses should include all individuals with diagnoses or procedures for CBDS within the population. The aim of the present study was to analyze time trends and consequences of treatment strategies for CBDS in Sweden 1989–2006 from data recorded in the Swedish National Register [14]. Patients with CBDS diagnosis and a code for bile duct intervention (choledochotomy, sphincterotomy, or both) were analyzed.

## Materials and methods

#### Study design

This study first provides incidence of cholecystectomy techniques and techniques used for treatment of CBDS, but the main theme was a pragmatic analysis of treatment strategies for CBDS. For this purpose, index admission was defined as the first hospital stay for each patient with a diagnosis of CBDS and a procedure code for CBD intervention (choledochotomy or ES or both). Patients with index admission and discharge data from 1 January 1989 to 31 December 2006 were included in the study group and were followed with respect to subsequent hospital admissions and, when relevant, date and cause of death. The database starts at 1 January 1988, allowing at least one year of observation without bile duct intervention before the index admission. Within the study group, the different treatment strategies for CBDS (choledochotomy with cholecystectomy or ES with or without cholecystectomy) were compared with respect to readmission with any biliary diagnosis (including acute pancreatitis), readmission with acute pancreatitis, and mortality.

#### Data acquisition

From the National Patient Register (NPR) [14] of the National Board of Health and Welfare in Sweden, information on age, sex, length of hospital stay, and procedures undertaken during hospital admissions for patients with biliary diagnoses from 1 January 1988 through 31 December 2006 were retrieved. The NPR provides information on procedures performed during an admission, but it does not specify the sequence in which different procedures are undertaken. Patients with diagnoses of malignant tumors of the stomach, liver, gall-bladder, bile duct, or pancreas were excluded. Information on date and (underlying) cause of death of

deceased patients was obtained from the Causes of Death Register. Patients were followed over time, and data from the two registers were linked through personal registration numbers unique for each citizen in Sweden. For all records reported to NPR, the data are checked for authenticity. A quality control at NPR [14] is conducted to confirm that compulsory variables (personal identification number, hospital, and main diagnosis) are reported. Obviously, incorrect data are corrected. In 2003, 0.9 % of all diagnoses and 0.5 % of acute somatic diagnoses were missing in the hospital stays reported.

Diagnoses and procedure codes

The diagnoses considered were as follows:

Biliary diagnoses: ICD 9: 574, 575, 576, 577A. ICD 10:
K 80 (including all subdiagnoses specified with third code nr), K81, K82, K83, K85
Acute pancreatitis diagnoses: ICD 9: 577A. ICD 10: K85
CBDS diagnoses: ICD 9: 574D-E-F. ICD10: K80.3, K80.4, K80.5
Cholecystectomy: 5350, -51, -52, -53, -56, -57, -59. JKA20, JKA21
Endoscopic sphincterotomy: 5388, 5394. JKE02
Choledochotomy: 5300, -02, -04, -06, -09, 5351, -52, -56, -57. JKB00, JKB01
Transcystic laparoscopic CBD exploration: JKB11

## Statistics

Incidence is reported as number of admissions or procedures per 100,000 inhabitants in Sweden during the year considered. Data are presented as median values with 25 and 75 percentiles, means and standard deviations, or proportions. Proportions were compared using the chi-square test or Fisher's exact test when appropriate. Cox regression survival curves were used to illustrate time to recurrent events. Differences between curves were tested with the log-rank test. Mortality within 90 days of index admission was calculated as standardized mortality ratio (SMR), using age-, gender-, and calendar year-specific death rates from Statistics Sweden [15]. The Standardized Mortality Ratio is presented as mean and 95 % confidence intervals, and it was used as mortality exceeds that of the background population up to 90 days after gallstone surgery [16]. Case fatality rate (CFR), i.e., deaths per 100 patients treated is given as comparison. SPSS version 16.0 (SPSS Inc. Chicago, IL) was used for all calculations.

#### Ethics

Approval for this study was obtained from the Regional Ethical Review Board of Umeå University, Umeå, Sweden, registration number: 05–147 M.

