Effect of Electrocoagulation and Direct Pressure Application on Bleeding from Liver Bed During Laparoscopic Cholecystectomy

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ABSTRACT:

Objective: To compare the efficacy of electrocoagulation and direct pressure application in controlling haemorrhage from the liver bed during laparoscopic cholecystectomy.

Study Design: Randomized controlled trial.

Place and Duration of the Study: Department of General Surgery, Sir Ganga Ram Hospital, Lahore, Pakistan, from July 2021 to December 2021.

Methodology: A total of 218 patients of either gender, aged 18 to 60 years and with bleeding from the liver bed during laparoscopic cholecystectomy were randomly allocated to two groups of haemorrhage control techniques. In group A, electrocoagulation was used and in group B, direct pressure was applied to the bleeding area for 5 minutes. Efficacy in controlling bleeding was compared in both groups.

Results: The mean age of all study participants was 44.6 $\pm$ 13.5 years. The majority of the patients were females (89%). The mean body mass index (BMI) of all participants was 25.3 ± 3.09 kg/m^2. Intraoperative bleeding was secured in 86.2% of patients in Group A *vs.* 81.7% of patients in Group B. However, the difference was not statistically significant (p=0.356). In 27 (12.4%) cases, bleeding could not be controlled by both of these techniques. In these cases, endosuturing was applied in 19 (70.4%) cases, spongostan in 6 (22.2%) cases, and endo-clips in 2 (7.4%) cases. Intraoperative drain and conversion to open procedure was required in 1 patient each, both belonging to the direct pressure application group.

Conclusion: The efficacy of electrocoagulation in securing haemorrhage from the liver bed is better than the direct pressure application technique.

Key Words: *Laparoscopic cholecystectomy, Haemorrhage, Electrocoagulation, Surgical hemostasis, Liver bed.*

How to cite this article: Awais M, Masood MH, Ahmed A, Irshad S, Aslam I, Gondal KM. Effect of Electrocoagulation and Direct Pressure Application on Bleeding from Liver Bed During Laparoscopic Cholecystectomy. *J Coll Physicians Surg Pak* 2023; **33(07)**:754-759.

INTRODUCTION

Laparoscopic cholecystectomy is considered the gold standard treatment option for symptomatic gallstones.[1] It was first introduced by Francois Dubois in Paris in 1988, after which the technique got multiple advancements in terms of improved magnification and better visualisation.[2] It is proven to have better postoperative outcomes in terms of efficacy and safety in comparison to open cholecystectomy.[3]

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E-mail: drarslanahmed@outlook.com
Received: May 09, 2023; Revised: May 11, 2023; Accepted: June 15, 2023
DOI: https://doi.org/10.29271/jcpsp.2023.07.754

Although laparoscopic cholecystectomy provides patients with the benefit of early postoperative recovery and less postoperative pain, the threats associated with this minimally invasive technique should not be overlooked. Laparoscopic cholecystectomy can cause biliary complications such as bile leakage, biliary fistula, jaundice, cholangitis, sepsis, and non-biliary complications such as haemorrhage, damage to adjacent structures, and intestinal perforation.[4] Bleeding from the liver bed is one of the most common complications, often requiring conversion to open cholecystectomy or even re-operation if detected post-operatively.[5]

In laparoscopic cholecystectomy, damage to the middle hepatic vein or arteries between the gallbladder and liver may occur during the dissection of the gallbladder from the liver bed, especially in the case of cholecystitis. Bleeding from the middle hepatic vein is dangerous as it may cause carbon dioxide embolism and shock. It is therefore important to devise effective ways of controlling haemorrhage from the liver bed. The

frequently employed hemostatic methods for controlling haemorrhage from the liver bed are electrocoagulation, direct pressure over the liver bed, and ultrasonic coagulation.[6] Although there are multiple studies in the literature comparing electrocautery with ultrasonic coagulation,[7,8] there is a paucity of data regarding the comparison of direct pressure application with electrocoagulation. Both these techniques are cost-effective and feasible means of controlling haemorrhage from liver bed in developing countries like Pakistan. The aim of this study was, therefore, to compare the efficacy of electrocoagulation *versus* direct pressure application in controlling haemorrhage from the liver bed during laparoscopic cholecystectomy.

