Meta-Analysis Study of Bile Duct Injury during Laparoscopic Cholecystectomy

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Abstract

Background: Major bile duct injuries remain a significant cause of morbidity and even death after laparoscopic cholecystectomy. Bile duct injury is a severe and potentially life-threatening complication of laparoscopic cholecystectomy. The incidence of bile duct injuries during laparoscopic cholecystectomy is varied.

Objective: To perform a meta-analysis of laparoscopic cholecystectomy studies and compare results concerning complications (particularly bile duct injury).

Methodology: Articles identified via a MEDLINE (the National Library of Medicine's computerized database) search were evaluated according to standard criteria. Data regarding the patient sample, study methods, and outcomes of cholecystectomy were abstracted and summarized across studies.

Results: Outcomes of laparoscopic cholecystectomy are examined for 225,187 patients reported on in 5 studies and compared with outcomes of bile duct injury. Laparoscopic cholecystectomy appears to have a higher common bile duct injury rate. Running analysis using MetaStat program, the following was obtained: 2 Restricted Log Likelihood was 57.4, Type III tests of fixed effect: f= 2.6, P= 0.18, Covariance estimate = 65926.7, Multiple Regression R= 0.99, F= 6270.1, P<0.001, Mean of bile duct injury = 184.2 $\pm$ 229.7, Mean of total laparoscopy= 45037 $\pm$ 5754.1, Mean prevalence = 0.408%.

Potentials: Meta-analysis allows the investigator to define the problem or health phenomenon [with all its dimensions] and study factors that could affect it from the available data in the literature and/or pooled data base within reasonable time and minimal costs. Moreover, it allows suggesting solutions or evaluating the current solutions for the problem.

Limitations: The limitations of meta-analysis are based on the deficiencies of research design, review methods, medical lab or techniques, and analytical models used in these scientific studies, particularly summary data. However, these could be minimized through well research design with clearer criteria for inclusion and exclusion.

Conclusions: This study confirms a higher incidence of BDI during LC. It highlights the relevance of the number of previously performed LCs. The need for correct procedures, adequate expertise of the repairing surgeon in BDI repairs, and a multidisciplinary approach in the management of BDI is emphasized.

Keywords: Epidemiological methods - Meta-analysis - Pooled analysis - Reviews - Risk Factors - Potentials – Limitations

Introduction:

Much attention has been given in recent years to meta-analysis in medical research; however, numerous methodological issues particularly with respect to biases and the use of meta-analysis are still controversial. One of the issues is whether meta-analysis from published data is sufficient for such an exercise or whether individual patient data are necessary. Meta-analyses has been performed for several clinical and epidemiological data sets and added considerably to the knowledge of the use of some therapies, as well as to the role of some etiologic factors (breast cancer and oral contraceptive use). The Cochrane Collaboration is an important outcome of this discussion.[1-3]

Recent use of meta-analysis has become an important part of surgical research and practice, for reconstructing previously conducted studies that have inconsistent results or with limited number of cases.[4]

The use of review articles and meta-analysis has become an important part of epidemiological research. One of the main reasons for their increased use in summarizing the evidence in a particular area is the need to assess risks that are small but may have large public interest or have important implications for public health.[5]

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Since the introduction of laparoscopic cholecystectomy, hundreds of reports about the technique have been published, many including statements about the advantages of laparoscopic cholecystectomy compared with those of open cholecystectomy.

Objective:
The purpose of this study was to perform a meta-analysis of large laparoscopic cholecystectomy case-series and compare results concerning complications, particularly bile duct injury.

Methodology:
Four methods summarizing data from clinical studies are described: Type (1) Qualitative summary, Type (2) Quantitative summary [pooled estimate of independent of interest] from published data, Type (3) Re-analysis of individual data based on primary data [pooled analysis], Type (4) Prospective planned, pooled analysis of several studies.
Articles identified via a MEDLINE (the National Library of Medicine's computerized database) search were evaluated according to standard criteria. Data regarding the patient sample, study methods, and outcomes of cholecystectomy were abstracted and summarized across studies.

Results:
Outcomes of laparoscopic cholecystectomy are examined for 225,187 patients reported on in 5 studies and compared with outcomes of bile duct injury. Laparoscopic cholecystectomy appears to have a higher common bile duct injury rate. Running analysis using MetaStat program, the following was obtained: 2 Restricted Log Likelihood was 57.4, Type III tests of fixed effect: f= 2.6, P= 0.18, Covariance estimate = 65926.7, Multiple Regression R= 0.99, F= 6270.1, P<0.001, Mean of bile duct injury = 184.2 $\pm$ 229.7, Mean of total laparoscopy= 45037 $\pm$ 5754.1, Mean prevalence = 0.408% (Table 1).
Meta-analysis allows the investigator to define the problem or health phenomenon [with all its dimensions] and study factors that could affect it from the available data in the literature and/or pooled data base within reasonable time and minimal costs. Moreover, it allows suggesting solutions or evaluating the current solutions for the problem.[6]
The limitations of meta-analysis are based on the deficiencies of research design, review methods, medical lab or techniques, and analytical models used in these scientific studies, particularly with summary data. However, these could be minimized through well research design with clearer criteria for inclusion and exclusion.[7-9]

