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Evaluation of Surgical Site Infection in Bile Spillage Cases Compared to Non-Bile Spillage Cases Following Laparoscopic Cholecystectomy

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***Abstract*—**Bile spillage occurs frequently during laparoscopic cholecystectomy, yet its impact on postoperative outcomes remains unknown. It might not be as innocuous as some surgeons tend to believe and in fact might be associated with post-operative surgical site infections (SSI). It often leads to patient dissatisfaction, emergency department visit, with subsequent readmission and additional procedures. Thus, this study sought to examine whether bile spillage is indeed associated with increased risk of postoperative wound infections after laparoscopic cholecystectomy. We hypothesize that patients who experience bile spillage (BS) during operation, have an increased risk of SSI compared to those who do not. This is a prospective observational study conducted in the Department of Surgery, Patan Hospital over a period of one year. Patients undergoing laparoscopic cholecystectomy were included and bile spillage, if happened was noted. All cases were followed up for 30 days and SSI was diagnosed as per Center for disease control and prevention (CDC) defined criteria. Fisher's test was applied to compare SSI in bile spillage versus non bile spillage cases. A total of 112 patients were included in the final analysis. Bile spillage occurred in 20 cases and absent in the rest i.e., 92 cases. Among bile spillage cases, SSI was found in 4 cases (20%), whereas in non-bile spillage cases SSI was found in 8 cases (8.7%). However, it was statistically not significant (p value > 0.05). 11 (92%) cases were superficial SSI and one was organ-space infection. No mortality or 30-day readmission was found in our study period. Spillage of gallbladder content does not lead to an increase in SSIs. However, as the rate of SSI is still higher, surgeons should be careful to avoid iatrogenic gallbladder perforation and in case of bile spillage, thorough peritoneal irrigation with normal saline should be done.

***Keywords*—**Biliary spillage, organ space infection, Laparoscopic cholecystectomy, surgical site infection.

I. Introduction

CHOLILITHIASIS refers to calculus formed in the gallbladder. It presents a significant public health problem, affecting around 10% of the adult population and between 3% to 15% in Asia [1], [2]. In the Nepali population, it was found to be 2% to 6% [3]. Most of the gallstone do not cause symptoms i.e., 80% and approximately 2-3% become symptomatic per year with cumulative risk of 10% at 5 years. Half of the patients with symptoms develop a second attack within a year but in 30% of all cases, there is only one symptomatic attack [1].

In the 25 years, laparoscopic cholecystectomy has been established as the gold standard in surgery for cholelithiasis with clear advantage over open cholecystectomy as its minimal access, shorter length of stay in hospital, less pain and scarring, faster recovery and rapid convalescence, less post-operative infection [4]. It was associated with quicker return to normal activities [5]. Bile duct injuries was found similar to those during open era ranging from 0.1% to 0.5% but can be up to 3% [6].

Gallbladder perforation is the most common intraoperative problem or complication encountered by most surgeons, especially during learning curve of cholecystectomy. Perforation usually occurs either secondary to traction of forceps or from electro cautery thermal injury. It may occur as many as one third of patients during cholecystectomy [6]. It is unclear what consequences, if any are secondary to gallbladder perforation. For most patients, perforation does not result in any immediate complications or clinical difference [7], while some studies suggest that accidental gallbladder content spillage may cause more postoperative pain, ileus and infection, when compared with uncomplicated cases [8].

Compared to open cholecystectomy, laparoscopic cholecystectomy was found to have less incidence of SSI. Still port site infections and in few instances, deep/organ-space infection are seen following lap cholecystectomy in daily practice. Various factors may be associated with frequency of SSIs in laparoscopic cholecystectomies (LC) such as method of disinfection of laparoscopic instruments, microdamage to the reusable instruments, bacteriobilia, gallbladder content spillages, use of antibiotics, laparoscopic converted to open approach, concurrent bile duct repair, acute cholecystitis, male gender and patient comorbidity [9]. SSI after laparoscopic cholecystectomy increases patient dissatisfaction, emergency department visits, with subsequent readmissions, additional procedures [10]

SSIs are most common healthcare associated infection (HAI) accounting for 31% of all HAIs among hospitalized patients [11]. SSIs rate is much lower in laparoscopic surgery than conventional surgical procedure. However, it is not uncommon [12].