METHODOLOGY

A randomized controlled trial was conducted in the Department of General Surgery, Sir Ganga Ram Hospital, Lahore, from July 2021 to December 2021, after getting ethical approval from the Institutional Review Board of the hospital. Patients of either gender, aged 18 to 60 years, and having bleeding from the liver bed during laparoscopic cholecystectomy were included in this trial. Patients were excluded if they had American Society of Anesthesiologists (ASA) Classification grade ≥3, obstructive jaundice, dilated common bile duct (>1 cm on ultrasound), cirrhosis, bleeding disorder (INR >1.5), renal impairment (serum creatinine >2 mg/dl) or liver impairment (serum bilirubin >1.5 mg/dl).

A non-probability consecutive sampling technique was employed and a sample size of 218 patients (109 in each group) was calculated using World Health Organization (WHO) sample size calculator version 2.0. Patients were randomly assigned in a 1:1 ratio to two study groups using a computerized random number table generator. Patients underwent three-port laparoscopic cholecystectomy under general anaesthesia. After the dissection of the gall bladder from the liver bed, the patients were observed for any visible bleeding. In group A, direct electrocoagulation of the liver bed was performed. In group B, the surgical gauze was placed in the liver bed with direct application of pressure over it with the help of the grasping forceps for 5 minutes. If bleeding did not stop after 5 minutes, the pressure was reapplied for another 5 minutes. If bleeding stopped within 10 minutes, then it was labelled as "secured" and "efficacy" was confirmed. In cases where the bleeding did not stop, bleeding "unsecured" was labelled and the other technique (Group A or B) was applied. Persistent bleeding was controlled by the application of endoclips, endosuturing, or application of topical hemostatic agents such as oxidized regenerated cellulose (ORC), gelatin or collagen depending upon the availability. If bleeding still persisted, then the operation was converted to open cholecystectomy.

The data were initially recorded into specially designed proforma. The data were later entered into SPSS version 23.0 and analysed through its statistical package. Demographic details such as age, gender, BMI, date of admission, date of operation, and comorbidities such as diabetes and hypertension were recorded. Quantitative variables such as age and BMI were presented as mean $\pm$ SD and qualitative variables such as gender, obesity, comorbidities, and efficacy were presented as numbers (%). Efficacy was compared in both groups using the chi-square test. The association of various demographic and patients' characteristics with efficacy was assessed by the chi-square test and Fisher's exact test where there were 5 or fewer observations in a group. A p-value of <0.05 was considered statistically significant.

RESULTS

Out of a total of 218 patients enrolled in the trial, 109 patients were included in the electrocoagulation group (Group A) and 109 patients in the direct pressure application group (Group B). The mean age of all patients was 44.6 $\pm$ 13.5 years. The majority of these patients were females (89%). The mean BMI of all participants was 25.3 ± 3.09 kg/m^2 and 88 (40.4%) patients were obese. The distribution of demographic variables was fairly uniform between the two groups. Assessment of comorbidities showed that 25 (11.5%) patients enrolled in this study were diabetic and 26 (11.9%) patients were known hypertensive. The demographic and baseline characteristics of patients in both study groups are given in Table I.

In 183 cases out of a total of 218 cases, the time period for the control of bleeding from the liver bed during laparoscopic cholecystectomy was less than 10 minutes, thus giving an overall efficacy of 83.9% for all patients. The efficacy in the electrocoagulation group (Group A) was 86.2% and in the direct pressure application group (Group B) was 81.7%. The difference was, however, not statistically significant (p = 0.35). Figure 1 depicts the application of electrocoagulation and direct pressure application for the control of haemorrhage from the liver bed.

