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Bile duct injuries (BDI) in the advanced laparoscopic cholecystectomy era

Christopher W. Mangieri[1,3] · Bryan P. Hendren[1] · Matthew A. Strode[1,2] · Bradley C. Bandera[1] · Byron J. Faler[1]

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Abstract

Background Laparoscopic cholecystectomy is the most commonly performed laparoscopic procedure. It is superior in nearly every regard compared to open cholecystectomies. The one significant aspect where the laparoscopic approach is inferior regards the association with bile duct injuries (BDI). The BDI rate with laparoscopic cholecystectomy is approximately 0.5%; nearly triple the rate compared to the open approach. We propose that 0.5% BDI rate with the laparoscopic approach is no longer accurate.

Methods The National Surgical Quality Improvement Program (NSQIP) registry was retrospectively reviewed. All laparoscopic cholecystectomies performed between 2012 and 2016 were extracted. A total of 217,774 cases meeting inclusion criteria were analyzed. The primary data points were the overall BDI incidence rate and time of diagnosis. BDI were identified by ICD-9 and ICD-10 codes. Secondary data points were variables associated with BDI.

Results The BDI rate was 0.19%. 77% of cases were diagnosed after the index surgical admission. Intra-operative cholangiography (IOC) use was associated with a higher BDI rate and higher identification rate of a BDI intraoperatively (*P* value < 0.0001). Resident teaching cases were protective with a RR score of 0.56 (*P* value < 0.0001). The presence of cholecystitis increased the risk of a BDI with a RR score of 1.20 (*P* value < 0.0001). There was a low conversion rate of 0.04% however converted cases had a nearly hundredfold increase in BDI at 15% (*P* value < 0.0001).

Conclusions The performance of laparoscopic cholecystectomies in North America is no longer associated with higher BDI rates compared to open. IOC use still is not protective against BDI, and cholecystitis continues to be a risk factor for BDI. When a cholecystectomy requires conversion from a laparoscopic to an open approach the BDI increases a hundredfold; which may raise the concern if this approach is still a safe bailout method for a difficult laparoscopic dissection.

Keywords Bile duct injury · BDI · Laparoscopic cholecystectomy · Procedural safety

Since the advent of the laparoscopic cholecystectomy by Dr. Muhe in 1986 the procedure has become one of the most commonly performed operations worldwide [1]. Over three quarter of a million laparoscopic cholecystectomies are performed annually in the United States making it the most commonly performed laparoscopic procedure [2, 3]. Due to the relative ease in the learning curve of the operation combined with the significantly improved recovery for patients compared to open procedures, laparoscopic cholecystectomies quickly became the surgical standard in the 1990s.

Yet, with that unprecedented transition to laparoscopic cholecystectomies no prospective randomized control trials were ever performed comparing it to the prior open cholecystectomy gold standard [4]. Academic scrutiny following the transition cited that bile duct injuries (BDI) were

The main institution, Dwight D. Eisenhower Army Medical Center, is a participant member of the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) and is authorized by the ACS to scientifically research and publish NSQIP data.

✉ Christopher W. Mangieri
christopher.w.mangieri.mil@mail.mil

1 Dwight D. Eisenhower Army Medical Center (DDEAMC), Fort Gordon, GA, USA

2 Roswell Park Cancer Institute, Buffalo, NY, USA

3 General Surgery Department, Dwight D. Eisenhower Army Medical Center (DDEAMC), 300 East Hospital Road, Fort Gordon, GA 30905, USA

significantly increased compared to open procedures. The incidence of BDI during the open cholecystectomy era was established at 0.1–0.2% which starkly contrasted with the nearly tenfold increase in BDI with laparoscopic cholecystectomies in early studies [5, 6]. The last large national based studies of BDI associated with laparoscopic cholecystectomy published in the mid-2000s determined the BDI rate had plateaued to approximately 0.5% [3, 7–9]. That rate remained significantly higher than BDI rates during the open era with severe morbidity and mortality association [3, 7–9]. Subsequent smaller institutional reports published since the last landmark studies have suggested that BDI rates between laparoscopic and open cholecystectomies are now comparable in current times [10, 11].