## Results

All admissions with benign biliary diagnosis

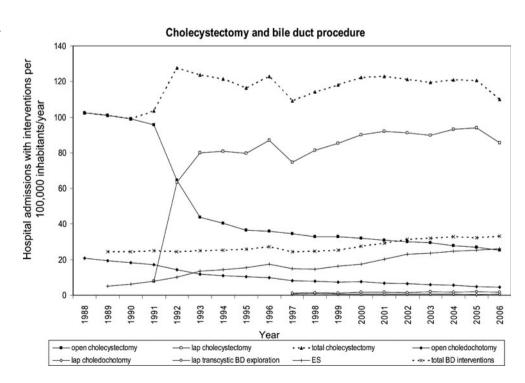
Between 1 January 1988 and 31 December 2006, 298,874 patients with 450,166 admissions for benign biliary diagnoses were identified. Figure 1 reports incidence of open and laparoscopic cholecystectomy, open and laparoscopic choledochotomy, and ES. The incidence of open cholecystectomy fell drastically from 1991 to 1993 (from 95.6 to 43.8 per 100,000 inhabitants per year) and then slowly declined to 25.3 per 100,000 inhabitants per year in 2006. Laparoscopic cholecystectomy reached a level of approximately 80 per 100,000 inhabitants per year very soon after its introduction in 1991 and increased to 85.6 per 100,000 inhabitants in 2006. Choledochotomy (open or laparoscopic) declined from 19.4 to 5.2 per 100,000 inhabitants per year from 1989 through 2006. For ES, an increase from 5.1 to 26.1 per 100,000 inhabitants per year took place from 1989 through 2006. Thus, the total annual number of CBD interventions increased from 24.5 per 100,000 inhabitants per year in 1989 to 31.3 per 100,000 inhabitants per year in 2006. In 2006, the incidence of open choledochotomy was 4.6 and laparoscopic choledochotomy 0.6 per 100,000 inhabitants per year. In addition, the incidence of laparoscopic transcystic exploration of CBD was 1.8 per 100,000 inhabitants per year.

#### Treatment strategy of CBDS in the study group

#### Patient characteristics

The study group comprised 26,815 patients. Table 1 illustrates age and gender of these patients during three six-year periods covered by the audit. An overall increase in number of patients and a modest but statistically significant change in age distribution among patients can be seen, with more patients below the age of 60 and above the age of 80 treated for CBDS in 2001-2006 compared to the previous two periods. Women comprised 60 % (15 976) of all patients, and were younger than men (36.0 % of all women and 23.4 % of all men were below 60 years of age). Patients older than 80 years of age were significantly more often submitted to treatment for CBDS in 2001-2006, than in 1989-1994. Table 2 shows number of patients treated according to strategies including choledochotomy, ES, or both procedures at index admission during the three time periods. Although the percentage of choledochotomy (laparoscopic and open) declined from

Fig. 1 Hospital admissions (per 100,000 inhabitants per year) with cholecystectomy, choledochotomy, and endoscopic sphincterotomy (ES) from 1988 to 2006. *BD* bile duct, *Lap* laparoscopy, *ES* endoscopic sphincterotomy, *total BD interventions* choledochotomy + transcystic exploration + endoscopic sphincterotomy



<b>Table 1</b> Age and gender of patients with index admission for common bile duct stones treated with choledochotomy, endoscopic sphincterotomy, or both procedures	Patient age versus time, years	Men	Women	Total
	All periods			
	0–59	2,533 (23.4)	5,756 (36.0)	8,289 (30.9)
	60–79	5,507 (50.8)	6,075 (38.0)	11,582 (43.2)
	80+	2,799 (25.8)	4,145 (26.0)	6,944 (25.9)
	Total	10,839 (100.0)	15,976 (100.0)	26,815 (100.0)
	1989–1994			
	0–59	632 (19.3)	1,718 (34.9)	2,350 (28.7)
	60–79	1,892 (57.8)	2,133 (43.3)	4,025 (49.1)
	80+	752 (23.0)	1,072 (21.8)	1,824 (22.2)
	Total	3,276 (100.0)	4,923 (100.0)	8,199 (100.0)
	1995–2000			
	0–59	781 (23.0)	1,799 (35.8)	2,580 (30.6)
	60–79	1,753 (51.7)	1,938 (38.5)	3,691 (43.8)
	80+	859 (25.3)	1,294 (25.7)	2,153 (25.6)
Numbers within parentheses are percentages There was a significant difference ( $p < 0.001$ ) in age proportions in men, women, and total number of patients between the time periods for all comparisons	Total	3,393 (100.0)	5,031 (100.0)	8,424 (100.0)
	2001–2006			
	0–59	1,120 (26.9)	2,239 (37.2)	3,359 (33.0)
	60–79	1,862 (44.7)	2,004 (33.3)	3,866 (37.9)
	80+	1,188 (28.5)	1,779 (29.5)	2,967 (29.1)
	Total	4,170 (100.0)	6,022 (100.0)	10,192 (100.0)

