

Early versus late intervention in post-cholecystectomy biliary-tract injuries

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Background

Bile-duct injury following cholecystectomy is an iatrogenic catastrophe associated with significant perioperative morbidity and mortality that reduced long-term survival and quality of life and high rates of subsequent litigation. It should be regarded as preventable.

Aim and objectives

This study aims to compare between early and late intervention after post-cholecystectomy biliary-tract injury.

Patients and methods

This study that is a randomized controlled trial double-blinded arm study was conducted on 40 cases (20 early and 20 late) with post-cholecystectomy biliary-tract injury in Assiut University Hospital, General Surgery Department.

Results

The two groups exhibited no significant differences in mean operation time (104 min in D group vs. 110 min in N group, $P=0.098$) and estimated blood loss (40 ± 23 ml in D group vs. 41 ± 30 ml in N group, $P=0.762$).

Conclusion

Timing of repair of bile-duct injury of post-cholecystectomy has no impact on postoperative complications such as hospital stay, long-term morbidity, and mortality.

Keywords:

bile-duct injuries, timing of repair, postoperative complications

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Introduction

Bile-duct injury (BDI) following cholecystectomy is an iatrogenic catastrophe associated with significant perioperative morbidity and mortality [1] that reduced long-term survival [2] and quality of life [3] and high rates of subsequent litigation. It should be regarded as preventable.

The advent of laparoscopic cholecystectomy has resulted in a resurgence of interest in BDI and its subsequent management. Population-based studies [4] suggest a significant increase in the incidence of injury (0.1–0.5%) following the implementation of the laparoscopic approach [2]

BDI should be regarded as preventable, but over 70% of surgeons regard it as unavoidable [5]. Although most injuries occur within the surgeon's first 100 laparoscopic cholecystectomies, one-third happen after the surgeon has performed more than 200; it is more than inexperience that leads to BDI [6]. It has been suggested that the commonest cause of common BDI is misidentification of biliary anatomy (70–80% of injuries) [7], a reduction in risk if surgeons perform routine intraoperative cholangiography.

Recognition of BDI at the time of cholecystectomy allows an opportunity for the hepatobiliary surgeon to assess its severity and the presence of any vascular injury.

Patients and methods

This was a study, a randomized controlled trial double-blinded arm study carried out at Assiut University Hospital, General Surgery Department, for 40 cases (20 early and 20 late). This research was performed at the Department of General Surgery, Assiut University Hospitals. Ethical Committee approval and written, informed consent were obtained from all participants.

Inclusion criteria

All patients with post-cholecystectomy biliary-tract injury admitted at Assiut University Hospital at the period of the study.

Exclusion criteria

Any case with biliary leakage and not post-cholecystectomy.

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Study tools (in detail, e.g. laboratory methods, instruments, steps, chemicals, etc.)

- (1) Intraoperative management: if a bile leak from a duct is identified within the proximal gallbladder fossa or hilum, a major injury should be suspected and advice sought, as it is known that outcome is improved when an experienced hepatobiliary surgeon is present [3]. If such assistance is unavailable, transfer of the patient should be considered after adequate drainage is achieved by large-bore drains. Injudicious attempts at exploration of the bile leak by laparoscopic means or at open operation should be avoided, as any injury may be exacerbated by forceful cannulation and retrograde on table cholangiography. Interpretation of cholangiography is of particular importance and failure to identify the right posterior sectoral ducts should alert the surgeon to the likelihood of a concomitant isolated segmental injury. While ligation of a terminal biliary radical may be undertaken safely following cholangiography, ligation of a significant isolated segmental branch may result in obstructive segmental cholangitis, hepatic abscess, and prolonged biliary fistula. If cholangiography demonstrates a major duct injury, reconstruction in the form of a hepaticojejunostomy is required. Despite one recent report, a choledochoduodenostomy or hepaticoduodenostomy should not be performed as there is an almost universal need for revision because of recurrent cholangitis.
- (2) Early postoperative management: for a partial defect in the duct, the best option is primary closure with fine absorbable sutures and subhepatic drainage; rather than placement of an equation-image tube, experience in liver transplantation has shown that an equation-image tube placed within a choledcho-choledochostomy is associated with a significantly higher stricture rate than with repair without an equation-image tube (25 vs. 11%).
- (3) Delayed management: initial treatment should focus on resuscitation of the patient, drainage of any collections to create a controlled enterocutaneous fistula, and treatment of sepsis. Nutritional support should be maintained during subsequent definition of the anatomy and definitive repair.