The objective of this study was to use a large scale nationally validated database to determine if the BDI rate with laparoscopic cholecystectomy has now become equivalent or superior compared to the open era. Analysis of other variables historically associated with BDI was also performed.

Methods

Retrospective analysis of the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) registry was performed. The registry systematically records hundreds of pre-operative, peri-operative, and post-operative variables collected from approximately 700 participant hospitals in the United States and Canada by trained registrars [12, 13]. All registry information within NSQIP is de-identified data. To include de-identification of participant hospitals per section 924 (c) of the Public Health Service Act (42 U.S.C. 299c-39(c)) and the ACS NSQIP Data Use Agreement. The NSQIP registry has been nationally validated and determined to be of high scientific quality permitting academic research [12, 14]. The NSQIP annual registries from 2012 to 2016 were analyzed in this study. As a participant member of NSQIP Dwight D. Eisenhower Army Medical Center is authorized by the ACS to scientifically research and publish NSQIP data. Due to the de-identified nature of the NSQIP registry no institutional review board (IRB) authorization is required.

All laparoscopic cholecystectomy cases contained in the registry were identified by using the current procedural terminology (CPT) codes 47562 (LAPAROSCOPY SURG CHOLECYSTECTOMY) and 47563 (LAPS SURG CHOLECYSTECTOMY W/CHOLANGIOGRAPHY). All laparoscopic cholecystectomy cases were extracted and then filtered using International classification of diseases (ICD) codes to identify only relevant cases. Relevant cases were considered procedures performed for the most common indications for a cholecystectomy. ICD-9 and ICD-10 codes for cholecystitis, symptomatic cholelithiasis, biliary dyskinesia, and gallstone pancreatitis were used to extract the relevant cases. Laparoscopic cholecystectomies performed for malignancy or primary hepatic diseases were excluded. Following the identification of the relevant cases. a total of 217,775 procedures were left for analysis.

Determination of a BDI was performed by utilizing the ICD-9 and ICD-10 codes for any diagnosis that could be considered a BDI. ICD-9 terminology has several codes that could be considered a BDI to include 576.3, 576.4, 576.0, 868.02, 995, 997.4, 997.49, 998.13, 998.2, 998.51, 998.59, 998.89. ICD-10 terminology is more specific for a BDI and has a standalone category S36.13. The 2012–2014 NSQIP registries used ICD-9 codes, the 2016 registry used ICD-10, and the 2015 registry used both. If a BDI ICD-9 or ICD-10 code was listed in the NSQIP registry under main post-operative diagnosis, post-operative diagnosis other, readmission reason, return to OR reason, or reoperation reason, that case was categorized as containing a BDI. A BDI was categorized as being diagnosed intra-operatively or during the index admission if the BDI ICD code was listed in the post-operative diagnosis, post-operative diagnosis other, return to OR, or reoperation lines in the NSQIP registry. If a BDI ICD code was present in the reoperation or return to OR line that case was further checked to ensure those operations were not performed at a readmission. All other BDI ICD code entries in the registry were categorized as the BDI diagnosis being made in the post-operative course following the index admission. A BDI case would not be contained in the NSQIP registry if the diagnosis was made at a different hospital from where the index surgery was performed since NSQIP only tracks data for the case from the index hospital. With the varying CPT codes utilized for BDI combined with several locations those codes were recorded in the NSQIP registry accurate identification of BDI was a complex process requiring careful attention to detail.

