

The Effect of the PALES 2020 Zero BDI Campaign in preventing Bile Duct Injury among General Surgeons performing Laparoscopic Cholecystectomy in the Philippines

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Abstract

Introduction: The Philippine Association of Laparoscopic and Endoscopic Surgeons (PALES) initiated the Zero BDI Campaign in 2017 to prevent bile duct injury (BDI) during laparoscopic cholecystectomy (LC). We aim to evaluate the effect of the campaign in preventing BDI among general surgeons performing LC and describe the contributing factors, types and management of BDI.

Methodology: This is a cross-sectional study conducted during the PALES 2020: Virtual Congress through an electronic survey. Data were gathered using Microsoft Excel. Statistical analysis was done using EPI info version 6.

Results: Two hundred ninety-eight (84.9%) out of responses 351 were included. Among them, 57 (19.13 %) surgeons reported a total of 103 BDI. 51 (17.11%) respondents had a 82 BDI before the campaign, and 16 (5.37%) surgeons reported BDI in 21 LC cases after the campaign. Among the surgeons who reported BDI, 45 (78.95%) of them had injury in acute cholecystitis, 12 (21.05%) in chronic cholecystitis and none in asymptomatic cholelithiasis. Those with BDI, 14 (24.56 %) were referred to another surgeon for repair, 14 (24.56 %) were converted to open repair over T-tube and 13 (22.81 %) were converted to open biliary reconstruction and a few performed laparoscopic intervention. Surgeons who performed more than 100 LC annually were 5.39 times more likely to have BDI. Conversion to open cholecystectomy, operative time and technique used to identify the Triangle of Calot were not associated with higher risk of BDI.

Conclusion: There was a clinical decrease in incidence of BDI during LC after the PALES 2020 – Zero BDI Campaign was introduced.

Keywords: bile duct injury (BDI), laparoscopic cholecystectomy, critical view of safety, Zero BDI Campaign

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Introduction

Since the advent of minimally invasive surgery, laparoscopic cholecystectomy (LC) has been the gold standard in the management of gallbladder disease. The beneficial effects of LC like shorter postoperative hospital stay, faster overall recovery time and better cosmetic outcome have been well established and documented.¹ However, bile duct injuries (BDI) still occur and several series described a

0.5 to 0.6% incidence during LC¹ while others report injuries as high as 1.1% that may result to severe to potentially life-threatening complications.²

The Philippine Association of Laparoscopic and Endoscopic Surgeons (PALES) initiated the Zero BDI Campaign three years ago with the goal of preventing BDI in the country. Currently, our local data is limited and the incidence of BDI in the Philippines has yet to

be defined.³

In this study, we aim to evaluate the effect of the PALES 2020 – Zero BDI Campaign in preventing BDI among general surgeons performing LC. By doing so, we can evaluate if the campaign is effective in educating and preventing BDI. The result will help determine the possible cause of BDI occurring in the Philippines and develop strategies and/or recommendations to prevent it especially in areas with high prevalence.

Furthermore, we would like to describe the contributing factors to BDI and the surgeons' experience in terms of the types of BDI and its management.

Methodology

This is a cross-sectional study aimed to evaluate the effect of the PALES 2020 – Zero BDI Campaign in preventing BDI among general surgeons performing LC. The sampling population was from the PALES 2020: Virtual Congress. This served as a platform to collect data such as the email address of the participants which was used to send the survey form. Participants included were fifth year surgical residents, fellows-in-training and consultants performing LC in the country. Surgeons of specialties other than general surgery were not included.

A letter was sent to PALES asking permission to use the email address of the participants which they granted. An email was sent to the participants containing the link to the survey form. The survey form consisted of a message to the participants, an informed consent form and the questionnaire. They were asked to answer a 10-item multiple choice questionnaire for 10 minutes. Data acquired were tabulated and correlated accordingly. They were allowed to answer the survey only once.

No withdrawal criteria were considered in this study as long as the minimum sample size was achieved.