Bile spillage occurs frequently during laparoscopic cholecystectomy yet its impact on postoperative outcomes remains unknown. It might not be as innocuous as some surgeons tend to believe and in fact might be associated with postoperative SSI [13]. It often leads to patient dissatisfaction,

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emergency department visit, with subsequent readmission and additional procedures [10]. While some authors [13] found no increase in SSI following bile spillage compared to non-bile spillage cases, others found bile spillage to be associated with SSI [13], [14]. Therefore, we sought to examine whether BS is indeed associated with increased risk of postoperative wound infections after laparoscopic cholecystectomy.

II. Methodology

This is a prospective, analytical, cross sectional study conducted at the Department of Surgery, Patan Hospital, PAHS, Lagankhel over a period of 7 months (June 2019 to January 2020). The objective of the study was to determine the rate of SSIs following laparoscopic cholecystectomy in bile spillage cases, to find out the rate of SSIs following laparoscopic cholecystectomy in non-bile spillage cases, and to compare SSI between bile spillage and non-bile spillage cases.

Minimum sample size calculated was 101.35. Considering 10% drop out rate, corrected sample size for this study was 112. Sample collection was discontinued after sample size was met (7 months period from June 2020 to January 2021).

All LC were included and patient who underwent conversion to open cholecystectomy, empyema gallbladder, acute cholecystitis and patient not giving consent were excluded from the study.

Data were collected using structured proforma covering all relevant subjects of the study. Consent was filled and demographic and clinical profile was filled up during preoperative assessment in OPD. Intra-operative factors were filled as per OT note filled by attending surgeon/assistant surgeon. During 1st follow up; wound was assessed by the researcher or in our absence colleague residents. Detailed orientation to study and assessment criteria was given to them. Weekly follow up regarding SSI was done up to 30 days by phone conversations using a questionnaire. Questionnaire during phone conversation was followed as shown in Table I.

TABLE I
Questionnaire for Telephone Interview to Patients

Do you have pain in the wound site?
Did you notice these wound conditions, complications-
Redness
Swelling
Pain despite of analgesic
Discharge
Other concern
Do you have Fever?

Pre-op work assessment and investigations in all planned laparoscopic cholecystectomy was done in OPD which included clinical history and examination, lab investigations (hemogram, coagulation profile, blood sugar, liver function test), ultrasound abdomen and American Society of Anesthesiologists (ASA) class as per Pre-Anesthetic Checkup (PAC).

All patients underwent surgery under general anesthesia following the hospital's protocol. As part of the procedure, a single dose of 1 gram of Cefazolin injection was administered to all patients undergoing laparoscopic cholecystectomy at the time of first incision. An infra umbilical 10-mm port was opened, pneumoperitoneum created. The other three trocars were placed under direct vision with 10-mm trocar placed in the epigastrium, a 5-mm trocar in the right subcoastal area in the mid-clavicular line, and a 5 mm trocar in the right anterior axillary line between the 12th rib and iliac crest. During the procedure, in case of spillage of bile from the gallbladder into the peritoneal cavity, thorough peritoneal lavage was performed with copious amount of normal saline. Gallbladder specimen was sent for histopathological examination. After the surgery was finished, the following parameters were documented in the operating theater (OT) notes: the presence or absence of gallbladder perforation, and if present, the type of content that had spilled. Gallbladder spillage was defined as the leakage of any amount of bile, stones, or pus from the gallbladder during the surgery. The duration of the surgery, defined as the time from the initial skin incision to the closure of the skin using skin stapling, was also recorded. These operations were conducted by either consultants or residents who were under the supervision and assistance of a consultant.