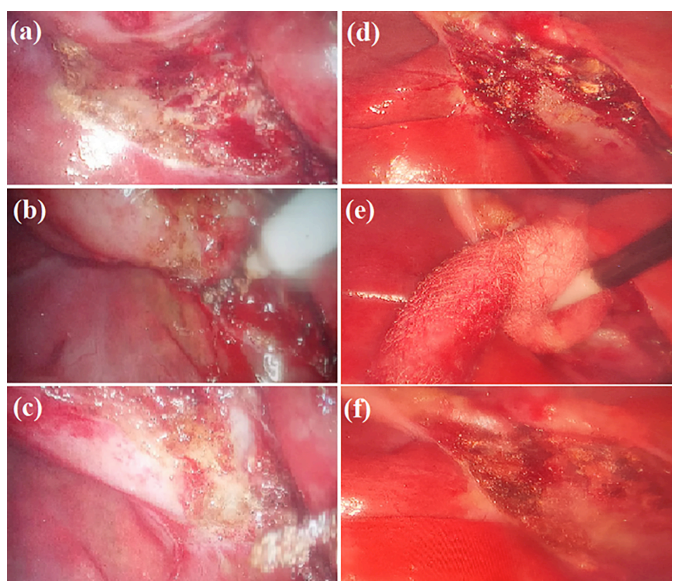

Figure 1: Bleeding from liver bed controlled by electrocoagulation and direct pressure application. (a-c) show control of bleeding by electrocoagulation. (d-f) show control of bleeding by the application of a gauze piece and direct pressure for 5 minutes.

Table I: Demographic characteristics of study participants.

Variables	Group A (n = 109)	Group B (n = 109)
Age, years	49.3 ± 13.5	40.0 ± 11.9
Gender		
Males	7 (6.4%)	17 (15.6%)
Females	102 (93.6%)	92 (84.4%)
Body Mass Index (BMI), kg/m^2	25.2 ± 2.9	25.5 ± 3.3
BMI categories		
Obese**	45 (41.3%)	43 (39.4%)
Non-obese*	64 (58.7%)	66 (60.0%)
Diabetes Mellitus		
Present	6 (5.5%)	19 (17.4%)
Absent	103 (94.5%)	90 (82.6%)
Hypertension		
Present	19 (17.4%)	7 (6.4%)
Absent	90 (82.6%)	102 (93.6%)

**Normal weight and overweight according to WHO Asian Classification for BMI i.e., BMI (18.5-22.9) and (23.0 to 24.9), respectively. **Obese according to WHO Asian Classification for BMI i.e., BMI >24.9*

Table II: Outcome of study participants in the two groups.

Variable		Group A (n = 109)	Group B (n = 109)	p-value
Bleeding secured (Efficacy)				
Yes		94 (86.2%)	89 (81.7%)	0.35
No		15 (13.8%)	20 (18.3%)	
Time period for bleeding control				
<5 minutes	Efficacy (Yes)	69 (63.3%)	3 (2.8%)	<0.001*
5 - 10 minutes		25 (22.9%)	86 (78.9%)	
11 - 15 minutes	Efficacy (No)	10 (9.2%)	19 (17.4%)	
16 - 20 minutes		2 (1.8%)	1 (0.9%)	
>20 minutes		3 (2.8%)	0 (0%)	
Placement of intraoperative drain				
Yes		0 (0%)	1 (0.9%)	1.0
No		109 (100%)	108 (99.1%)	

** p <0.05 was considered statistically significant. Chi-square test was applied for efficacy. Fisher's exact test was applied for time period as the value in at least one of the cells was less than 5 observations.*

Table III: Effect of various patient characteristics on the outcome.

Patient characteristics	Efficacy		p-value
	Yes n (%)	No n (%)	
Age groups			
<45 years	113 (91.1%)	11 (8.9%)	0.001*
≥45 years	70 (74.5%)	24 (25.5%)	
Gender			
Female	162 (83.5%)	32 (16.5%)	0.774
Male	21 (87.5%)	3 (12.5%)	
Body Mass Index category			
Obese	80 (90.9%)	8 (9.1%)	0.021*
Non-obese	103 (79.2%)	27 (20.8%)	
Diabetes			
Yes	6 (24.0%)	19 (76.0%)	<0.001*
No	177 (91.7%)	16 (8.3%)	
Hypertension			
Yes	21 (80.8%)	5 (19.2%)	0.570
No	162 (84.4%)	30 (15.6%)	