The sample size was calculated based on the estimation of population proportion of

consultants / fellows-in-training / fifth year surgical residents' performing laparoscopic cholecystectomy. A 50% proportion was used since there were no previous studies on this aspect. Assuming that the proportion is 50% with a maximum allowable error of 5% and reliability of 90%, computed population size is 269.

Data was processed and encoded using Microsoft Excel. Statistical analysis was done using EPI info version 6. Evaluation of the effect of the PALES 2020 – Zero BDI Campaign in preventing BDI among general surgeons performing LC was done using frequency and percentages. 95% confidence interval of the proportion was calculated.

Descriptive statistics was used to summarize the Socio-Demographic Profile of the respondents. Fisher's exact and Chi-square test was used to determine the difference between with and without BDI. McNemar test was used to determine the difference from before July 2017 to August 2017 onwards in terms of number of LC done annually. Odds ratio and corresponding 95% confidence intervals from binary logistic regression was computed to determine significant predictors for BDI. Missing variables was neither replaced nor estimated. Null hypotheses were rejected at 0.05 α -level of significance. STATA 13.1 was used for data analysis.

The research protocol was reviewed and approved by the Institutional Ethics Review Committee of the FEU-NRMF Institute of Medicine.

Results

A total of 351 responses were received from the survey conducted by PALES. These were screened for double entries and completeness. Two hundred ninety-eight (84.9%) responses were included in this study.

Among the included responses, 251 (84.23%) were from consultants, 16 (5.47%) were from fellows-in-training and 31 (10.40%) were from fifth-year surgical residents. 178 (59.73%) were PALES Fellows, 8 (2.68%) were Associate Members, and 112 (37.58%) were

Non-members. The respondents were distributed among different chapters with a majority of 109 (36.58%) coming from Metro Manila.

Most of the respondents (197, 66.11%) had completed postgraduate training in laparoscopy and 101 (53.02%) respondents had none. Two hundred twenty (73.83%) surgeons attended the PALES2020-ZERO BDI Campaign and 78 (26.17%) failed to attend. Among those who attended the said campaign, 48 (16.11%) of them had it 3 years ago, 87 (29.19%) attended 2 years ago and 85 (28.52%) attended within a year ago.

We documented the conversion rate to open cholecystectomy of LC performed by the respondents. Seventy six (25.50%) never converted to open surgery, 194 (55.10%) respondents had 0.1-5% conversion rate, 23 (7.72%) respondents had 5.1-10% conversion rate, 3 (1%) respondents had 10.1-20% conversion rate, 1 (0.34%) respondent had 20.1-30% conversion rate and 1 (0.34%) respondent had more than 30% conversion rate.

More than half of the respondents (186, 62.42%) had an average LC operative time of 60 minutes. Twenty three (7.72%) of them performed LC for an average of 30 minutes, 87 (29.19%) had an average of 120 minutes and 2 (0.67%) had an average of 180 minutes or more.

Included in the survey was the technique utilized in identifying the Triangle of Calot.

The most common answer was the utilization of the Strasberg Critical View of Safety by 264 (88.59 %) respondents. Nine (3.02%) of them preferred the infundibular technique, 4 (1.34%) respondents used the Cystic duct – Common hepatic duct junction, 18 (6.04%) surgeons used Rouviere’s sulcus – base of segment 4 – umbilical ligament (R4U) line and 3 (1%) used none.

The PALES2020-Zero BDI Time-Out was observed intraoperatively by 278 (93.29%) surgeons and 20 (6.71%) did not.

The Socio-Demographic Profile of the respondents were summarized in Table 1.

Among the 298 respondents, 57 (19.13 %) surgeons reported a total of 103 BDI. The conditional mean was computed at 1.81 BDI per surgeon.

Table 2 summarizes the numbers of respondents with and without BDI in terms of their socio-demographic profile. Among those with BDI, 54 (94.74%) of them were consultants, 2 (3.51%) were 5th year resident and 1 (1.75%) was a fellow-in-training. Majority (49, 85.96%) of those with BDI were PALES fellows and 8 (14.04) respondents were non-member. More than half (29, 50.88%) of the respondents were from Metro Manila Chapter. Forty six (80.7%), of those with BDI claimed to had attended Postgraduate training in Laparoscopy. Majority of them (43, 75.44%) attended the PALES2020-ZERO BDI Campaign.