Following categorization of all included laparoscopic cholecystectomy cases into either the BDI cohort or no-BDI cohort, additional analysis was performed. Determination of intraoperative cholangiogram (IOC) use was performed by referencing for IOC codes in the "principal CPT code" or "other CPT code" lines in the NSQIP registry. Of note, the NSQIP registry simply indicates if an IOC was performed or not during the case; there is no data in the registry that indicates when the IOC was performed during the case or the interpretation of the IOC. If cholecystitis was present (to include acute, chronic, or unspecified cholecystitis) that was identified by ICD codes in the diagnoses NSQIP registry lines. Laparoscopic cholecystectomies requiring conversion to an open procedure were identified by any open CPT codes listed in "other CPT code" lines. The National Correct Coding Initiative (NCCI) does not permit a specific CPT code for a converted procedure [15]. Lastly, any attempt at definitive management (either surgical or endoscopic) of a BDI either during the index surgery or a subsequent procedure was determined by CPT codes for biliary tree repair, reconstruction, or intervention.

Statistical analysis

Two-sample *t* testing was performed to compare continuous variables. Comparison of categorical variables was performed with Fisher's exact testing or Pearson's Chi square testing. Statistical significance was established at a *P* value of 0.05. All descriptive statistics were processed using the International Business Machine (IBM) Statistical Package for Social Sciences (SPSS) version 25.0.0 analytical software (IBM Inc., Armonk, New York).

Table 1 Case characteristics

Characteristics	*N* or average	Percentage
Laparoscopic cholecystectomies analyzed	217,775	
Non-IOC cases	166,102	76.27
IOC cases	51,673	23.73
Demographics		
Age	49 (±17)	
Male	64,346	29.55
Female	153,429	70.45
Surgery characteristics		
Elective surgery	138,121	63.42
Non-elective surgery	79,654	36.58
Operative time	65 min (±39)	
Cases with cholecystitis	147,609	67.78
Cases without cholecystitis	70,166	32.22
Conversion to open procedure	83	0.04
Resident involvement[a]	5334[a]	17.17[a]
No resident involvement[a]	25,737[a]	82.83[a]

[a]Only 2012 NSQIP registry analyzed

Results

A total of 217,775 laparoscopic cholecystectomy cases were analyzed after inclusion criteria filtration was performed on the NSQIP registry for the years 2012–2016. The characteristics of the cases analyzed are listed in Table 1. Most of the procedures were performed in an elective manner on middle-aged females. Cholecystitis was involved in over two-thirds of the cases. There was a very low rate of conversions to an open procedure (0.04%). Only the 2012 NSQIP registry was able to be analyzed for resident involvement (that was the last year resident involvement information was collected by the ACS) with under 20% of all laparoscopic cholecystectomies performed as teaching cases. Teaching cases appeared protective for BDI with our findings with a relative risk (RR) score of 0.56 (*P* value < 0.0001).

There were 433 cases in which a BDI was identified correlating to an incidence rate of 0.19%. Table 2 provides the statistics for all BDI characteristics analyzed. Figure 1 compares the BDI incidence rates between the case variables analyzed. The majority (77%) of BDI were identified post-operatively after the patient was discharged from their index surgical admission. Only in 99 cases (23%) was a BDI recognized intra-operatively or during the index admission. There was only one mortality identified in the 433 cases involving a BDI; a 57 year-old female who died on post-operative day 2 due to intra-abdominal sepsis secondary to an uncontrolled biliary leak. Due to only one identified death in the BDI group, no mortality statistical analysis was performed.

