

Bile duct injury during laparoscopic cholecystectomy: An Indian e-survey

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Backgrounds/Aims: In the absence of national registry of laparoscopic cholecystectomy (LC) or its complications, it is impossible to determine incidence of bile duct injury (BDI) in India. We conducted an e-survey among practicing surgeons to determine prevalence and management patterns of BDI in India. Our hypothesis was that majority of surgeons would have experienced a BDI during LC despite large experience and that most surgeons who have a BDI tend to manage it themselves. **Methods:** An 18-question e-survey of practicing laparoscopic surgeons in India was done. **Results:** 278/727 (38%) surgeons responded. 240/278 (86%) respondents admitted to a BDI during LC and 179/230 (78%) affirmed to more than one BDI. A total of 728 BDIs were reported. 36/230 (15%) respondents experienced their first BDI even after >10 years of practice and 40% had their first BDI even after having performed >100 LCs. 161/201 (80%) of the respondents decided to manage the BDI themselves, including 56/99 (57%) non-biliary surgeons and 44/82 (54%) surgeons working in non-biliary center. 37/201 (18%) respondents admitted to having a mortality arising out of a BDI; the mortality rate of BDI was 37/728 (5%) in this survey. Only 13/201 (6%) respondents have experienced a medico-legal case related to a BDI during LC. **Conclusions:** Prevalence of BDI is high in India and occurs despite adequate experience and volume. Even inexperienced non-biliary surgeons working in non-biliary centers attempt to repair the BDI themselves. BDI is associated with significant mortality but litigation rates are fortunately low in India. (*Ann Hepatobiliary Pancreat Surg* 2020;24:469-476)

Key Words: Laparoscopic cholecystectomy; Bile duct injury; E-survey; Prevalence; Bile leak

INTRODUCTION

Laparoscopic cholecystectomy (LC) has become standard surgical treatment for gallstone disease. There is a wide range (0.5% to 1.5%) of incidence of BDI during LC,^{1,2} compared to 0.3% for open cholecystectomy (OC).³ Incidence (number of BDIs divided by number of LCs) data is available from countries in Europe and USA where population and registry data is available.^{2,4} With a population of about 1.3 billion, a large number of LCs are performed in India. It is not possible to document incidence of BDI since there is no national registry of LC or its complications. Prevalence (number of surgeons who had a BDI divided by number of surgeons doing LC) data is available from surveys in many western and developed countries including USA,⁵ Canada,⁶ Italy,⁷ Sweden,⁸ UK,⁹

Japan, Korea and Taiwan,¹⁰ but there are no studies from low-middle income countries (LMIC), including India.

We conducted an e-survey amongst practicing surgeons to find out prevalence and management patterns of BDI in India. We hypothesized that majority of surgeons in India continue to experience a BDI during LC even after adequate experience with LC. We also hypothesized that most surgeons who have a BDI tend to manage it themselves.

MATERIALS AND METHODS

Questionnaire

An anonymous e-survey was developed using Survey Monkey[®], an online survey development cloud-based software (www.surveymonkey.com). 17 questions were closed

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type (multiple choices) and 1 was free response type (open ended). The questions were self-explanatory, but any doubts raised by the respondents were clarified by the authors on email/over phone. Four professors reviewed the questions and confirmed them to be representative of the content validity of the survey. The survey was filled twice by different individuals to identify errors in wording, grammar or syntax. The 'Logics' feature on Survey Monkey[®] allowed the respondents to skip to a specific question based on their answer to a previous close-ended question. The respondents could skip the questions they didn't want to answer or change their answers before the final submission. The average survey response time was five minutes. Internet Protocol addresses were checked to avoid duplication of responses.

Four questions aimed to establish the nature of practice of the surgeon viz. private setup, corporate hospital or institute-based practice (Q 1) and the experience with LC (Q 2) and whether the respondent surgeon is a biliary or non-biliary surgeon (Q 16), working in a biliary or non-biliary center (Q 17). The respondents were then asked if they have ever had a post-cholecystectomy BDI (Q 3) and whether they have had more than one BDI (Q 4). We asked them to report a BDI during LC either done by them or supervised by them and not to include BDIs occurring in the hands of other surgeons/units and referred to them for definitive management. Respondents who admitted to a BDI during LC were then taken through questions to ascertain number of years of laparoscopic surgery experience (Q 5) and number of LCs (Q 6), specifically prior to their first BDI. Responses were obtained regarding associated bilio-vascular injury (BVI) (Q 7), use of intraoperative cholangiography (IOC) (Q 8), time of detection of BDI (intraoperative, postoperative or follow-up) (Q 9), respondent's role in the operating team in the LC i.e. chief operating surgeon, assisting senior surgeon as junior colleague, assisting junior surgeon as senior colleague or leader of operating team (even if not scrubbed in the case) (Q 10), choice of management (self-management or referral) (Q 11), management strategy (Q 12), any BDI during laparoscopic converted to open or open cholecystectomy (Q 13), any mortality related to BDI (Q 14) and any medico-legal litigation arising out of the BDI (Q 15). The last question (Q 18) was a text-based question which aimed to collect similar information regarding sub-