Socio-Demographic Profile of Survey Respondents	Total (n=298)
Current Position	
Consultant	251 (84.22%)
Fellow-in-training	16 (5.37%)
5th Year Resident	31 (10.40%)
PALES Membership	
Fellow	178 (59.73%)
Associate Member	8 (2.68%)
Non Member	112 (37.58%)

PALES Chapter	
Northern Luzon	20 (6.71%)
Central Luzon	17 (5.70%)
Southern Tagalog	40 (13.42%)
Cebu Eastern Visayas	23 (7.72%)
Western Visayas	7 (2.35%)
Northern Mindanao	15 (5.03%)
Southern Mindanao	10 (3.36%)
Metro Manila	109 (36.58%)
None	57 (19.13%)
Postgraduate Training in Laparoscopy	
Yes	197 (66.11%)
No	101(53.02%)
Attended the PALES2020-ZERO BDI Campaign	
Yes, please specify	
3 years ago	48 (16.11%)
2 years ago	87 (29.19%)
<1 year ago	85 (28.52%)
No	78 (26.17%)
Conversion Rate to Open Cholecystectomy	
0	76 (25.50%)
0.1-5%	194 (55.10%)
5.1-10%	23 (7.72%)
10.1-20%	3 (1%)
20.1%-30%	1 (0.34%)
>30%	1 (0.34%)
Average Laparoscopic Cholecystectomy Operative Time	
30 minutes	23 (7.72%)
60 minutes	186 (62.42%)
120 minutes	87 (29.19%)
≥ 180 minutes	2 (0.67%)

Table 1. Socio-Demographic Profile of Survey Respondents, Philippines 2020

Socio-Demographic Profile of Survey Respondents	With BDI (n=57)	Without BDI (n=241)
	Frequency (%)	
Current Position		
Consultant	54 (94.74%)	197 (81.74%)
Fellow-in-training	1 (1.75%)	15 (6.22%)
5th Year Resident	2 (3.51%)	29 (12.03%)
PALES Membership		
Fellow	49 (85.96%)	129 (53.53%)
Associate Member	0	8 (3.32%)
Non Member	8 (14.04%)	104 (43.15%)

PALES Chapter		
Northern Luzon	1 (1.75%)	19 (7.88%)
Central Luzon	5 (8.77%)	12 (4.98%)
Southern Tagalog	10 (17.54%)	30 (12.45%)
Cebu Eastern Visayas	5 (8.77%)	18 (7.47%)
Western Visayas	1 (1.75%)	6 (2.49%)
Northern Mindanao	1 (1.75%)	14 (5.81%)
Southern Mindanao	0	10 (4.15%)
Metro Manila	29 (50.88%)	80 (33.2%)
None	5 (8.77%)	52 (21.58%)
Postgraduate Training in Laparoscopy		
Yes	46 (80.7%)	151 (62.66%)
No	11 (19.3%)	90 (37.34%)
Attended the PALES2020-ZERO BDI Campaign		
Yes, please specify		
3 years ago	14 (24.56%)	34 (14.11%)
2 years ago	15 (26.32%)	72 (29.88%)
<1 year ago	14 (24.56%)	71 (29.46%)
No	14 (24.56%)	64 (26.56%)

Table 2. Comparison of with and without BDI in terms of Socio-Demographic Profile of Survey Respondents

There were 51 respondents who had a total of 82 BDI before July 1, 2017. From August 2017 to the present, when PALES 2020 ZERO BDI

Campaign was launched, only 16 surgeons reported BDI in 21 LC cases. (Table 3)

Number of Laparoscopic Cholecystectomies Done Annually	Before July 1, 2017 (n=82)	August 2017 to Present (n=21)	Comparison before and after (P-value)
	Frequency (%)		
1-50	23 (28.05)	5 (23.81)	0.315
51-100	25 (30.49)	9 (42.86)	
101-150	7 (8.54)	3 (14.29)	
151-250	5 (6.1)	0	
251-500	11 (13.41)	4 (19.05)	
More than 500	11 (13.41)	0	

Table 3. Number of Bile Duct Injuries (BDI) in Laparoscopic Cholecystectomies Performed by Respondents, Philippines, before July 1, 2017 and from August 2017 to Present

Among the surgeons who reported BDI, 45 (78.95%) of them observed injury while performing LC in acute cholecystitis, 12 (21.05%) had an injury while operating on chronic cholecystitis and none were observed in cases with asymptomatic cholelithiasis (Table 4).