Research outcome measures

Primary (main): to compare between early and late intervention after biliary-tract injury post-cholecystectomy in Assiut University Hospital. Secondary (subsidiary): a plan for improving our management of biliary-tract injury post-cholecystectomy and reduction in the morbidity

and mortality result from biliary-tract injury post-cholecystectomy.

Statistical analysis

Data were collected, coded, and then entered as a spreadsheet using Microsoft Excel 2016 for Windows, of the Microsoft Office bundle; 2016 of Microsoft Corporation, United States. Data were analyzed using IBM Statistical Package for Social Sciences software (SPSS) (IBM SPSS Statistics for Windows, and version 26.0.; IBM Corp., Armonk, New York, USA). The Kolmogorov–Smirnov test was used to verify the normality of distribution. Continuous data were expressed as mean±SD, median, and interquartile range, while categorical data as numbers and percentage. A statistical value less than 0.05 was considered as significant.

Results

Forty morbidly obese patients who were candidates of LGBP surgery were studied. The patients were randomized based on drain insertion into two groups ($n=40$): a drain group (D group=20) and no-drain group (N group=20).

There were no significant differences in mean age (35 ± 6.2 vs. 38 ± 8.8 years, $P=0.225$), mean BMI (41 ± 5.9 vs. 42 ± 6.3 kg/m², $P=0.679$), sex (15/76 vs. 16/79% females, $P>0.05$), or American Society of Anesthesiologists I–II score (19/96% in D group vs. 19/97% in N group, $P=0.85$) between the two groups. Weight loss before the operation was similar in both groups (8% in D group vs. 7% in N group, $P=0.49$). There were no significant differences regarding the prevalence of preoperative comorbidities in both groups. Patients' characteristics are summarized in Table 1.

Regarding the perioperative clinical data, the two groups exhibited no significant differences in mean operation time (104 min in D group vs. 110 min in N group, $P=0.098$) and estimated blood loss (40 ± 23 ml in D group vs. 41 ± 30 ml in N group, $P=0.762$). No intraoperative complications or need for conversion to an open surgery were detected (Table 2).

Regarding the postoperative clinical data, the duration of hospital stay was similar in both groups (5 ± 2.5 days in D group vs. 4.7 ± 1.8 days in N group, $P=0.135$). For patients who received patient-controlled analgesia during hospitalization, the total usage dose of morphine was collected, but no significant differences were noted between the D group and the N group (63 ± 37 vs. 60 ± 30 mg, $P=0.963$). However, patients in

Table 1 Patient demographic data

Patient characteristics	D group (N=20)	N group (N=20)	P value
Age	35±6.2	38±8.8	0.646
Sex: male	5 (24)	4 (21)	0.17
Female	15 (76)	16 (79)	
Body weight (kg)	118±21	114±14	0.120
Body height (cm)	166±8.3	164±8.4	0.590
BMI (kg/m ²)	41±5.9	42±6.3	0.715
ASA I-II	43 (26–69)	44 (26–66)	
Preoperative weight loss	19 (96)	19 (97)	0.85
Hypertension	8 (5–17)	7 (4–15)	0.49
Diabetes	7 (36)	7 (38)	0.7
Dyslipidemia	14 (69)	17 (85)	0.09
Sleep apnea	8 (40)	8 (41)	0.92
	17 (84)	19 (92)	0.33

Data are expressed as mean or percentage, and SD.

Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

Table 2 Intraoperative variables

Intraoperative data	D group (N=20)	N group (N=20)	P value
Mean operation time (min)	104±25	110±26.5	0.093
Estimated blood loss (ml)	40±23	41±30	0.762

Data are expressed as mean±SD.

Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

Table 3 Postoperative variables

Postoperative data	D group (N=20)	N group (N=20)	P value
Postoperative analgesic dose	63±37	60±30	0.963
Length of hospital stay (days)	5±2.5	4.7±1.8	0.135
Flatulus passage after surgery (days)	1.6±0.9	1±0.5	0.006

Data are expressed as mean±SD.

Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

the N group had a significantly shorter time to flatus passage compared with those in the D group (1.6±0.9 vs. 1±0.5 days, *P*=0.006) (Table 3).