In the post operative period, patients were accessed for SSIs at discharge. After discharge, patients were called after 1 week for routine follow up and accessed for SSIs. Thereafter, patients were followed up weekly for 30 days by phone and following the questionnaire as mentioned above. Consent for this procedure was taken during consent for enrolment in the study; Phone conversation was conducted and was answered by the patient himself/herself or patient's relative (staying in the same house). In case of suspicion of SSI; the patient was called for follow up and assessed in OPD. If local signs of inflammation or purulent discharge from the wound were noted, stitches were opened up and the pus was sent for culture and sensitivity. Ultrasonography to rule out any collection was done in patients with clinical suspicion of deep and organ specific infection, if patients had a temperature > 38 °C (excluding the postoperative day 1), not responding to 48 hours of antibiotics, having increased pain, and showing signs of tenderness in the abdomen. If collection is found therapeutic, aspiration of collection was done. The quantity and type (pus/ bile/blood) of content were noted. Fluid was sent for culture and sensitivity. Postoperative superficial or deep incisional soft tissue SSIs and intra-abdominal abscess (organ/space SSI) was assessed by CDC defined criteria.

Informed consent was taken pre-operatively explaining the details of the study. Confidentiality was maintained. No alterations regarding management of the patient were done. The patient was allowed to accept/withdraw from the study any time. All data were collected on preformed pro forma and entered in MS Excel. The data were analyzed using EPI INFO version 7.2.2.2 and EZR version 1.

III. Results

A total of 115 patients underwent laparoscopic cholecystectomy from June 25, 2020 to January 18, 2021. Three were excluded from this study for being cases of acute cholecystitis, data collection was stopped after sample size was

met (112).

Bile spillage was present in 20 cases out of 112 (17.85%).

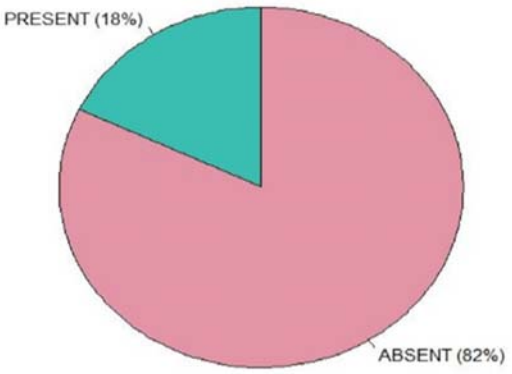

Fig. 1 Bile spillage among all cases of laparoscopic cholecystectomy

The mean age of study population was 43.53 ± 12.45 years, the minimum and maximum age was 16 years and 71 years respectively. Mean age in bile spillage cases was 46 years and in non-bile spillage cases was 43 years. 90 patients out of 112 (79.34%) patients included in study were of female gender, 22 (20.66%) being male.

Majority of patients undergone laparoscopic cholecystectomy were for symptomatic cholelithiasis 90 (80%), followed by chronic calculus cholecystitis (7) and acute biliary pancreatitis (12). Two cases were operated for gallbladder polyp and one for mucocele.

TABLE II
SOCIO-DEMOGRAPHIC CHARACTERISTICS

Parameters	Category	Bile Spillage Cases ($n_1 = 20$)		Non-bile spillage Cases ($n_2 = 92$)	
		Frequency	Percentage	Frequency	Percentage
Age (in Years)	-	46 years (Mean)	-	43 years (Mean)	-
Sex	Male	3	15.00	19	20.66
	Female	17	85.00	73	79.34

TABLE III
PATIENTS CO-MORBIDITIES AND OTHER PARAMETERS

Parameters	Category	Bile Spillage Cases ($n_1 = 20$)		Non-bile Spillage Cases ($n_2 = 92$)		*P* value
		Frequency	Percentage	Frequency	Percentage	
Diabetes	Present	3	15.00	9	9.78	0.364*
	Absent	17		83		
Hypertension	Present	5	25.00	19	20.66	0.434*
	Absent	15		73		
BMI (kg/M^2) Mean (SD) = 23.90 Variance = 15.513	< 25	14	70	62	67.39	0.41**
	> 25	6	30	30	32.61	
ASA Class	I	11	55.00	60	65.22	0.196**
	II	9	45.00	32	34.78	
Preoperative Diagnosis	Symptomatic Cholelithiasis	16	80.00	74	80.43	0.581*
	Chronic Calculus Cholecystitis	0	0.00	7	7.6	
	Acute Biliary pancreatitis	4	20.00	8	8.69	
	Others	0		3	3.2	
Duration of OT	≤ 2 Hours	14	70.00	72	78.26	0.299*
	> 2 Hours	6	30.00	20	21.74	