** p <0.05 was considered statistically significant. Chi-square test was applied for age groups and BMI categories. Fischer's exact test was applied for gender, diabetes, and hypertension as the expected count in at least one of the cells was less than 5 observations.*

In a total of 35 (16.1%) cases, the bleeding was not controlled by the respective technique. In such cases, bleeding was labelled as unsecured (efficacy "no") and the technique of the other group (Group A or B) was applied. In 27 (12.4%) cases, the techniques of both groups were unable to secure bleeding. In these cases, endosuturing was applied in 19 (70.4%) cases, hemostatic agents such as spongostan in 6 (22.2%) cases and endoclips in 2 (7.4%) cases. Intraoperative drain was placed only in 1 patient belonging to Group B. Conversion to open cholecystectomy was also

required only in one patient in Group B. Table II shows the outcome of study participants in both study groups.

The effect of various demographic variables and other patients' characteristics on the overall efficacy of the study was also studied. Age (p = 0.001), obesity (p = 0.021), and diabetes (p = <0.001) had a statistically significant effect on efficacy. No association of gender and hypertension with efficacy was found. The effect of various demographic and other patients' characteristics on the outcome is given in Table III.

DISCUSSION

Gallstone disease is the commonest disease of the hepatobiliary system which occurs more commonly in females in the middle age group.[9] The results from demographic data of the present study clearly depict that gallstone disease is more prevalent in females. The majority of patients in this study were females (89%), thus giving a female-to-male ratio of around 8:1. This is parallel to the findings of most of the studies present in the literature. Similar results were observed in studies by Agarwal *et al.,* and Balaji *et al.* also showed similar results in which more than two-thirds of the patients were females.[4,10] A Pakistani study conducted in Polyclinic Hospital, Rawalpindi, showed a female-to-male ratio of 7:1.[11] A thorough review of the literature showed that although acalculous cholecystitis may be more prevalent in males, gallstone disease is generally a phenomenon linked to the female gender.[12] The reason for the higher incidence of gallstone disease in females is probably linked to hormonal effects on the development of gallstones. The rise in female sex hormones, particularly estrogen and progesterone, physiologically, through exogenous intake or during pregnancy is linked to increased excretion of cholesterol in bile and decreased gallbladder motility. This stasis and supersaturation of bile are believed to be associated with the development of gallstones in females.[13]

The mean age of the study participants in the current study was 44.6 $\pm$ 13.5 years. There was no significant difference in the mean age of males and females. Most of the studies in the literature have mentioned a similar age distribution. In a study conducted in Nepal, the mean age of cholelithiasis patients was 44.5 $\pm$ 14.5 years, which is very similar to the present study.[14] Similar results were also observed in a Pakistani study conducted by Rahman *et al.,* in which it was concluded that prolonged exposure to risk factors is the reason why gallstones develop after middle age.[15] The mean BMI of the study participants was 25.3±3.09 kg/m^2, which as per WHO Asian Classification, falls in the range of obesity. The BMI was higher in females and the difference between genders was significant (p = 0.026). Similar results were observed in a Pakistani study by Mehmood *et al.,* where almost 67% of the patients were either obese or over-weight.[16] Obesity is linked to the development of gallstones through derangement in metabolic profile and predisposition to other metabolic disorders such as diabetes, which are independent risk factors for gallstone disease.[17]

Bleeding from the liver bed is the most common intraoperative complication of laparoscopic cholecystectomy.[18] The comparison of electrocoagulation and direct pressure application in the current study shows that electrocoagulation is superior to direct pressure application in controlling haemorrhage from the liver bed (86.2% *vs.* 81.7%). The difference was, however, not statistically significant. Similar results were also observed in a previous comparative study from Mayo Hospital, Lahore, which showed that electrocoagulation was superior to direct pressure in the control of bleeding (96% vs 85%).[19] The authors of that study concluded that although electrocoagulation is an effective, feasible, and readily available method of bleeding control, it nevertheless, carries a grave risk of thermal conduction and deep burns to the surrounding tissues. A study by Chaoliang *et al.* found direct pressure application to be an effective means of controlling bleeding from the liver bed. They advocated that direct pressure application can be used as a first--line method to control bleeding and other methods can be used if direct pressure fails to secure hemostasis.[20]