Majority (21, 36.84 %) of the respondents who had BDI classified their injury as Strasberg A. Five (8.77 %) incurred Strasberg B injury, 6 (10.53 %) had Strasberg C injury, 9 (15.79 %) had Strasberg D injury, 9 (15.79 %) had Strasberg D injury and 7 (12.28 %) answered not applicable as presented in Table 5.

Indications for Laparoscopic Cholecystectomy	Number (%) (n=57)
Asymptomatic or Pre-work clearance	0
Acute Cholecystitis	45 (78.95%)
Chronic Cholecystitis	12 (21.05%)

Table 4. Distribution of indications for laparoscopic cholecystectomies in patients who incurred bile duct injury (BDI), Philippines, 2020

Type of bile duct injury	Number (%) (n=57)
Strasberg A	21 (36.84%)
Strasberg B	5 (8.77%)
Strasberg C	6 (10.53%)
Strasberg D	9 (15.79%)
Strasberg E	9 (15.79%)
Not applicable	7 (12.28%)

Table 5. Types of Bile Duct Injury (BDI) in laparoscopic cholecystectomies performed by respondents, Philippines, 2017-2020

Intervention performed	Number (%) (n=57)
Refer to another surgeon	14 (24.56%)
Cannulation and drainage	1 (1.75%)
Drain placement only	3 (5.26%)
Conversion to open repair over T-tube	14 (24.56%)
Conversion to open biliary reconstruction	13 (22.81%)
Laparoscopic repair over a T-tube	7 (12.28)
Laparoscopic biliary reconstruction	1 (1.75%)
Not applicable	4 (7.02%)

Table 6. Intervention performed upon recognizing the bile duct injury (BDI) in laparoscopic cholecystectomies performed by respondents, Philippines, 2017-2020

Of the interventions that were performed during the index operation, 14 (24.56 %) referred to another surgeon for repair, 14 (24.56 %) converted to open repair over T-tube and 13 (22.81 %) converted to open biliary reconstruction. A small percentage performed laparoscopic intervention after identifying BDI intraoperatively as shown in Table 6.

Summarized in Table 7 are the factors that may associate with bile duct injury. Surgeons who performed less than or equal to 100 LC annually were 82% less likely to have BDI. Those who performed more than 100 LC annually were 5.39 times more likely to have BDI. Conversion rate to open cholecystectomy, average LC Operative time and technique used to identify the Triangle of Calot were not associated with higher risk of BDI.

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Factors Associated with Bile Duct Injury	Odds ratio (95% CI)	P-value
Number of Laparoscopic Cholecystectomies Done Annually		
≤ 100	0.18 (0.09 to 0.38)	<0.001
> 100	5.39 (2.6 to 11.17)	<0.001
Conversion Rate to Open Cholecystectomy		
≤ 5%	1.50 (0.49 to 4.57)	0.479
>5%	0.67 (0.22 to 2.04)	0.479
Average Laparoscopic Cholecystectomy Operative Time		
≤ 60 minutes	1.66 (0.85 to 3.22)	0.137
> 60 minutes	0.60 (0.31 to 1.17)	0.137
Technique Used to Identify the Triangle of Calot		
Strasberg CVS	0.90 (0.37 to 2.19)	0.818
Infundibular	1.22 (0.24 to 6)	0.811
Cystic duct – Common hepatic duct junction	4.34 (0.60to31.53)	0.146
Rouviere’s sulcus – base of segment 4 – umbilical ligament (R4U) line	0.84 (0.23 to 2.99)	0.784
None	-	-