sequent BDIs. The questionnaire is attached (Supplement 1).

In order to attain uniformity we used the following definitions; these were explained to the respondents on phone/email, in case they had any doubts.

Bile duct injury

1. Unexplained intraoperative visualization of bile.
2. Visualization of bile in the drain placed intraoperatively.
3. Visualization of bile in a percutaneous catheter drain (PCD) placed postoperatively.
4. Surgical obstructive jaundice due to benign biliary stricture (BBS).

Biliary surgeon

A surgeon who performs elective hepatico-jejunostomy on a regular and frequent basis.

Biliary center

A facility where infrastructure and expertise for interventional radiology, therapeutic endoscopy and biliary reconstructive surgery are available.

Survey population

The senior author (VKK) emailed members of Uttar Pradesh State Chapter of Association of Surgeons of India (UPASI), Society of Endoscopic and Laparoscopic Surgeons of India (SELSI), faculty members in institutions offering superspecialty training programs in surgical gastroenterology and alumni of our department over last three decades explaining the purpose of the survey. The respondents were invited to click on the embedded question or the hypertext link, which invoked the web browser and presented the web-based questionnaire. Once completed by the respondents, the questionnaires were transmitted anonymously to the sender. Responses were received by email in a format which enabled transfer to Microsoft Excel and SPSS. The respondents were assured of complete anonymity and informed that their responses would be collated for analysis for presentation/ publication; no incentives were offered. The eligible participants were given 5 weeks' to complete the questionnaire from 24. 4. 2020 till 30. 5. 2020.

Exemption from review was obtained from the institutional ethics committee (2018-62-IP-EXP) of Sanjay Gandhi

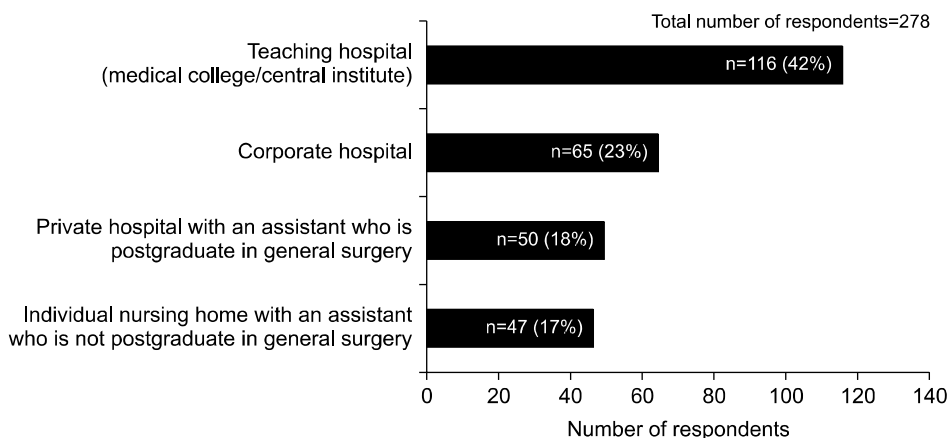


Fig. 1. Bar chart to show the demography of surgical practice of respondents.

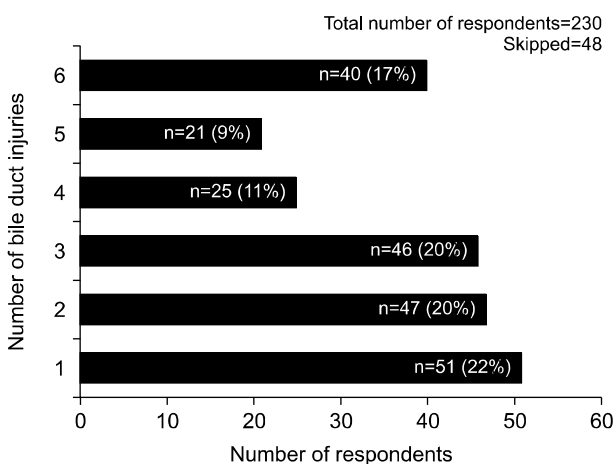


Fig. 2. Bar chart to show number of bile duct injuries experienced by the respondents.