166,102 (76%) laparoscopic cholecystectomies were performed without the use of IOC and the remaining 51,674 (24%) cases used IOC. The respective incidence for a BDI with a procedure performed with and without the use of IOC was 0.23 and 0.19% reaching statistical significance with a *P* value of < 0.0001 (RR score 1.23). For the 99 cases when a BDI was diagnosed intraoperatively or during the index admission IOC was used 33.3% of the time. IOC was performed only 26.05% of the time in the other 334 cases when

Table 2 BDI characteristics

BDI occurrences	*N*	Incidence rate (%)	*P* value
Total BDI events	433	0.19	
BDI with IOC[a]	120[a]	0.23[a]	< 0.0001
BDI without IOC[a]	313[a]	0.19[a]	< 0.0001
BDI with cholecystitis[a]	310[a]	0.21[a]	< 0.0001
BDI without cholecystitis[a]	123[a]	0.18[a]	< 0.0001
BDI with resident involvement[a,b]	6[a,b]	0.11[a,b]	< 0.0001
BDI without resident involvement[a,b]	52[a,b]	0.20[a,b]	< 0.0001
BDI with conversion to open procedure[a]	12[a]	14.46[a]	< 0.0001

[a]Statistical significance achieved

[b]Only 2012 NSQIP registry analyzed

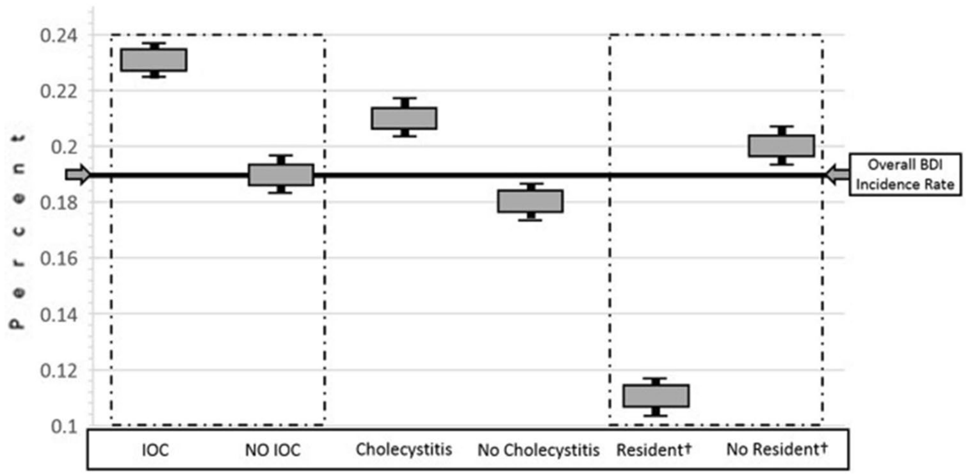

Fig. 1 BDI incidence rates. †Only 2012 NSQIP registry analyzed

the BDI was diagnosed after the index admission. The higher IOC usage rate in the BDI cases diagnosed intraoperatively or during the index admission reached statistical significant with a P value of < 0.0001.

Approximately 68% of all the laparoscopic cholecystectomies performed had cholecystitis as the principal postoperative diagnosis. 310 of the 433 cases of a BDI (71.6%) occurred in surgeries involving cholecystitis. The incidence for a BDI with cholecystitis present was 0.21% while the incidence rate for a BDI when cholecystitis was absent was 0.18%. The percentile difference of 0.03% between cases involving or not involving cholecystitis was statistically significant with a P value of < 0.0001 (RR score 1.20).

83 cases were converted to an open cholecystectomy which equated to a conversion rate of 0.04%. However, in that small portion of conversion cases there were 12 cases of a BDI identified. The BDI incidence during a conversion to an open procedure was nearly a hundredfold higher at 14.46% resulting in a RR score of 65.44 for a BDI (P value < 0.0001).

Attempt at definitive surgical management of the BDI either during the index surgery or within a week of injury occurred in 19 cases. Delayed surgical reconstruction of the BDI was performed in 92 cases. The other 322 cases of a BDI were treated with either endoscopic or interventional radiology procedures. The only mortality that was identified in the registry set did not occur in any of the cases involving repair of a BDI.

