Population based studies should not be used to justify a policy of routine
cholangiography to prevent major bile duct injury during laparoscopic cholecystectomy.

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ABSTRACT

Background: Iatrogenic bile duct injury at time of cholecystectomy is a rare but devastating event. A two fold higher frequency of bile duct injury during cholecystectomy without cholangiography is reported in population based studies. Some interpret this as a cause and effect relationship and thus mandate routine cholangiography. A critical appraisal of population studies is required to determine whether these studies are suitable in determining the role of routine cholangiography.

Methods: Literature search was performed using combinations of the forced search terms “duct injury”, “population” and “cholangiography” to identify population based studies assessing the relationship between cholangiography and iatrogenic bile duct injury.

Results: All seven population based studies reported a numerically higher rate of bile duct injury when an intraoperative cholangiogram was not obtained during cholecystectomy. Five predate the critical view technique. Only one was limited to laparoscopic cholecystectomy. All studies identified cholangiography as a likely marker for disease severity or surgical technique. **Six studies did not** demonstrate a cause and effect relationship by not including effect modifiers. The only study to address confounders reported the same rate of injury irrespective of the use of cholangiography.

Conclusion: Critical appraisal of population based studies does not support their use in justifying a policy of routine cholangiography to prevent major bile duct injury.

INTRODUCTION

Intraoperative cholangiography (IOC) was developed in 1930's with the aim of confirming a clear main bile duct to minimize the risk of postoperative biliary related complications from an obstructed biliary tree.[1, 2] The concept of cholangiography protecting against iatrogenic bile duct injury (BDI)[3] first arose in the 1970's at a time when such complications after open cholecystectomy (OC) were reported in between 0.125%[4] and 0.3%[5] of patients and yet the evidence to support such a claim seemed tenuous. Following the introduction of laparoscopic cholecystectomy (LC) *Strong* noted the persistent unacceptable incidence of BDI and questioned whether this was intrinsic to the operation itself or related to deficiencies in training or attitudes.[6] Attempts to show a link between intraoperative cholangiography and a lower risk of BDI yielded conflicting results.[7, 8] Therefore a significant body of alternate opinion and practice exists. Surveys of surgeons indicate only 15% of American academic surgeons[9] and 31% of the members of the Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland[10] perform routine IOC during LC.

Prominent authors have rightly stated an IOC alone cannot prevent BDI.[11, 12] If the bile duct is mistaken for the cystic duct and the IOC inadvertently performed through an incision in the bile duct, at least a side hole bile duct injury has occurred (Strasberg type D[5]) irrespective of the indication or timing of cholangiography (although not all authors agree[5]). If the IOC is interpreted correctly and corrective steps taken, excision of the common hepatic duct will be avoided (Strasberg type E) meaning the injury will not be exacerbated. This suggests a protective role of the IOC once the mistake has occurred - if

the same surgeon doing the same operation had made the same mistake without performing IOC, the error may have gone unnoticed and the common hepatic duct excised. As surgeons do not always interpret the IOC correctly[4, 13], the critical view of safety (CVS)[14-18] and technique used in establishing this[14, 15, 18] may be more important than IOC.

Given the lack of randomized studies demonstrating causality, proponents of routine IOC often base the argument on findings from cross sectional population based studies which have reported lower rates of BDI when IOC had been performed.[19-25] A causal relationship between IOC omission and BDI is inferred. However, this temporal and covariate association does not prove causality of this rare event unless effect modifiers, important missing variables and confounders had been taken into account – this is not unique to studies of bile duct injury. Advanced mathematics and multivariable analysis cannot eliminate the problem of unknown and unmeasured effect modifiers. Population based studies are not able to control for IOC indication, disease severity and surgical technique as these lack administrative codes. Despite excellent severity adjustment, biased results can occur if important but unmeasured variables are not included: in one unrelated model, patient characteristics were over 300 times more important than hospital characteristics in predicting mortality after surgery.[26]

For a variety of reasons, recent publications and consensus statements from several continents have not recommended routine IOC.[15, 16, 27-31] Others have concluded routine IOC be the standard of care.[32] Given this state of clinical equipoise and

accepting that a randomized trial recruiting the estimated 30 000 patients deemed necessary[33] would seem improbable, it is timely to critically review the quality, methodology and findings of population based studies[19-25] to determine whether these studies should be used to justify a policy of routine IOC to prevent major BDI.