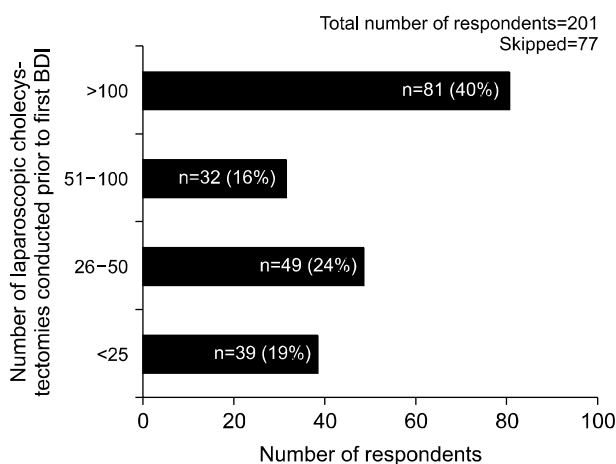


Fig. 3. Bar chart to show number of laparoscopic cholecystectomies conducted prior to the first bile duct injury. RYHJ, Roux-en-Y hepaticojejunostomy.

Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow India. We adhered to the Checklist for Reporting Results of Internet E-surveys to report the data.¹¹

RESULTS

A total of 2,916 emails were sent, 727 persons opened the survey and we received 179 responses over email and 99 responses via the web link. The overall response rate of survey was 278/727 (38%).

Fig. 1 shows the demography of surgical practice of respondents (Q 1). 132/278 (47%) respondents had more than 15 years of experience in LC (Q 2). 102/201 (51%) were biliary surgeons (Q 16) and 119/201 (59%) worked in a biliary center (Q 17).

As many as 240/278 (86%) of respondents had experienced at least one BDI in their practice (Q 3) and 179/230

(78%) affirmed to more than one BDI (Q 4). Fig. 2 depicts breakup of the number of BDIs experienced by respondents.

Majority i.e. 141/230 (61%) experienced their first BDI within 5 years of their laparoscopy career, while 36/230 (15%) experienced a BDI even after being in practice for >10 years (Q 5). Fig. 3 shows number of LCs performed by respondents before the first BDI (Q 6). BVI during BDI was reported by 14/201 (7%) respondents (Q 7). Only 11/201 (5%) routinely use intraoperative cholangiography (IOC) at their centers (Q 8). Fig. 4 shows time of detection of the first BDI; 196/201 (97%) of the respondents identified a BDI as bile leak either on-table or in the drain and only 5/201 (2%) reported it manifesting as a benign biliary stricture on follow up (Q 9). The first BDI occurred in the hands of 125/201 (62%) respondents when they were the operating surgeon. The respondent

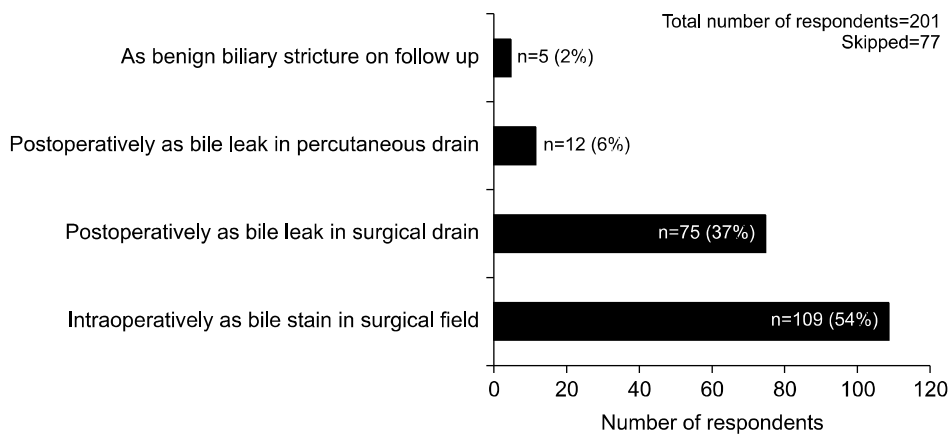


Fig. 4. Bar chart to show time of detection of the first bile duct injury.