Discussion

After rapidly being established as the surgical standard for cholecystectomies in the 1990s the laparoscopic procedure was labeled as being risker for the occurrence of a BDI [16, 17]. Subsequent research found with time and greater experience BDI rates with laparoscopic cholecystectomies decreased from the initially cited high rates in the 1–3% range, but never reached the lower accepted incidence of 0.1–0.2% established in the open era [18]. The first large scale research studies performed in the mid-1990s determined the BDI rate for laparoscopic procedures was approximately 0.5% [19]. The last large scale studies performed a decade after the initial studies still found the laparoscopic BDI rate to be 0.5% [3, 7–9].

Little to no investigation has been performed since that time and current core surgical textbooks continue to identify laparoscopic cholecystectomies as more likely to cause a BDI versus an open approach [20, 21]. However, several of those last landmark studies were flawed in either their presentation of the BDI rate associated with the laparoscopic approach or the general interpretation of the study results. Specifically, the Flum studies that reviewed over one and a half million cholecystectomy cases never distinguished between an open or laparoscopic approach in their analysis. Yet, the 0.5% BDI incidence rate cited in those studies is largely attributed to laparoscopic cholecystectomies since that was the predominant manner in which cholecystectomies were being performed during the time period researched. We propose that those older studies are not applicable to the current surgical environment.

A BDI incidence rate of 0.19% with laparoscopic cholecystectomies was found in this study after analysis of over 217,000 procedures. Our findings correlate with recent smaller studies that identified similar laparoscopic BDI rates in the 0.1% confine [10, 11]. In particular the Halbert study which cited a BDI incidence rate of 0.08% was more comparable in size to our study with approximately 150,000 cases analyzed [11]. Yet, that study only identified BDI via patients who underwent surgical repair of the injuries by either hepatectomy, hepaticoenterostomy, or primary biliary repair which likely underreported the actual incidence rate. Approximately 75% of the BDI identified in our study were managed endoscopically which we believe more accurately identifies the current management practice of such injuries [22, 23]. The findings of more recent studies combined with our findings strongly suggest that laparoscopic cholecystectomies are no longer more prone to BDI compared to an open approach.

Once the correlation between the laparoscopic approach and increased BDI rates was established in the literature, a plethora of theories for this finding were offered. Many publications concluded that the laparoscopic "learning curve" was the etiology of the increased BDI rates [24–26]. One of the major factors in the "learning curve" was the difficulty of surgeons translating their open surgical skills into laparoscopic surgery. Specifically, the impediment of learning tactile feedback with laparoscopic instruments and adapting to processing two-dimensional images in a three-dimensional surgical field [27]. Subsequent studies discovered that laparoscopic experience alone wasn't the sole cause for increased BDI rates since a third of BDI occurred in cases outside the liberal definition of a "learning curve" (after 200 cases) [28]. Previous research also indicated a BDI was less likely during residency teaching which was also present in our study [28]. A plausible and academically supported reason why laparoscopic BDI rates have decreased is a significant portion of current surgeons are simply more adept at laparoscopic surgery due to behavioral patterns and formal training practices [29, 30]. Also recent initiatives by surgical associations like SAGES Safe Cholecystectomy Task Force (SCTF) further push the current surgical generation, which likely is more proficient with performance of a laparoscopic cholecystectomy, to make a BDI a never event [31].

A BDI will always be a risk with the performance of a laparoscopic cholecystectomy. The consensus of polled surgeons described a BDI as unavoidable in certain situations [32]. Two of the most researched and argued inherent risks for a BDI during a laparoscopic cholecystectomy are the presence of cholecystitis and IOC use. Cholecystitis has been shown to increase BDI due to the associated inflammation obscuring differentiation between the cystic duct and biliary tree [8, 33, 34]. Our results confirm those previous findings that cholecystitis still increases the risk of a BDI. IOC use has been an ongoing surgical debate into its ability to prevent a BDI but has generally been accepted as useful in detecting a BDI [3, 35]. IOC use in our study did not have a protective effect on BDI. IOC use was associated with a slight increase in BDI with a RR of 1.23. But, with the lack of knowing the indications for IOC use in the cases analyzed and the IOC practices of the surgeons involved it is difficult to make any definitive conclusions. Our results correlated with previous studies that IOC use does provide better identification of BDI intraoperatively. Even more salient is the finding that out of the 334 cases of a BDI diagnosed during a readmission only 26% of the cases had an IOC performed during the index procedure. While an IOC may not be protective against a BDI it could very well help prevent a readmission for a BDI if performed routinely during the index case identifying the BDI earlier.