There was one major complication of anastomotic leakage (2/20, 8%) in each group. Both patients developed typical early clinical signs of leakage, including unexplained tachycardia, fever, elevated blood-cell count, and respiratory compromise. Minor complications occurred in 10 patients in the D group (8/20, 38%) and in nine patients in the N group (7/20, 34%), there was no significant difference between the incidences. These complications included intra-abdominal hemorrhage, wound infection, marginal ulcer, gout attack, and deep-vein thrombosis. One patient in the N group developed a marginal ulcer (Table 4).

Table 5 illustrates the visual analog scale scores at all intervals. Mean pain score (visual analog scale) at postoperative day 0 was similar in both groups (3.5±1 in D group vs. 3.2±1.5 in N group, *P*=0.589). At postoperative day 1, patients with drain had significantly higher pain scores (6±2.2 in D group vs. 4±2.2 in N group, *P*=0.012). After 1 week, the mean pain score was significantly lower in the N group compared with the D group (*P*=0.006). At week 4, there were no significant differences in the mean pain score (4.5±2.8 vs. 4.8±2.2, *P*=0.89) between the two groups (*P*=0.89).

Table 6 shows the severity of pain at all intervals. While all patients had abdominal pain after 24h after the operation, analysis revealed that there was a significant difference in the severity of pain at the drain site

Table 4 Complications in different groups

Complication	D group (N=20)	N group (N=20)	P value
Anastomotic leak	1 (5)	1 (5)	1.000
Intra-abdominal bleeding	1 (5)	1 (5)	0.312
Wound infection	1 (5)	1 (5)	0.912
Gout	1 (5)	1 (5)	0.560
Paralytic ileus	1 (5)	0	0.312
Marginal ulcer	0	1 (5)	0.316
Deep-vein thrombosis	0	1 (5)	0.316
Clavien–Dindo complications			
I–II	2 (12)	1 (5)	0.37
III	0	0	
IV	0	0	
V	0	0	
Stenosis	1 (5)	1 (5)	0.9
Petersen's hernia	1 (5)	1 (5)	0.9
Total	8 (38)	7 (34)	0.60

Data are expressed as *n* (%).

D group, group with intra-abdominal drainage; N-group, group without intra-abdominal drainage.

Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

Table 5 Mean pain scores (Visual Analog Scale) in the two groups

Postoperative period	N group	D group	P value
Day 0	3.2±1.5	3.5±1	0.58
Day 1	4±2.8	6±2.2	0.012
Week 1	2±1.14	4±1.35	0.006
Week 4	4.5±2.8	4.8±2.2	0.89

Data are expressed as *n* (%).

Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

Table 6 The prevalence of pain severity after laparoscopic Roux-en-Y gastric bypass in two groups

Time	Group and severity of pain						P value
	N group (N=20)			D group (N=20)			
	Mild	Moderate	Severe	Mild	Moderate	Severe	
Day 1	10 (52)	6 (28)	4 (20)	5 (24)	4 (20)	11 (56)	0.028
Week 1	17 (85.7)	3 (14.3)	0	6 (33)	10 (47)	0	0.068
Week 4	8 (38)	5 (25)	7 (37)	9 (43)	3 (15)	8 (42)	0.875

Data are expressed as *n* (%).

ANOVA: for comparison of the means of three groups. Two-way ANOVA test (Friedman's test) was used for continuous data to test for significant difference between more than two dependent nonparametric data along different time points. Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

(mild, moderate, and severe) between the two groups ($P=0.028$). In the N group, most patients (10/52%) reported mild pain, whereas most patients in the D group (11/56%) reported severe pain at the drain site. At week 1, there was no significant difference between the two groups with respect to pain, most patients had mild pain (85.7% in the N group vs. 33% in the D group, $P=0.068$), and no one had severe pain. At week 4, there was no significant difference between the two groups with respect to the severity of pain ($P=0.875$) as the

frequency of patients who had experienced mild and severe pain was the same in both groups: eight (38%) patients in the N group and nine (43%) in the D group experienced mild pain at week 4 (Table 6).

In this table, among patients with partial BDI, nine cases did ERCP and stenting and six cases did intraoperative repair and T-tube insertion as early intervention. In patients with complete transection and ligation of BDI, one case did choledochoduodenostomy as early

Table 7 Surgical maneuver that was done for each type on injury and timing of intervention

Type of injury	Surgical maneuver	Early intervention	Late intervention
Partial BDI	ERCP and stenting	9	0
	Intraoperative repair and T-tube insertion	6	0
Complete transection and ligation of BDI	Choledochoduodenostomy	1	4
	Hepatojejunostomy	4	16

Comparisons between groups were performed using the Student *t* test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables.