 Table 2
 Number of patients with common bile duct stones, treated according to strategies including choledochotomy, endoscopic sphincterotomy (ES), or both procedures versus time period

Time period	ES	Choledochotomy	ES and choledochotomy	Total patients
1989–1994	2,986 (36.4)	5,017 (61.2)	196 (2.4)	8,199 (100.0)
1995-2000	5,331 (63.3)	2,876 (34.1)	217 (2.6)	8,424 (100.0)
2001-2006	7,969 (78.2)	1,999 (19.6)	224 (2.2)	10,192 (100.0)
Total	16,286 (60.7)	9,892 (36.9)	637 (2.4)	26,815 (100.0)

The distribution of procedures differs significantly between time periods (p < 0.001)

61.2 % (5,017 of 8,199) of all interventions 1989–1994 to 19.6 % in 2001–2006, still 1,999 of 10,192 patients were treated with choledochotomy during the latter time period, and 91.5 % of these patients underwent an open procedure. Patients treated with concurrent cholecystectomy and ES at index admission were younger (52 years; range: 4-92 years), than patients treated with choledochotomy (65 years; range: 0-97 years) or ES and choledochotomy (69 years; range: 16-93 years) during the whole audit period.

#### Cholecystectomy at index admission

Table 3 illustrates cholecystectomy in relation to index admission for CBDS. The percentage of all patients who underwent cholecystectomy in the interval from one year before until six years after index admission declined from 71.4 % (5,849 of 8,189 patients) in 1989–1994 to 57.0 % (4,802 of 8,424 patients) in 1995–2000. Furthermore, cholecystectomy was performed less frequently at index admission during the latter part of the audit. In 1989–1994, 60.0 % of all patients had a cholecystectomy during index admission, compared to 30.1 % in 2001–2006. Of 4,919 cholecystectomies performed during the index admission in 1989–1994, 4,614 (93.8 %) were done as open procedures, compared to 1,769 of 3,072 cholecystectomies (57.6 %) at index admission in 2001–2006. Of all 9,892 patients with choledochotomy at index admission, 8,996 patients (90.9 %) underwent cholecystectomy during that admission, compared to 1,647 of 16,286 patients (10.1 %) with ES at index admission.

#### Readmissions

Figures 2 and 3 illustrates risk of first readmission, related to time from index admission to first readmission with

Time period	А	В	С	D	Total patients
1989–1994	430 (5.2)	4,919 (60.0)	500 (6.1)	2,350 (28.7)	8,199 (100.0)
1995-2000	497 (5.9)	3,197 (38.0)	1,108 (13.2)	3,622 (43.0)	8,424 (100.0)
2001-2006 <sup>a</sup>	459 (4.5)	3,072 (30.1)	1,626 (16.0) <sup>a</sup>	5,035 (49.4)	10,192 (100.0)
Total	1,386 (5.2)	11,188 (41.7)	3,234 (12.1)	1,1007 (41.0)	26,815 (100.0)

 Table 3 Cholecystectomy (open and laparoscopic) before, during, and after index admission with treatment of common bile duct stones versus time period