* Fisher exact test
** Chi-square test

TABLE IV
POST-OPERATIVE WOUND CHARACTERISTICS

Parameters	Category	Bile spillage cases		Non-bile spillage cases		P-value
		Frequency	Percentage	Frequency	Percentage	
SSI	SSI Present	4	20	8	8.7	0.28
	SSI Absent	16	80	84	91.3	

Mean duration of operation among all cases was found to be 98 minutes, with laparoscopic cholecystectomy in which there is gallbladder perforation/bile spillage taking slightly longer duration (108 minutes) compared to those in which bile spillage was not present (95.92 minutes).

SSI was found to be present in 20% cases in which there was bile spillage compared to 8% cases in which there was not bile spillage. Fisher's test was applied after making two by two table and p-value was found to be 0.2801(non-significant).

Eleven cases with SSI were superficial, one was organ space infection. All superficial SSI were in Umbilical port. In the organ space infection, diagnosis was done with the help of transabdominal ultrasonography which revealed heterogeneous collection with air foci in gallbladder fossa and subhepatic region, likely infected. Laparoscopic lavage was done and drain placed on POD6.

No re-admission was found within 30 days in the study.

Empirical antibiotics on follow up were used in all 12 cases of SSI, wound was opened and regular dressing was done in 11 cases. Culture and sensitivity of wound discharge revealed

growth in seven cases with *Klebsiella* spp. and coagulase negative *Staphylococcus aureus* isolated being most common organisms.

TABLE V
COMPARISON OF SSI IN BILE SPILLAGE AND NON-BILE SPILLAGE CASES

Parameters	Category	Bile Spillage Cases ($n_1 = 4$)		Non-bile Spillage Cases ($n_2 = 8$)	
		Frequency	Percentage	Frequency	Percentage
Type of SSI	Superficial	4	100.00	7	87.50
	Organ Space	0		1	12.50
Need of Opening wound	Yes	4	100.00	7	87.50
	No	0		1 (organ space infection)	12.50
C/S status	Sent	1	25.00	7	87.50
	Not Sent	3	75.00	1	12.50
Antibiotic Use for SSI	Yes	4	100.00	8	100.00
	No	0	0.00	0	

Analysis was done using Easy-R software and Fisher's exact test was applied to test the statistical significance of comorbidities and duration of operation to SSI.

TABLE VI
SSI IN TWO GROUPS WITH DIFFERENT CHARACTERISTICS (N = 12)

Parameters	Category	Bile Spillage Cases with SSI	Non-bile Spillage Cases with SSI	p-value
Age	< or = 42 years	2	4	0.65*
	> 42 years (median)	2	3	
Sex	Male	1	2	0.863*
	female	3	6	
DM	Present	1	2	0.238*
	Absent	3	6	
HTN	Present	3	2	0.162*
	Absent	1	6	
Symptomatic Cholelithiasis	Present	3	8	0.535*
	Absent	1	0	
Acute biliary pancreatitis and others	Present	1	0	0.535
	Absent	3	8	
Duration of OT	≤ 2 Hours	3	4	0.221
	> 2 Hours	1	4	

*Fishers exact test

IV. DISCUSSIONS

Since its introduction in 1987, laparoscopic cholecystectomy has gained popularity in modern times to the extent that it is being regarded as the gold standard for treating symptomatic gallstone disease [16], [17]. Though SSIs are reported less commonly in minimally invasive procedures like laparoscopic cholecystectomy than open surgery, SSIs are still considered one of the most important surgical complications. In our study SSIs overall was found to be 10.7%, most of them being port site infections with only one being organ space infection. Rate of wound infection varies greatly from 1.08% to 14.5% in the studies conducted by Jawien et al. [19] and Malatani et al. [18], respectively. Most of the infections were in the umbilical port site (91.6%). Gaur et al. concluded that the umbilicus is the commonest site for sepsis following laparoscopic cholecystectomy [20]. Probable explanation for this may be due to deep umbilical depression which is difficult to clean or may be due to routine protocol of our hospital to extract the gallbladder through the umbilical port. Organ space infection was one in number and none were deep infection, whereas Jawein et al. [19] noted superficial infection in 60.6%, deep infection in 21.2% and organ/space infection in 21.2%.