METHODS

PubMed searches were performed using the following criteria: (duct injury[Title]) AND population[Title/Abstract]; (cholangiography[Title]) AND population[Title/Abstract]; (cholangiography[Title]) AND (duct injury[Title]). The Cochrane database was searched using term “bile duct injury” in the section “Gall stones surgery”. Abstracts were reviewed to determine relevance. The references of identified papers were studied for additional sources. The Preferred Reporting Items for Systematic reviews and Meta Analyses (PRISMA) statement does not specifically address population based studies.[34]

Major bile duct injury was defined as unintended occlusion, incision, transection or excision of the bile duct made by the surgeon (Strasberg types D and E) which typically presents as jaundice, sepsis or bile leak. A minor bile duct injury was defined as a leak from the gallbladder fossa or cystic duct (Strasberg type A), occlusion or leak of a segmental or sectional duct (Strasberg types B and C) which may be asymptomatic.

Strasberg C injury may represent a major BDI depending on the volume of liver drained.

Evaluating the ability of population based studies to determine the role of IOC in preventing major BDI, the following factors would need to be considered: relevance to the laparoscopic era; relevance to the critical view of safety era; surgical technique; indication for IOC; pathological state of the gallbladder (e.g. cholecystocholedochal fistula) and whether the hepatobiliary triangle is fatty or fibrotic. Some bile leaks are not anatomically defined and are definitively managed percutaneously (operatively placed drain or image guided) and **are unlikely to** represent major BDI. A bile leak after early T-tube removal following duct exploration also does not represent a BDI. A long time frame to diagnosis will capture thermal related biliary stricturing related to the technique of dissection. For IOC to be classed as routine it needs to be attempted 100% of the time. Prospectively collected data encompassing these factors would be ideal.

A population based study was defined as a study that assessed a population of one geographically isolated region e.g. state or nation. Papers from single institutions or surgical associations were excluded as these represent selected populations.

RESULTS

The literature search identified 7 **unique** population based studies (Figure 1). **The 2015 paper by Törnqvist et al[35] was not included as it represents a reanalysis of the their 2012 study[24].**

Table 1 details the findings and Table 2 the features of the very diverse studies. Whether cholecystectomy was completed laparoscopically or by laparotomy was reported in 5

papers but how many operations commenced laparoscopically is unknown. Only one study was restricted to LC[21] but it predated the critical view of safety[36] era. Only one paper was based on a prospective database and documented the BDI level.[24] Only two studies occurred during the CVS era.[23, 24] The definition of BDI in each study was different but all included the need for operative repair or reconstruction of the bile duct. All **but** one[24] used administrative codes to identify patients with a bile duct injury. Three reports included injuries managed endoscopically.[19, 22, 24] Three included injuries managed by percutaneous drainage.[19, 21, 24] Tangential bile duct injuries were excluded from four of the northern hemisphere articles[20, 21, 23, 25] while being included in the two Australian publications[19, 22] and the GallRiks paper.[24] All studies excluded patients with hepatopancreatobiliary malignancy.

The rate of major BDI for all cholecystectomies ranged from 0.11%[24] to 0.50%.[20] The definition of routine cholangiography ranged from 60%[23, 37] to 75%[20] of cholecystectomies having IOC. The intent of IOC could not be determined in any of the studies e.g. exclusion of choledocholithiasis, unclear anatomy, diagnosis of BDI. There was up to a twofold higher rate of bile duct injury in cholecystectomies without IOC compared to operations with a cholangiogram (ranging from 1.65[21] and 2.05[19, 22]).