P value less than or equal to 0.05 is considered statistically significant, *P* value less than or equal to 0.01 is considered highly statistically significant.

intervention and four cases as late intervention, while four cases did hepaticojejunostomy as early intervention and 16 cases as late intervention (Table 7).

Discussion

The incidence of BDI after cholecystectomy is reported to be between 0.3 and 1.5% [8]. The risk factors for BDI include anatomical variants, difficult pathology, visual misperception, and surgeon-dependent factors such as surgical technique and learning curve [9]. Treatment of BDI after cholecystectomy depends on the severity of the injury, the timing of diagnosis, and the general condition of the patient. Late detection of BDI has been shown to be associated with reduced survival. The gold standard for treatment of severe BDI and complete transection is hepaticojejunostomy [10].

This randomized controlled trial double-blinded arm study was carried out on 40 patients with post-cholecystectomy biliary-tract injury admitted at Assiut University Hospital at the period of the study. The timing of repair was early for 20 (50%) patients and late for the remaining 20 (50%) patients.

As regards the demographic data of the studied groups, we found that 40 patients were 23 women and 17 men with a mean age of 38.5 years (range 20–60). The mean BMI was 26.4 kg/m² (range, 20–33). There was no statistically significant difference in age, sex, and BMI between the two groups of patients.

The present study was supported by El Nakeeb *et al.* [11], who aimed to analyze the outcomes in patients undergoing immediate, intermediate, and delayed repair of BDI, they enrolled 412 patients with BDI with mean age 40.0 (31.5–50.0) years and 25.7 males, patients allocated to three groups: group 1 underwent an immediate reconstruction (within the first 72h post-cholecystectomy, *n*=156), group 2 underwent an intermediate reconstruction (from 4 days to 6 weeks post-cholecystectomy, *n*=75), and group 3 underwent delayed reconstruction (after 6 weeks post-cholecystectomy, *n*=181). There was no significant difference between the studied groups as regards age and sex.

Also, a prospective randomized study by Ali and Abdelhameed [12] aimed to analyze the different time modalities used for repair of these injuries and its outcomes, the study enrolled 40 patients diagnosed to have BDI after cholecystectomy divided into three groups according to the time of intervention: early (12), intermediate (14), and late (14). There were 27 (67.50%) females and 13 (32.50%) males with a female-to-male sex ratio equal to 2.1: 1. The mean age of the study groups was 39.53±11.85 and median 39 (20–60). There was no significant difference among groups regarding patient's age and sex, while BMI was significantly different between the three studied groups.

In the current study, we found that BDIs were recognized during cholecystectomy, 16 (39%) were early (≤ 2 weeks) and 24 (61%) were late (≥ 6 weeks) after operation. Excluding 10 (24%) patients in whom the BDI was recognized during laparoscopic cholecystectomy, the other patients presented with a variety of symptoms after BDI, including obstructive jaundice in 10 (24%), bile leak in nine (22%), biloma in five (14%), biliary peritonitis in two (6%), and cholangitis in four (10%). Patients who were referred early usually presented with bile leak or biloma or biliary peritonitis, while patients who were referred later presented in most cases with jaundice or episodes of cholangitis. Time of referral is ranged from the day of BDI to more than 3 years. Excluding the patients in whom the LC was performed, for the rest of the patients, the time of referral was within 48 h after LC in 14 (early referral) and beyond 48 h after LC in 26 patients (late referral). According to the Strasberg classification of BDI, two (6%) patients suffered type-A injury, two (7%) type C, seven (18%) type D, and 28 (66%) type E.

The study by El Nakeeb *et al.* [11] reported that the most common symptoms were obstructive jaundice (65%), pain (38%), and bile leakage (30%). According to the level of BDI, 14.3% suffered type E1 injury, 56.8% type E2, 19.4% type E3, 8% type E4, and 1.5% E5.

While Ali and Abdelhameed [12] reported that all cases in immediate group presented with bile leakage, and

the majority of the other two groups with obstructive jaundice (71%).