In our study of 112 patients, we had the mean age of 43.53 years, females were 80% and males were 20%. Similar results were found by Porwal et al., where 87% were female and 13% were male patient [21]. Bile spillage rate was 17.85% which is similar to that found by Jain et al. i.e., in 18 out of 113 cases [13]. Acute or chronic inflammation of gall bladder obscures the normal anatomic plane resulting in difficult manipulation and eventual gall bladder wall perforation. Another factor for bile spillage is surgeons in initial phase of learning curve as there is higher chance of gall bladder perforation while dissecting gallbladder from gall bladder fossa. Bile spillage rate in our study was lower than the study by Peponis et al., where it occurred in six out of 10 patients (59%) [15]. One needs to notice that in that study, half of the cases were acute cholecystitis where an inflamed gallbladder is to be dissected off liver and inadvertent entry into gallbladder or liver bed is likely. Acute cholecystitis was excluded from our study being an infective condition.

Among bile spillage cases, SSI was found be in four out of 20 cases (20%) which is higher than the non-bile spillage cases, where SSI was found to be in eight out of 92 cases (8.7%). Though SSI was higher after bile spillage, it was not found to be statistically significant (p value > 0.05). It is similar to results obtained by Peponis et al. [13], Jain et al. [15]. In a study by Sarli et al. [22] involving 1127 patients that underwent laparoscopic cholecystectomy for cholelithiasis, bile spillage was observed in 11.6% cases; they found no difference in postoperative complications between patients with and without bile spillage. The result of no difference in SSI may be because of prophylactic antibiotics (cefazolin), retrieval of spilled stones, adequate peritoneal cavity irrigation and increasing surgical expertise in the above studies. This is in contrary to a previous study by Rice et al. from the Mayo Clinic, who concluded that intra peritoneal spillage of gallbladder content during LC significantly increased the risk of intra-abdominal abscess and port site SSI [10].

Another study by Peponis et al., a prospective study in 1001 LC patients, bile spillage was present in 59% (591) and significantly associated with port site SSI 7.1% (p = 0.001). This could be due to inclusion of acute calculus cholecystitis and empyema cases (approximately half of cases) in that study; both could be an infective scenario and contribute to SSI and has been excluded from our study [15].

Superficial wound site infections were found in 11 out of 12 patients with SSI with 1 case of organ/space infection. The wound was laid open and swab taken for culture and antibiotic sensitivity. Antibiotics was prescribed for all cases, and there was no mortality or 30 day readmission for SSI. Similar results were found by the study conducted by Mir et al., where nine out

of 100 LC had superficial SSI [23].

Duration of operation was less than 2 hours in most of the cases, with bile spillage cases taking slightly longer (30% cases taking more than 2 hours) compared to non-bile spillage cases (21%). Longer duration may be due to difficult cases (adhesions, inflammation) leading to difficult dissection leading to Gallbladder perforation and extra time taken to peritoneal irrigation and suction. Age was not found to be significant factor for bile spillage or SSI. BMI was similar in both groups (23.15 in bile spillage and 24.07 in non-bile spillage cases). In both groups, ASA class I was higher and no patient of class III and higher were operated [23].

Once bile or stone spillage occurs during LC, every effort should be made to minimize the spillage by suctioning the bile or collecting the stones on retrieval bag followed by thorough peritoneal irrigation and suctioning. However, care should be taken to avoid spreading of stones to difficult sites so that conversion to open for stones retrieval is unnecessary [24].

V. Conclusions

SSI did not increase in bile spillage cases compared to non-bile spillage cases following laparoscopic cholecystectomy. However, as the rate of SSI is still higher, surgeons should be careful to avoid iatrogenic gallbladder perforation.

VI. Limitations

It was single centered study. Time period for the study was limited and so the sample was smaller although calculated sample size target was met. More extensive study needs to be conducted in future to determine exact significance of bile spillage/gallbladder perforation during laparoscopic cholecystectomy.

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