Both papers from Western Australia[19, 22] found IOC to be protective against all intraoperative injuries (combination of major BDI, bile leaks, vascular and bowel injuries and haemorrhage).

In the only paper to focus on LC[21] BDI rates were the same when surgeon percentage of IOC use was examined (<15%, 15 – 45%, 46% - 75%, >75%). Here, Flum et al. showed omission of IOC was associated with a higher rate of BDI for surgeons who performed IOC more than 75% of the time: 4 fold increase ($p < 0.001$)[21]. Because LC converted to open were excluded from this paper, two years later Flum et al.[20] reassessed the issue of BDI during cholecystectomy (OC + LC). Infrequent cholangiographers (IOC during <25% of cholecystectomies) had a higher rate of BDI when a cholangiogram was performed (0.78% with IOC vs. 0.49% without IOC, $p < 0.001$) – this group accounted for 47% of all cholecystectomies. Selective (26% - 75%) cholangiographers and routine (>75%) cholangiographers who did not obtain an IOC had a higher rate of injury. Routine cholangiographers had a lower rate of BDI than infrequent cholangiographers (0.43% vs. 0.52%, $p < 0.001$).

The most recent study has adopted a very different approach.[23] Only major bile duct injuries requiring biliary enteric drainage in patients aged over 65 years of age in the state of Texas were analyzed. Multivariable analysis showed the rate of BDI was higher when IOC was not performed (OR 1.76, 95% CI 1.34 – 2.32). To exclude potential bias in the correlation between IOC use and BDI, two instrumental variable analyses were employed using percentage of hospital IOC use and percentage of surgeon IOC use as the instrumental variables. This showed no difference in the rate of BDI in cholecystectomies with and without IOC (OR 1.26, 95% CI 0.81 – 1.96 and OR 1.31, 95% CI 0.91 – 1.89 respectively).

DISCUSSION

Population based studies should not be used to justify a policy of routine cholangiography in order to prevent bile duct injury. Both papers from Western Australia[19, 22] strongly support the idea that surgeons who perform IOC are somehow different from those who do not and that IOC use is a marker of surgical technique and surgical difficulty. Instrumental variable analysis (at hospital and surgeon level) by Sheffield et al.[23] further supports the idea that correlation between IOC and BDI in the first 6 papers[19-22, 24, 25] may have occurred due to uncontrolled confounders by including higher risk patients into the no IOC group. Accounting for hospital and surgeon IOC use, the authors found no difference in the rate of major bile duct injury in cholecystectomies with and without IOC[23] but the authors suggest this study may have been underpowered with wide confidence intervals for the odds ratios. When Törnqvist et al. reanalysed their 2012 data using instrumental analysis (but only at the hospital level) the association between IOC and all types of BDI at “purely elective cholecystectomy” disappeared.[35]

Majority of studies predate laparoscopy and adoption of the critical view of safety technique. To define the role of routine IOC in the modern era, and avoid unintentionally selecting higher risk cholecystectomies into the no IOC group, a randomized trial of 30 000 patients would be required.[33] A well-constructed and conducted randomized trial could prove causality by eliminating bias from currently unknown variables including: disease severity[38], injury occurring before cholangiography[39]; unsuccessfully attempted IOC (3% in author’s unpublished data), IOC misinterpretation[4, 13] and

injury occurring after cholangiography[13, 39]. Routine IOC increases the rate of needless ERCP or bile duct exploration[29] and (to a small degree) staff exposure to radiation[40].

Avoiding bile duct injury thus remains a controversial and emotive topic. Johnston's triad of dangerous disease, dangerous anatomy and dangerous surgery encompasses the issues responsible for iatrogenic biliary lesions[41], but the aim of this review was to determine whether population based studies should be used to support a policy of routine IOC at time of LC in order to reduce major bile duct injuries. This is not the same as asking whether routine IOC is justified (e.g. reducing severity of BDI, detection of asymptomatic choledocholithiasis) or cost effective.