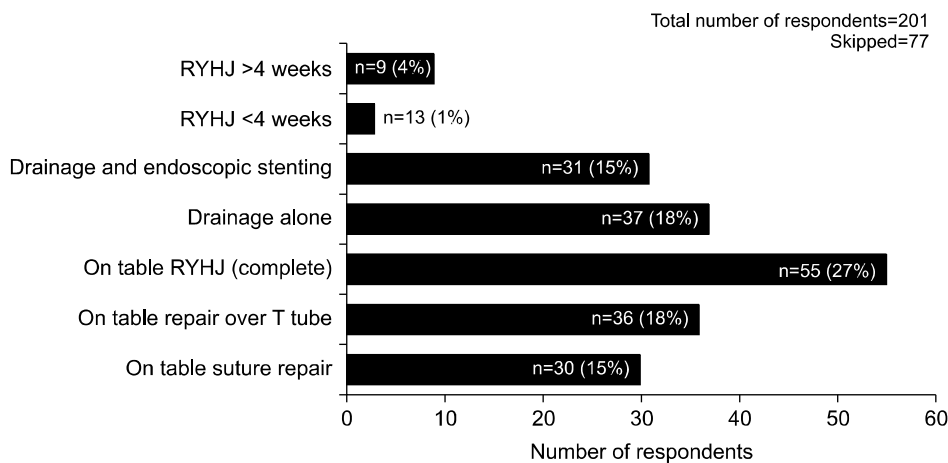


Fig. 5. Bar chart to type of management strategy used by the respondents. RYHJ, Roux-en-Y hepaticojejunostomy.

was assisting a senior surgeon in 39 (19%) instances, assisting a junior surgeon in 12 (6%) and was not scrubbed (but was the team leader) on 25 (12%) occasions (Q 10). 161/201 (80%) of the respondents decided to manage the BDI themselves and only 40/201 (20%) referred the patient to another center (Q 11). Fig. 5 lists the management strategy used by respondent surgeons (Q 12). Table 1 shows a comparative analysis between respondents who opted to manage their BDI on their own vs. those who referred the patient to a higher center with regard to their nature of surgical practice, number of prior LC performed, satisfying criteria of a biliary surgeon and working in a biliary center as outlined in the questionnaire. Table 2 compares the specific type of management strategy of the BDI chosen by various groups of surgeons. 86/201 (43%) respondents had had a BDI in laparoscopic converted to open or open cholecystectomy also (Q 13). 37/201 (18%) respondents admitted to having a mortality arising out of a BDI (Q 14); these 37 deaths occurred in a total of 728

BDIs reported in the survey, resulting in a mortality rate of 5% in this survey. 13/201 (6%) respondents have experienced a medico-legal case related to a BDI in their own hands (Q 15).

NOTE Not all numbers tally as all respondents did not answer all the questions.

DISCUSSION

Our web based survey, probably the first of its kind from India, showed that most of the respondents had experienced a BDI and most had experienced more than one BDI during LC in their career. Moreover, most of the injuring surgeons preferred to manage the BDI themselves and very few referred the patient to higher center for definitive management of the BDI. BDI was associated with significant mortality but litigation rate was not very high.

The response rate in our survey was 38% which compares with 43% in UK survey,⁹ 45% in US survey,⁵ 58%

Table 1. Comparison between surgeons who opted to manage the duct injury themselves vs. surgeons who referred to a higher center

Surgical practice and experience		Self-managed n=161	Referred n=40	Total No.
Nature of practice	Individual nursing home based with an assistant who is not post graduate in general surgery	20 (69%)	9 (31%)	29
	Private hospital with an assistant who is post graduate in general surgery	24 (63%)	14 (37%)	38
	Corporate hospital	42 (91%)	4 (9%)	46
	Teaching hospital (medical college/central institute)	75 (85%)	13 (15%)	88
Number of LC before first BDI	< 25	27 (69%)	12 (31%)	39
	26-50	36 (73%)	13 (27%)	49
	51-100	23 (72%)	9 (28%)	32
	> 100	75 (92%)	6 (8%)	81
Biliary surgeon	Yes	96 (94%)	6 (6%)	102
	No	65 (66%)	34 (34%)	99
Working in a biliary center	Yes	110 (92%)	9 (8%)	119
	No	51 (62%)	31 (38%)	82

LC, laparoscopic cholecystectomy; BDI, bile duct injury

Table 2. Type of management strategy of the bile duct injury chosen by various groups of surgeons