Numbers within parentheses are percentages

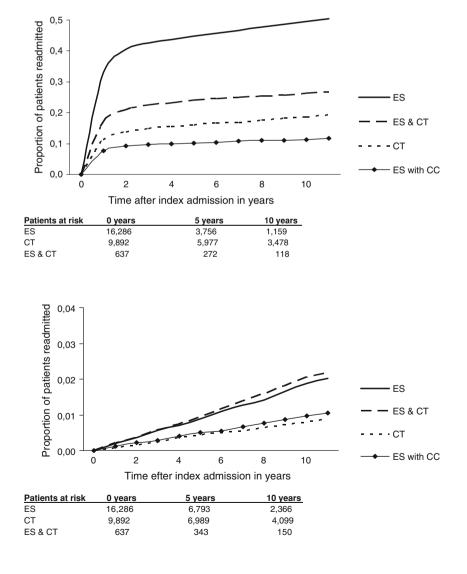
A within one year before index admission, B during index admission, C within six years after index admission, D no cholecystectomy within six years after index admission

<sup>a</sup> No patients 2001–2006 are followed for six years. The difference in distribution of cholecystectomy between A, B, C, and D in the three time periods is highly significant (p < 0.001)

biliary diagnosis and/or acute pancreatitis. Patients subjected to the treatment strategy of ES with or without cholecystectomy at index admission were significantly more likely to require readmission with biliary diagnosis than patients who had undergone the treatment strategy including choledochotomy. If cholecystectomy was performed during the index admission, the risk for readmission was reduced considerably. Ten years after index admission with ES strategy, 46 % of patients had been readmitted at least once with a biliary diagnosis, compared to 18 % of

Fig. 2 Risk of first readmission with biliary diagnosis including acute pancreatitis, related to time after index admission of study group (n = 26,815patients). ES treatment including endoscopic sphincterotomy with or without cholecystectomy; CT treatment including choledochotomy with previous or concurrent cholecystectomy. Patients at risk number of patients entering the time interval. The differences between curves are highly significant. ES with CC ES with concurrent cholecystectomy (n = 1,647)

Fig. 3 Risk of first readmission with acute pancreatitis, related to time after index admission of study group (n = 26,815patients). ES treatment including endoscopic sphincterotomy with or without cholecystectomy; CT treatment including choledochotomy with previous or concurrent cholecystectomy. Patients at risk number of patients entering the time interval. The differences between curves are highly significant. ES with CC ES with concurrent cholecystectomy (n = 1,647)



**Table 4** Cause of death for patients who died within 90 days of index admission: all biliary diagnoses excluding acute pancreatitis, acute biliary pancreatitis specifically, and all other causes

Time period	All biliary diagnoses <sup>a</sup>	Acute biliary pancreatitis	All other causes	Patients deceased
1989–1994	111 (45.1)	0 (0.0)	135 (54.9)	246 (100.0)
1995-2000	71 (31.7)	2 (0.9)	151 (67.4)	224 (100.0)
2001-2006	89 (39.6)	5 (2.2)	131 (58.2)	225 (100.0)
Total	271 (39.0)	7 (1.0)	417 (60.0)	695 (100.0)

Number of patients with different diagnoses

Numbers within parentheses are percentages

<sup>a</sup> All biliary diagnoses excluding acute pancreatitis

patients with choledochotomy strategy. The cumulative risk of readmission at least once with acute pancreatitis 10 years after index admission was 0.6 % with the choledochotomy strategy and 1.7 % with the ES strategy (p < 0.001). The risk of readmission with biliary diagnoses including pancreatitis was almost equal between all patients subjected to choledochotomy, regardless of whether cholecystectomy was performed before or at index admission. Comparing readmissions for the subgroup of patients with index cholecystectomy (Table 3, group B), the choledochotomy group, had more readmissions than the ES group (Fig. 2).