Prospectively collected data (rather than reliance on administrative codes) is crucial as it has been pointed out elsewhere codes suffer from a lack of a precise clinical definition and context[42], are incomplete[43], prone to error[42] and underreporting[44]. The differing definitions used will capture minor BDI skewing the findings. Accounting for the presence of choledocholithiasis is crucial in evaluating minor bile leaks as the most common cause is a cystic duct leak which is often accompanied by choledocholithiasis (e.g. 75% of bile leaks were managed endoscopically and 38% of cystic duct stump leaks were associated with choledocholithiasis in a recent endoscopic report of 113 patients[45]). Increasing the timeframe during which injury is diagnosed (from 30 days[19, 22, 24] to 12 months[20, 23, 25]) will capture late (ischaemic or thermal)

strictures which relate more to the technique of dissection rather than anatomical misinterpretation. The pathology of the gallbladder is the other surgically relevant missing confounder as there are no administrative codes for levels of operative difficulty as suggested by Nassar et al.[38] In a study from Bchler's group[46] a shrunken gallbladder increased the BDI rate by 15 times (3% vs. 0.2%; $p < 0.05$). BDI occurs in at least 20% of patients with a cholecystocholedochal fistula (which occurs in 1-2% of cholecystectomies)[47] and may have been captured by the first six studies which did not exclude choledocholithiasis. The indication for cholangiography (choledocholithiasis, anatomy, disorientation, defining an injury) is not discussed in these studies and represents another missing variable. Patients who died with a bile duct injury before intervention were excluded as all studies defined BDI by the need for intervention e.g. in a major tertiary unit 1.5% of patients with BDI died of sepsis prior to reconstruction.[48]

The first five studies were performed during the now outdated *infundibular technique* era which limits their relevance to Strasberg's *critical view of safety* cholecystectomy[36] with a *stop point* if the posterior window cannot be achieved.[14] Strasberg first raised the idea of the critical view[5] in 1995 but the concept probably did not gain much attention[49, 50] until after a more detailed explanation his 2002[36] article. An IOC unintentionally performed through a choledochotomy may result in a less severe BDI if the surgeon correctly interprets the IOC and stops. In fact, in a study of 10 123 LC starting prior to the critical view of safety era with 100% IOC rate, Pekolj et al. identified 17 BDI but only 2 were hilar with the majority being side holes.[51] There is no level 1 evidence supporting the use of the CVS technique in order to avoid major bile duct

injury. While the beautiful pictures of the CVS in publications[17] are not always achievable in the operating room due to disease severity, in a recent blinded review of laparoscopic cholecystectomy videos the CVS was not achieved in any of the 6 patients with a major BDI[49]. Surgical trainees were twice as likely as attending surgeons to document CVS in their operative notes in another study (80.6% vs. 42.9%; $p = 0.002$).[50] However, surgeons may not understand the three components of the CVS – a blinded review of uncomplicated elective laparoscopic cholecystectomy videos found that when the surgeon documented the CVS stage, this could be substantiated in only 74% of cases.[49] The same authors demonstrated that in patients who experienced a complication following laparoscopic cholecystectomy, the CVS stage could only be substantiated in 13.5% of videos.[49] Obtaining the CVS, like IOC use (*vide supra*), may be marker of disease severity, surgical technique and attitudes to safety.

How should a policy of routine intraoperative cholangiography be defined – attempted during 100% of operations or achieved in only 60%[23, 37] or 75%[20]? While not clear in these population based studies, an unsuccessfully attempted IOC was probably considered as cholecystectomy without IOC.[19, 43] This is important as Flum's group[52] criticized an Italian paper[53] for including patients with BDI in the intention to treat group (i.e. cholecystectomy with IOC) because the injury occurred during dissection of the presumed cystic duct prior to the cholangiogram being achievable.