Table 7. Factors associated with Bile Duct Injury, Philippines, 2017-2020

Discussion

Patient safety is one of the forefront principles of any surgeon. Part of it is preventing iatrogenic injuries that may happen especially in one of the most common surgical procedures which is cholecystectomy. Together with the shift in surgical advancement from open surgery to laparoscopy is every surgeon’s quest to lower complications. Several studies have reported that the incidence of BDI in LC is higher at around 0.5 to 0.6% compared to an open technique which accounts for 0.1 to 0.3%.¹

During the First Virtual Congress of the PALES on May 2020 with a theme: *Optimizing Outcomes in MIS during Challenging Times*, it conducted a survey among surgeons who perform LC. More than half of our respondents had completed postgraduate training in

laparoscopy and majority attended the PALES2020-ZERO BDI Campaign. Among those with BDI, 46 (80.7%) had postgraduate training in laparoscopy and 43 (75.44%) attended the PALES2020-ZERO BDI Campaign. This showed idem result to a survey conducted in British Columbia, Canada wherein 97% of 114 respondents had completed formal training in laparoscopic cholecystectomy and one half of them reported bile duct injury.⁴ In this literature, they concluded that, there were actually more injuries in practicing surgeons for 10 years since the start of laparoscopy. Hence, BDI still occurs despite the volumes of procedures and increased experience.

According to Way, et al., the principal cause of BDI was misperception, not errors in knowledge, skills, not judgment⁵. Similarly, the Delphi consensus also identified that mis-

perception, not errors in knowledge, skills nor judgment.⁵ Similarly, the Delphi consensus also identified that mistaking the common bile / hepatic duct or the right hepatic duct for the cystic duct which is also called the “classic laparoscopic injury”, constituted the bulk of misidentification.⁶ Firmly held assumptions will not correct errors even if there are irregularities identified.

To decrease the incidence of BDI during LC, Iwashita et al. suggested that it is imperative to find a common ground among surgeons in order to establish an effective surgical education system.⁶ To date, several large-scale questionnaire surveys have been conducted⁹⁻¹⁰; however, very little specifically looked at the surgical techniques or the landmarks that have been reported as important in preventing bile duct injury.⁶

In our study, we were not able to establish the local incidence of BDI. Among the respondents, 57 out of 298 surgeons reported a total of 103 BDI. There were 51 respondents who had BDI before July 1, 2019 which decreased to 16 surgeons from August 2017 to the present, when PALES 2020 ZERO BDI Campaign was launched. The clinical decrease in incidence may be attributed to increased awareness and understanding by the surgeons of the standard steps in laparoscopic cholecystectomy through the campaign. As Berci and company recommended, specialized and standardized training in operative techniques and maneuvers during LC must be introduced in order to mitigate BDI.⁷

Acute cholecystitis was concluded to significantly increase the risk of sustaining BDI during cholecystectomy. The severity of cholecystitis according to the Tokyo grading directly result in higher risk, that is, Tokyo grade II doubles the risk and Tokyo grade III results to eightfold increase in risk.⁸ In our survey, majority of the BDI occurred while operating on an acute cholecystitis (44 out of 57, 77.19%). Vivek and colleagues attributed extensive adhesiolysis and challenging dissection in the Calot's triangle as predictors of difficult LC⁹ which may contribute to increasing the risk for BDI.

There are different classifications for BDI. The first to create a classification was H. Bismuth in 1982 that was based upon the location of the injury in the biliary tree. This classification has five types according to the distance from the hilar structure especially bile duct bifurcation, the level of injury, the involvement of bile duct bifurcation, and individual right sectoral duct.¹⁰ A modification of the Bismuth classification is the Strasberg classification that allows differentiation between small and serious injuries during laparoscopic cholecystectomy as type A to D. Strasberg classification Type E is thought-out as an analog of the Bismuth classification. The Strasberg classification is very simple and is easily applied to bile duct injuries however, one major disadvantage is that it does not describe additional vascular involvement at all. Therefore, it cannot demonstrate a significant discrimination for specific injury patterns.^{1,10}