#### Mortality

For all patients treated for CBDS, SMR 0-90 days after index admission (whether associated with cholecystectomy or not) decreased from 2.99 [95 % confidence interval (CI) 2.62-3.38) (CFR 246/8199 (3.0 %)) in 1989-1994, to 2.08 (1.82-2.37) (CFR 225/10192 (2.2 %)] in 2001-2006. For patients having cholecystectomy performed at index admission, SMR 0-90 days after index admission decreased from 3.23 (2.66-3.88) (CFR 113/4919 (2.3 %)) in 1989–1994 to 2.50 (1.76–3.44) (CFR 37/3075 (1.2 %)) in 2001-2006. Figure 4 shows standardized mortality ratio 0-90 days (95 % CI) for patients subjected to treatment strategies of choledochotomy or endoscopic sphincterotomy after index admission versus time periods. As can be seen, 95 % confidence limits overlapped widely for the two latest of the three six year periods. Table 4 gives causes of death for all patients who died 0-90 days after index admission classified as all biliary diagnoses, as acute pancreatitis specifically, or as other causes of death. Forty percent of all patients (271 of 695) who died within 90 days of index admission had a biliary diagnosis (45.1, 32.6, and 41.8 % during the three periods, respectively). Acute pancreatitis as cause of death was not identified during 1989–1994, whereas two patients had this diagnosis as cause of death in 1995-2000 and five patients in 2001-2006.

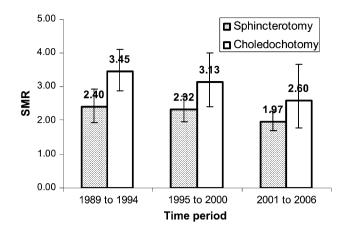


Fig. 4 Standardized mortality ratio 0-90 days (95 % confidence interval) for patients subjected to treatment strategies of choledochotomy or endoscopic sphincterotomy after index admission versus time periods. *SMR* standardized mortality ratio

#### Discussion

#### Principal findings

During the audit period, laparoscopic cholecystectomy replaced open cholecystectomy, and sphincterotomy superseded choledochotomy as the main therapeutic options for gallbladder surgery and CBDS in Sweden. Whereas the method for gallbladder surgery changed dramatically from 1991 to 1993, the transition from choledochotomy to endoscopic sphincterotomy took place gradually. The incidence of CBD intervention increased by 28 % from 1989 through 2006. The cholecystectomy rate during index admission for CBDS declined from 60.0 % in 1989-1994 to 31.1 % in 2001-2006. The incidence of readmission for any biliary diagnosis, and for acute pancreatitis specifically, was higher after the ES treatment strategy than after the choledochotomy treatment strategy. In contrast, in the 10.1 % of ES patients who were cholecystectomized at index admission, the risk of readmission was significantly reduced, and was the even lower than for the choledochotomy group where 90.9 % had cholecystectomy at the index admission. The SMR from index admission and 90 days onward declined from 1989-1994 through 2001-2006 for both strategies.

#### Relation to previous studies

The shift from choledochotomy to endoscopic treatment for CBDS observed in our study is in accordance with previous findings in Europe [6, 17] and in the United States. [7]. This policy change and the associated dissociation between ES and laparoscopic cholecystectomy should be scrutinized against evidence from systematic reviews of randomized controlled trials. According to Cochrane Reviews, laparoscopic cholecystectomy is associated with a more rapid convalescence than classical open cholecystectomy, and small-incision cholecystectomy should be considered equivalent to laparoscopic cholecystectomy in terms of early complications and postoperative recovery [18]. Both small-incision and laparoscopic cholecystectomy can be performed as day surgery [19–21]. Open choledochotomy with removal of CBDS is superior to open cholecystectomy and ES, whereas in laparoscopic surgery, choledochotomy and ES are equally effective in the short perspective, although ES usually requires more interventions per patient [22]. Primary closure of the CBD may be performed with short hospital stay in association with both small- incision cholecystectomy and laparoscopic cholecystectomy [9, 23]. The risks and benefits of T-tube drainage versus primary closure should be assessed in future randomized controlled trials [24, 25]. Outcomes of randomized controlled trials indicate that cholecystectomy should be offered to patients whose gallbladders remain in situ after ES and common bile duct clearance [26], and that early cholecystectomy (within 72 h after ES) is preferable compared to late (6–8 weeks after ES) [27]. It is therefore, of great concern that cholecystectomy performed during index admission in our audit declined from 60.0 to 31.1 %, and that the overall cholecystectomy rate near index admission fell from 71.3 to 57.0 % between the first and the second six-year period. The decrease in the cholecystectomy rate at first admission for treatment of CBDS and the concurrent increase of no or delayed cholecystectomy ("therapeutic splitting") has also been reported from Germany [28]. This parallels the shift from open choledochotomy to ES, as cholecystectomy is an integral part of choledochotomy for CBDS (if not done earlier).