Lastly, we evaluated the BDI rates in the setting of converting to an open procedure. The conversion rate in our study, 0.04%, was remarkably lower than the 3–5% conversion rate commonly cited [36, 37]. Conversion to an open procedure is a frequently taught alternative option during a difficult laparoscopic dissection or when a BDI is suspected. There is limited research regarding performing open cholecystectomies in the laparoscopic era, but the paucity of studies currently suggests an increased risk of BDI in cases when a conversion form a laparoscopic to an open approach occurs [38]. That finding could be due to the lack of open cholecystectomy experience with the younger surgical generation leading to a greater likelihood of a BDI when a procedure is converted [39–41]. Alternatively, this could reflect the altered anatomy and generally increased technical difficulty of these operations. Our results found the incidence of a BDI with a converted procedure was an outstanding 15%. Whether the BDI were caused during the laparoscopic or open portion of the procedure was unable to be ascertained from the NSQIP registry. It is certainly probable many converted cases were done for a BDI identified during the laparoscopic portion of the procedure. The salient point is there is a RR score of 65 for a BDI during a converted procedure. That finding brings serious contemplation to the following question; is conversion to an open cholecystectomy the safe and right answer for a difficult laparoscopic cholecystectomy with the current era of surgeons? More focused research is required for that answer.

There are certainly several limitations associated with this study. The NSQIP database relies on accurate input from the certified local registers to compile a high-quality registry. While the NSQIP registry has been validated for academic research the possibility of inaccurate data input is still a reasonable concern [12, 14]. Additionally, identification of a BDI in the NSQIP registry required a complex review process that could lead to inaccuracy. There were numerous ICD-9 codes that could be associated with a BDI leading to either over-inclusion or under-inclusion. We made the decision to err towards over-inclusion. Thus, any ICD-9 code that could be associated with a BDI was classified as a BDI in our analysis. That over-inclusion approach could have lead to our BDI incidence rate of 0.19% being falsely elevated. Also, there was no ability to individually scrub medical records in NSQIP to secondarily and independently confirm a BDI. Another potential shortcoming was over three-fourths of the BDI cases identified were diagnosed on readmission. That again brings the potential of inaccuracy based on how the readmission was coded. The NSQIP registry has been validated for readmission accuracy which helps limits our concerns of inaccurate data analysis [42]. Lastly, our conversion rate could have been falsely low due to converted cases simply being labeled with open CPT codes. Overall, we feel appropriate data extraction methods were utilized resulting in scientifically sound results within the constraints of the NSQIP registry.

Conclusion

The performance of a laparoscopic cholecystectomy in the United States and Canada is no longer associated with a higher risk of a BDI compared to an open cholecystectomy. The 0.19% incidence rate now rests in the historical low range of open cholecystectomies. The reduction in BDI rates is likely secondary to the current surgical generations adeptness in performing a laparoscopic cholecystectomy. IOC use still does not appear to be protective for a BDI. Cholecystitis still increases the risk of a BDI. While the current surgical generation is less likely to cause a BDI during a laparoscopic cholecystectomy, converting to an open procedure may no longer be the safer alternative, and further research into this would be warranted.

Compliance with ethical standards

Disclosures Drs. Christopher W. Mangieri, Bryan P. Hendren, Matthew A. Strode, Bradley C. Bandera, and Byron J. Faler have no conflicts of interest or financial ties to disclose.

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