A meta analysis of these heterogenous population based studies omitting significant confounders was not attempted. Importantly, the authors do not advocate

cholangiography to be abandoned altogether. Due to their time frame and inability to account for confounders, population based studies should not be used to support a policy of routine cholangiography to prevent major BDI. Cholecystectomy is a major operation requiring a well trained surgeon[39] which can translate to zero bile duct injuries in 10 000 consecutive laparoscopic cholecystectomies without routine cholangiography[54]. The key is sound surgical technique[55] and the cholangiogram is not a rabbit's foot[56] or panacea[57].

CONCLUSION

Population based studies should not be used to support a policy of routine cholangiography in order to protect against major bile duct injury. **Until an evidence based method of preventing bile duct injury is identified, sound surgical judgment remains key in protecting the biliary tree during an era which combines laparoscopy and the critical view of safety.**

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Figure 1. Study selection summary.

Article Number CC	BDI identified by need for ERCP	Minor bile leaks	Major BDI (%)	Minor BDI (%)	% LC with IOC	Major BDI / LC (%)	BDI trend during study
Fletcher 1999 [19] N = 19 176	Yes if LOS > 1 day	Included	44 (0.23%)	69 (0.36%)	45%	25 / 7 493 (0.33%)	increasing
Flum 2001 [21] N = 30 630	No	Excluded	76 (0.25%)	N/A	64%	76 / 30 630 (0.25%)	reducing
Flum 2003 [20] N = 1 570 361	No	Excluded	7 911 (0.50%)	N/A	N/A	N/A	N/A
Waage 2006 [25] N = 152 776	No	Excluded	613 (0.40%)	N/A	N/A	N/A	increasing
Hobbs 2006 [22] N = 33 309	Yes	Included	78 (0.23%)	182 (0.55%)	57%	50 / 19 414 (0.26%)	reducing
Törnqvist 2012 [24] N = 51 041	Yes	Included	185 (0.36%)	552 (1.10%)	N/A	N/A	stable
Sheffield 2013 [23] N = 92 932	No	Excluded	280 (0.30%)	N/A	43%	235 / 79 580 (0.30%)	stable
TOTAL N = 1 950 225	Mixture	Mixture	9 187 (0.47%)	803 (0.78%)	50%	386 / 137 299 (0.28%)	N/A

Table 1. Inclusions and findings of population based studies assessing relationship between intraoperative cholangiography and bile duct injury. CC: cholecystectomy, ERCP: Endoscopic Retrograde Cholangio Pancreatography, IOC: intraoperative cholangiography, LC: laparoscopic **cholecystectomy**, BDI: bile duct injury, N/A: not stated in the article and not used for calculation; LOS: Length of Stay, N/A: not available

Article	LC % of CC	CVS era (after 2002)	Prospective	Complexity	BD stone	Surgeon IOC use rate vs BDI	Side hole or CD leak	Days to diagnosis
Fletcher 1999 [19]	39%	Pre CVS	No	AP CH OJ AC PA	Included	N/A	Included	30
Flum 2001 [21]	100%	Pre CVS	No	OJ AC	Included	Same rate whether <15% IOC use or >90%	Excluded	90
Flum 2003 [20]	76%	Pre CVS	No	AP CH OJ AC	Included	Lower when IOC use >75%	Excluded	365
Waage 2006 [25]	N/A	Pre CVS	No	OJ CH	Excluded	N/A	Excluded	365
Hobbs 2006 [22]	58%	Pre CVS	No	AP CH OJ AC PA	Included	N/A	Included	30
Törnqvist 2012 [24]	N/A	Post CVS	Yes	EC	Included	N/A	Included	30
Sheffield 2013 [23]	86%	Mostly post CVS	No	AC OJ	Excluded	N/A	Excluded	365

Table 2. Features of population based studies assessing relationship between intraoperative cholangiography and bile duct injury. LC: laparoscopic cholecystectomy, CC: cholecystectomy, CVS: critical view of safety, GB: gallbladder, HB: hepatobiliary, BD: bile duct, CD: cystic duct, AP: acute pancreatitis, CH: cholangitis, OJ: obstructive jaundice, AC: acute cholecystitis, PA: previous biliary admission, EC: emergency cholecystectomy, N/A: not available

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