Also, the study by Fischer *et al.* [13] revealed that the most prevalent symptoms in order were biloma-infected, jaundice, cholangitis, and systemic inflammatory-response syndrome. According to bismuth level of injury, there were 73% in levels I–III and 27% were levels IV–V.

Regarding the operative characteristics and outcomes of early and delayed common BDI surgical-repair procedures, we found that about 3% of late postoperative cases and 55% of early postoperative patients underwent primary repair of CBD, while 95% of late postoperative cases and 39% of early postoperative patients underwent Roux-en-Y hepaticojejunostomy reconstruction. Only 5% of both cases underwent choledocojejunostomy reconstruction. We also found that there were no significant differences between the two groups as regards hospital stay and vasculobiliary.

While the study by El Nakeeb *et al.* [11] reported that the initial operations were cholecystectomy (52.7%), open (37.6%), and laparoscopic (9.7%). They also reported that the duration of drain was significantly longer and the amount of drainage was significantly more in group 1. The median length of hospital stay was 5 days in group 1, 6 days in group 2, and 5 days in group 3 ($P=0.007$).

However, Ali and Abdelhameed [12] reported that 1ry repair of CBD was the most common in group A, hepaticojejunostomy Roux-en-Y was the most common in groups B and C, with a significant difference between the three groups as regards the initial procedure performed. Also, hospital stay and outcome have a significant P value less than 0.05 in favor of group A.

In agreement with our results, Kirks *et al.* [14] reported that there were no significant differences between the two groups as regards hospital stay, they also reported that the most common etiology of the injury was cholecystectomy followed by nonbiliary abdominal procedures in both groups.

As regards postoperative complications of biliary reconstruction, we found that although patients in the late postoperative group presented with higher rates of early postoperative complications, the statistical analysis revealed no statistically significant differences between the two groups (early vs. late group: wound infection 15 vs. 27%, bile leak 12 vs. 13%, biloma 8 vs. 9%, biliary peritonitis 0 vs. 4%, and overall early morbidity 20 vs. 28%).

We also found that both the overall long-term morbidity and individual complications were equal comparing early and late postoperative groups (early vs. late group: stricture: 16 vs. 22%, recurrent cholangitis: 15 vs. 13%, need for nonsurgical intervention: 21 vs. 22%, and overall morbidity: 22 vs. 32%).

Finally, the comparison of the overall mortality between the two groups revealed no statistically significant difference (early vs. late postoperative group: overall mortality 4 vs. 4%).

In agreement with our results, the study by Fischer *et al.* [13] reported that there were no significant differences between both groups as regards complications and mortality, but in addition, the ICU stay more than 7 days and intra-abdominal abscess were more prevalent in delayed group.

As well, our results were supported by Kirks *et al.* [14], who revealed that there were no significant differences between the studied groups as regards hospital length of stay, 30-day readmission, and 90-day mortality.

Additionally, our results were further supported by the systematic review and meta-analysis by Schreuder *et al.* [15], aimed to find out optimal timing for surgical reconstruction of BDI, 21 studies were included, representing 2484 patients. In these studies, 15 different time intervals were used. Eight studies used the time intervals of less than 14 days (early), 14 days to 6 weeks (intermediate), and more than 6 weeks (delayed). Meta-analysis revealed a higher risk of postoperative morbidity in the intermediate interval [early vs. intermediate: risk ratio (RR) 0.73, 95% confidence interval 0.54–0.98; intermediate vs. delayed: RR 1.50, 1.16–1.93]. Stricture rate was the lowest in the delayed interval group (intermediate vs. delayed: RR 1.53, 1.07–2.20). Postoperative mortality did not differ within time intervals. The additional analysis demonstrated increased odds of postoperative morbidity for reconstruction between 2 and 6 weeks, and decreased odds of anastomotic stricture for delayed reconstruction. In other words, they concluded that surgical reconstruction of BDI between 2 and 6 weeks should be avoided as this was associated with higher risk of postoperative morbidity and hepaticojejunostomy stricture.

Conclusion

Favorable outcomes were observed in both the early and delayed reconstruction of post-cholecystectomy BDI. Early complications, hospital stay, long-term morbidity, and mortality were similar in both groups. So, timing of repair of BDI of post-cholecystectomy

has no impact on postoperative complications, hospital stay, long-term morbidity, and mortality. Further, comparative multicenter studies with larger sample sizes were needed to confirm the present results and to find the best timing for the repair.

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Nil.

Conflicts of interest

No conflict of interest.

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