The higher readmission rate for benign biliary diagnosis following ES strategy in the study group may be explained by the splitting of CBD clearance and cholecystectomy (with inconvenience for the patient and possibly increased health care costs). Patients treated with ES and concurrent cholecystectomy at index admission had a very low readmission rate, both with biliary diagnoses including acute pancreatitis, with a risk reduction from 45 to 10 % in 10 years. The incidence of acute pancreatitis increases with patient age [29], and therefore the present observation that the incidence of readmission for acute pancreatitis increases with observation time was not surprising.

## Mortality risk

As a measure of mortality risk, it was more appropriate to use SMR, which involves an adjustment for age and sex and time period of the population studied, instead of the more frequently given case fatality rate (CFR) [29]. A decrease over time of SMR 0-90 days after index admission was detected, for the entire study group and for patients treated with choledochotomy strategy or ES strategy analyzed separately. The SMR difference between index admission with choledochotomy strategy and index admission with ES strategy was small with overlapping 95 % confidence intervals, in spite of a ninefold greater cholecystectomy rate at index admission with choledochotomy. It is of interest that the mortality risk fell drastically and to a similar extent, for both choledochotomy and ERCP in the early 1990s in the United States. [7]. During the audit period covered by our study, 40 % of all post-intervention deaths up to 90 days had biliary diagnoses as the main or contributing cause of mortality, indicating that there is room for improvement in the treatment of CBDS. The factor deaths attributable to acute pancreatitis in the latter two six-year periods is of interest, but no clear conclusion can be drawn because of the small numbers of patients.

#### The persistent need for open biliary surgery

The present study demonstrates a shift from open cholecystectomy and open choledochotomy to laparoscopic cholecystectomy and ES, whereas laparoscopic choledochotomy has not been widely used in Sweden. During index admissions from 2001-2006, 1,999 choledochotomies were performed, the great majority via the open route. Furthermore, 2,489 open cholecystectomies were performed for benign biliary diseases in 2006 (Fig. 1). The requirement among surgeons to maintain skills in open gallbladder and bile duct surgery still remains. The same conclusion has been drawn from one population-based study [7] and one cohort study [30] in the United States, where educational measures to meet this demand are considered necessary [31, 32]. In Sweden, the need for efforts to reduce the surgical trauma associated with open gallbladder surgery has been emphasized [33].

#### Strengths and weaknesses of the study

The strength of the present study was the use of nationwide and validated databases comprising information on all patients with in-hospital procedures on CBDS in Sweden during an 18 year period. Outcomes reflect effectiveness of methods used—i.e., results obtained by Swedish surgeons with varying levels of expertise. As in all register studies, information on health status of individual patients was incomplete, and no morbidity adjustments were made in our study. Data for ambulatory procedures are not included in our calculations. Ambulatory procedures are included in official Swedish statistics from 2005 and onward. In 2006 [14], 1,173 of 11,756 cholecystectomies (10.0 %) and 403 of 3,581 endoscopic sphincterotomies (11.3 %) were performed as ambulatory surgery. Although omission of ambulatory procedure underestimates both cholecystectomy and ES incidence, this is unlikely to distort the conclusion reached in our audit. However, it does explain the reduction in cholecystectomy incidence seen during the latter part of our audit (Fig. 1).

#### Conclusions

In Sweden, the preferred method for treatment of common bile duct stones has shifted from choledochotomy to endoscopic sphincterotomy. From 1988 to 2006, the incidence of intervention on the common bile duct has increased 28 %. In patients fit for surgery, clearance of the common bile duct can be combined with cholecystectomy, as it probably reduces the need for biliary related readmissions.

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Conflict of interest The authors declare no conflict of interest.

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