Among our respondents with BDI, 21 (36.84%) identified theirs as Strasberg A. The same incidence of Strasberg D and Strasberg E were identified with 9 (15.79%) cases respectively. Less commonly were Strasberg C with 6 (10.53%) cases and Strasberg B with 5 (8.77%) cases. In a study by Çavuşoğlu, et. al, the most commonly encountered injury was Strasberg A followed by Strasberg E.¹⁹ Strasberg A involves cystic duct leak due to inappropriate clipping or gallbladder bed leaks from Luschka, and can be managed through ERCP with stenting and subhepatic drain.^{11,12}

When asked about how the respondents managed the BDI, mostly answered referral to another surgeon (14, 24.56%), conversion to open repair over T-tube (14, 24.56%) and conversion to open biliary reconstruction (13, 22.81%). Only a small percentage continued with laparoscopic repair over T-tube (7, 12.28%) and laparoscopic biliary reconstruction (1, 1.75%). In a study conducted by Fletcher and colleagues, BDI identified intraoperatively were repaired in an open technique in 77.4% of cases. Most of the respondents (57.7%) expressed that BDIs could theoretically be repaired laparoscopically but only 25% of them had done so in practice.¹³

Renz, et al. has stated that improved intraoperative processes was the result of numerous attempts to increase safety during laparoscopic cholecystectomy. One such endeavor included a detailed documentation of the CVS which was first reported by Strasberg 20 years ago.¹ The CVS refers to the hepatocystic triangle cleared of fat and fibrous tissue, exposure of the cystic plate and identification of two and only two structures entering the gallbladder.¹⁴ Several additional techniques are described to prevent bile duct injury during laparoscopic cholecystectomy such as infundibular technique, cystic duct – common hepatic duct junction, Rouviere’s sulcus – base of segment 4 – umbilical ligament (R4U) line as well as minimal use of electro-surgical unit just to name a few. In spite of the abundance of publications and arguments, no consensus has been agreed upon regarding the best setting and method. Though, achieving the CVS and intraoperative cholangiography (IOC) are among the most favored and effective method according to most surgeons.¹

As stated earlier, the most dreaded complication of laparoscopic cholecystectomy is iatrogenic BDI and if managed incompetently, may result to portal hypertension, secondary biliary cirrhosis and cholangitis. Some journals have stated that the quality of life may be compromised and survival may be reduced even with successful management.^{1,2} In general, the primary surgeon who performed the initial cholecystectomy will less likely manage the biliary injury successfully with biliary reconstruction success rates between 17 and 30%. Data from Renz et al. suggest that a hepatobiliary surgeon with comprehensive skill in biliary reconstruction should be the one to manage these injuries since results can be excellent with long-term success rates of more than 90%. An experienced multidisciplinary team (including interventional radiology, gastroenterology and surgery) in a tertiary referral center is often required in the management of these complicated injuries.¹

The Philippine Association of Laparoscopic and Endoscopic Surgeons (PALES) held its 10th Annual Convention through a Virtual

Congress due to the ongoing pandemic with the theme – Optimizing Outcomes in MIS during Challenging Times. One of its advocacies is the PALES 2020 – Zero BDI Campaign which was launched in 2017 to promote safe laparoscopic cholecystectomy in the country and so far, PALES has gone to 23 cities and municipalities. Another advocacy is the PALES 2020 – Zero BDI Timeout wherein surgeons conduct a momentary pause to confirm that the criteria for the Critical View of Safety (CVS) have been attained before clipping and transecting ductal or arterial structures.

The PALES continues to improve the quality of surgical care through its campaigns. The biggest of these projects is the PALES 2020 – ZERO BDI CAMPAIGN which contributed in the decrease of the incidence of the BDI incurred by surgeons while performing LC. The result of this survey preliminary result that surgeons who performed more than 100 LC annually were 5.39 times more likely to have BDI. Conversion to open cholecystectomy, operative time and technique used to identify the Triangle of Calot were not associated with higher risk of BDI.

We recommend that our society will establish a systematic way of reporting BDI in LC in order to gather its true incidence and continue its determination in executing its campaign.

Disclosure

The authors do not have any relevant financial relationship(s) with any commercial interest that pertains to the content of this research.

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