Type of repair	Individual surgeon in nursing home n=29	Surgeons with < 5 year experience with LC n=123	Non biliary surgeons n=99	Working in a non biliary center n=82
On table suture repair	3 (10%)	18 (15%)	11 (11%)	7 (9%)
On table repair over T tube	7 (24%)	19 (15%)	25 (25%)	23 (28%)
On table RYHJ	9 (31%)	31 (25%)	17 (18%)	10(12%)
Drainage alone	6 (21%)	27 (22%)	21 (21%)	21 (26%)
Drainage+endoscopic stenting	3 (10%)	22 (18%)	22 (22%)	17 (21%)
§RYHJ < 4 weeks	1 (3%)	2 (2%)	1 (1%)	2 (2%)
§RYHJ > 4 weeks	0	4 (3%)	2 (2%)	2 (2%)
Summary of management				
Drainage with or without endoscopic stenting	9 (31%)	49 (40%)	43 (43%)	31 (39%)
Repair of BDI	20 (69%)	74 (60%)	56 (57%)	44 (54%)

LC, laparoscopic cholecystectomy; RYHJ, roux-en-y hepaticojejunostomy; BDI, bile duct injury

in Italian survey,⁷ 61% in a multi-national survey¹⁰ and 75% in Canadian survey.⁶ A confidential mail-out questionnaire to gauge surgeons' perspective on BDI during LC had a response rate of 75%, but received only 114 completed responses.⁶ An anonymous retrospective multi-center questionnaire-based survey mailed to 316 heads of surgical units had a response rate of 58% and reported on 235 BDIs.⁷ Our web-based survey had 278 responses from practicing surgeons who reported a total of 728 BDIs.

Although there are several surveys on prevalence of BDI, most include small number of respondents. The

Swedish survey interviewed 76 surgical departments which had reported a BDI,⁸ Canadian survey included 114 surgeons,⁶ British survey included 117 respondents⁹ and in Italian survey, only 184 heads of surgical units responded.⁷ We received responses from 278 surgeons; other surveys with larger number of respondents are the multi-national survey of 372 surgeons from Japan, Korea and Taiwan¹⁰ and US survey of 1,661 surgeons.⁵

Prevalence of BDI in our survey was 86% (78% for more than one BDI). Most surgeons tend to exaggerate their successful results and understate complications. Since

ours was a self-reported survey (and not an external audit) of a surgical complication, we believe actual prevalence rates are even higher. We had greater (42%) participation from surgeons in teaching hospitals, half were biliary surgeons and more than 85% had >5 years' experience with LC. The general/laparoscopic surgical community which performs majority of LCs is likely to have more non-biliary surgeons working in non-biliary centers i.e. nursing homes or private hospitals. Prevalence of BDI is likely to be even higher in their hands than in our sample.

The 86% prevalence of BDI in our survey compares with 79% in Swedish survey,⁸ 72% (BDIs and near misses) in multi-national survey¹⁰ and 69% in Italian survey⁷ but is much higher than 53% prevalence in the Canadian survey,⁶ 45% in UK survey⁹ and 27-38% in US survey.⁵

Experience of surgeon is no protection against BDI during LC. While 60% of BDIs in our survey occurred during first 5 years of laparoscopic surgical practice, so-called 'learning curve',¹² as many as 15% of our respondents reported their first BDI after 10 years in practice. About 40% of respondents had performed more than 100 LCs before their first BDI. This has been reported earlier too. One-third of 65 BDIs in Belgium occurred in the hand of experienced surgeons.¹³ In Canada, almost two-thirds of surgeons experienced a BDI after 100 cholecystectomies.⁶ Similarly, 30% of the BDIs reported from Spain occurred when the surgeon had performed over 200 cases.¹⁴ In USA too, one-third of 704 BDIs occurred in hands of surgeons who had performed >200 LCs.⁵ These observations indicate that so called 'learning curve' in LC¹⁵ is a myth¹⁴ and BDIs reflect fundamental errors in technique of LC rather than experience.^{5,16,17} A national multicenter questionnaire survey in Italy, sent to 316 heads of surgical units, did not identify risk factors in 80% of BDIs and half of these occurred during LCs described as "technically easy". Hence no cholecystectomy can be considered as a simple routine procedure, immune to the risk of BDI.⁷ In survey from Japan, Korea and Taiwan,¹⁰ authors found prevalence rate of BDI reached >80% among surgeons who had performed >1,000 cases.