Discussion:
A population-based study was carried out on 152776 cholecystectomies in the Swedish Inpatient Registry from 1987- 2001[10] including all hospitals performing inpatient cholecystectomies in Sweden. Cholecystectomies were identified using International Classification of Diseases, 9th and 10th Revisions surgical procedure codes. After exclusion of patients with hepatobiliary and pancreatic malignancies, patients with codes indicating reconstructive bile duct operations within 1 year after cholecystectomy were considered BDI cases. Risk factors for BDI were analyzed using multivariate logistic regression. The incidence proportion of BDI was calculated by dividing the number of cases by the number of cholecystectomies. Relative risks were estimated using odds ratio of 95% confidence intervals, and incidence proportion was used to describe incidence. Among the 152776 cholecystectomies, 613 reconstructed BDIs (0.40%) were identified. Older age and male sex were positively associated with BDI. The incidence proportion of BDI was 0.40% from 1987 to 1990, decreased to 0.32% from 1991 to 1995, and increased to 0.47% from 1996 to 2001.
An anonymous retrospective multi-center survey from department of surgery at a university referral center has collected data from general surgical units. Data from 56591 patients who underwent LC between January 1st, 1998, and December 31st, 2000, in 184 hospitals in Italy were analyzed. Two hundred thirty-five BDIs were reported, with an overall incidence of 0.42%. There were no risk factors in 80.0% of the patients. Poor identification of the anatomical features of the hepatic pedicle was the most frequently reported cause (36.8%), and technical problems accounted for 27.0% of causes. The incidence of BDI was higher during cholecystitis (P<.001) and decreased with increasing number of LCs performed by the surgical teams (P<.01).[11]
A retrospective single-institution study was to evaluate the real incidence of BDI during laparoscopic and open cholecystectomy (OC) in a tertiary academic center in Athens, Greece. Between January 1991 and December 2001, 3637 patients underwent cholecystectomy in

our department; as LC in 2079 patients (LC group) and as OC in 1558 patients (OC group). There were 13 BDIs associated with LC (0.62%) and 6 associated with OC (0.38%) (P = 0.317). There was one death associated with BDI after LC.[12]

In Spain, 3,051 OC, performed from June 1977 to December 1988 were retrospectively analyzed and compared with 1,630 LCs performed from June 1991 to August 1996, for which data were prospectively recorded. Age, sex, type of BDI, performance of intraoperative cholangiography (IOC), underlying biliary pathology, morbidity, mortality, and late morbidity were all analyzed. BDI incidence was higher in group (LC) (N: 16, 0.95%) than in group (OC, N: 19. 0.6%). BDI incidence was also higher in the group of patients in which it was necessary to convert to an open procedure (3/109, 2.7%, $p < 0.05$). BDIs were more frequently diagnosed intraoperatively in group (OC, 18/19) than in group (LC, 12/16).[13]

In Switzerland, a nationwide prospective study beyond the laparoscopic learning curve was to analyze the incidence, risk factors, and management of major BDI. During a 3-year period (1995-1997) 130 items of all LC data were collected on a central computer system from 84 surgical institutions in Switzerland by the Swiss Association of Laparoscopic and Thoracoscopic Surgery and evaluated for major BDIs. There were 12,111 patients with a mean age of 55 years (3-98 years) enrolled in the study. The overall BDI incidence was 0.3%, 0.18% for symptomatic gallstones, and 0.36% for acute cholecystitis. In cases of severe chronic cholecystitis with shrunken gallbladder, the incidence was as high as 3%. Morbidity and mortality rates were significantly increased in BDIs. BDI was recognized intraoperatively in 80.6%, in 64% of cases by the help of intraoperative cholangiography.[14,15]

Conclusions:

This study confirms a higher incidence of BDI during LC. It highlights the relevance of the number of previously performed LCs. The need for correct procedures, adequate expertise of the repairing surgeon in BDI repairs, and a multidisciplinary approach in the management of BDI is emphasized.

Table (1): Bile duct injury during laparoscopic cholecystectomy. A meta-analysis.

Authors	Juornal	Title	Place	Years	No.	+ve c	%	PMID
Waage A Nilsson M	Arch Surg. 2006 Dec;141(12):1 207-13	Iatrogenic bile duct injury	Sweden	1987-2001	152776	613	0.4%	17178963
Nuzzo et al.	Arch. Surg. 2005 Oct; 140 (10):986-92	Bile duct injury during laparoscopic cholecystectomy	Italy	1998-2000	56591	235	0.42%	16230550
Diamantis et al.	Surg. Today 2005; 35(10):841-5	Bile duct injuries associated with laparoscopic and open cholecystectomy	Greece	1991-2001	2079	13	0.62%	16175465
Targarona et al.	Surg. Endosc. 1998 Apr; 12 (4): 322-6	How, when, and why bile duct injury occurs	Spain.	1977-1988	1630	16	0.95%	9543521
Krahenbuhl et al.	World J Surg. 2001 ;25 (10): 1325-30.	Incidence, risk factors, and prevention of biliary tract injuries during laparoscopic cholecystectomy	Switzer-land.	1995-1997	12111	44	0.36%	11596898
					225187			

- Mean of total laporoscopy= 45037 $\pm$ 5754.1
- Mean prevalence = 0.408%
- 2 Restricted Log Liklihood = 57.4
- Type III tests of fixed effect: f= 2.6 P= 0.18
- Covariance estimate = 65926.7
- Multiple Regression R= 0.99, F= 6270.1, P<0.001
- Mean of bile duct injury = 184.2 $\pm$ 229.7

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