Dissection of the gallbladder from the liver bed is an important step in laparoscopic cholecystectomy and carries the risk of uncontrolled bleeding owing to branches of the middle hepatic vein or damage to anomalous vessels in the liver bed which may be present in up to 20% of the individuals.[21] Multiple techniques for control of haemorrhage from the liver bed have been mentioned in literature with varying efficacies. These include direct pressure technique, electrocoagulation, endoclipping, endosuturing, and energy devices such as LigaSure and harmonic scalpel.[22] Electrocoagulation is advantageous in terms of reduced duration of surgery, less chances of conversion to open cholecystectomy, and reduced duration and cost of hospitalisation. It is considered a preferable alternative to direct pressure technique or endoclipping as it avoids the risk of postoperative complications such as slippage of clips, dislodgement of the clot, re-bleeding, or ulceration.[23] Thus, in the hands of an experienced surgeon, it can be a feasible option in developing countries where energy devices such as LigaSure and harmonic scalpel are not readily available.

The association of various patients' characteristics with overall efficacy was also studied. Age more than 45 years and diabetes were both found to be associated with poor efficacy (p<0.05). A study from eight hospitals in Mexico City found age above 45 years and comorbidities including diabetes to be associated with increased conversion rates to open cholecystectomy.[24] In contradiction to this, a study by Arora and Kumar did not find any association of comorbidities such as hypertension and diabetes with intraoperative complications.[25] A detailed discussion of each of these

factors will be beyond the scope of the current study. However, it can be concluded that, there is still a grey area regarding the possible role of various demographic and patients' factors in determining the outcome of laparoscopic surgery. Further studies are needed to clarify these unresolved issues.

In the present study, the authors have tried to limit the systematic biases through careful selection of study design and methodology, nonetheless, the study is not without limitations. The findings from this study are limited because it is a single-centred study conducted on a relatively small number of patients, thus generalisation of the results may not be possible. The study is conducted in a large tertiary care hospital of a metropolitan city, where the expertise and facilities are much better as compared to the periphery, where the situation may be completely different. The present study has compared direct pressure with electrocoagulation. Newer hemostatic methods are now readily available in many centers in developing countries. The authors, therefore, recommend multi-centered studies on a larger number of patients and on other hemostatic methods as well, in order to generate evidence-based results that can enhance our understanding of the subject.

CONCLUSION

In conclusion, gallstone disease is more common in middle-aged females. Bleeding from the liver bed during laparoscopic surgery can be satisfactorily controlled by direct pressure or electrocoagulation. However, electrocoagulation has a slightly better efficacy than direct pressure application in controlling haemorrhage. In the absence of newer hemostatic methods such as energy devices, electrocoagulation can serve as a reliable alternative, particularly in developing countries. Further, large-scale, multicenter studies are needed to provide evidence-based knowledge to help in the control of bleeding complications of laparoscopic cholecystectomy.

ETHICAL APPROVAL:

The ethical approval of this study was obtained from the ethical committee of the Fatima Jinnah Medical University, Lahore.

PATIENTS' CONSENT:

Informed consent was taken from all the participants of this study after explaining the risks and benefits of both procedures.

COMPETING INTERESTS:

The authors declare no conflict of interest.

DISCLOSURE:

The current study is based on the master's thesis of one of the authors. The thesis was submitted as a partial fulfilment for attaining an MS degree in General Surgery.

AUTHORS' CONTRIBUTION:

MA: Concept, literature review, write-up, and data collection.
MHM: Literature review and write-up.
AA: Literature review, write-up, and data analysis.
SI: Literature review, write-up, and data collection.
IA: Technical guidance and supervision of research.
KMG: Concept, technical guidance, supervision of research, and final approval.
All the authors have read and approved the final version of the manuscript to be published.

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