We included bile leak as BDI in our questionnaire according to Strasberg's classification (Types A, C and D).¹⁸ Most surveys from West, citing decreasing incidence of BDI following LC, have identified BDI as only those biliary injuries which needed surgical intervention thus miss-

ing out those injuries which were managed by drainage with or without endoscopic stenting.^{5,19} Others have included only those BDIs which were treated at same center where LC was done, missing out on injuries managed at other centers.²⁰ Moreover, even so-called minor BDIs can cause severe morbidity and death. Academic Medical Center, Amsterdam, Netherlands, reported a total of 800 BDIs, 216 of these were Strasberg Type A injuries, but mortality in these 216 cases was as high as 9/216 (4.2%).²¹

Only 2.5% of our respondents reported BBS subsequent to BDI. Bile leaks (on-table or postoperatively in the drain) are more likely to be remembered by the surgeon and hence reported as BDI. Patients having a complication like BBS following LC are likely to go elsewhere than to injuring surgeon. Tertiary level referral hospitals in India report large number of post-cholecystectomy BBS.^{22,23}

More than 2/3rd of our respondents, many of whom were non-biliary surgeons working in non-biliary centers, opted to manage the BDI on their own, including on-table repairs and RYHJ. Some of these may have been minor injuries which could be managed with simple measures. It could also reflect mentality of the injuring surgeon to "fix the leak" then and there and thus avoid postoperative morbidity and litigation related to bile leak. This is worldwide experience,⁸ despite suggestions of better outcomes if the patient is referred to a higher center.²⁴ While immediate repair (end-to-end repair over T tube or RYHJ) by a biliary surgeon may be acceptable, it is not recommended for a non-biliary surgeon working in non-biliary center e.g. nursing home or private hospital to repair a BDI. Such attempts are rarely successful, cause more (higher) injury to the bile duct, can cause vascular injury and thus make future repair challenging even for biliary surgeon.²⁵ Immediate repair by the injuring general/laparoscopic non-specialist surgeon in the injuring hospital itself is one of the risk factors for litigation being filed and decided against the surgeon.²⁶

Associated BVI was reported by 7% of surgeons. This probably reflects on-table assessment based on intraoperative blood loss. Most surgeons would not routinely do vascular evaluation (e.g. Doppler, CT angiography or MR angiography), especially in setting of acute BDI. Figures quoted in literature for BVI vary from 0.25%²⁷ to 36%²⁸ depending on method used for documentation.

BDI can cause mortality due to uncontrolled intraabdo-

minimal and systemic sepsis. We recorded a mortality of 5% (37 deaths in a total of 728 BDIs). Since ours is a self-reported survey by a very select group of surgeons and not a longitudinal study, the actual figures can be even higher. Way back in 1994, Gouma and Go²⁹ reported mortality of 7.8% in 77 patients with BDI. In another report from India, Mishra et al.³⁰ reported 6 deaths in 137 patients with BDI. It was 3.5% in a single large institution (Academic Medical Center, Amsterdam, Netherlands) experience of 800 BDIs.³¹ BDI also increases life-time risk of biliary-related death. In a recent analysis of 711,454 cholecystectomies in USA, patients with bile leak were more likely (2.4% vs. 1.4%) to die at one year than those who did not and those with BDI were more likely (7.2% vs. 1.3%) to die at one year than those who did not.¹

Fortunately, litigation rates for BDI during LC are low in India. Only 6% of responding surgeons had medico-legal cases filed against them for BDI caused during LC. This is much lower prevalence than reported from other countries. In a report from the Great Britain and Ireland, 22% of 117 respondents reported a medico-legal experience following LC.⁹

In this web-based survey of surgeons, probably first such from India a LMIC, we found most surgeons have had at least one BDI during LC. BDI occurred even in the hands of “experienced” biliary surgeons. Many non-biliary surgeons working in non-biliary centers still attempt to repair the BDI themselves, contrary to the recommendations of various guidelines. BDI carries significant risk of death; mortality of BDI in this survey was 5%. BDI resulted in litigation against the surgeon though the rates were lower than in the West.

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CONFLICT OF INTEREST

The authors have nothing to disclose.

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AUTHOR CONTRIBUTIONS

Conceptualization: SS, VKK. Data curation: SS, RS, MD. Data Analysis: SS, AB, RS, MD, VKK. Original Writing: SS, VKK. Writing review and editing: SS, AB, VK.

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