The Professional Medical Journal
www.theprofesional.com

DOI: 10.29309/TPMJ/18.4791

ORIGINAL PROF-4791

CLIPPED OR CLIPLESS CHOLECYSTECTOMY;
WHICH OPTION TO CHOOSE TO PREVENT POSTOPERATIVE BILIARY LEAKAGE IN PATIENTS OF CHOLECYSTITIS

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Article received on:
13/03/2018
Accepted for publication:
19/05/2018
Received after proof reading:
02/06/2018

ABSTRACT… Background: Cholecystectomy is the surgical removal of the inflamed gallbladder. Advancement in technology has led to many treatment options and methods of cholecystectomy but the selection of right method depends upon severity of disease along with available resources and expertise. **Objective:** To compare the frequency of biliary leakage with clipless versus clipped laparoscopic cholecystectomy for management of cholecystitis. **Material & Methods: Study design:** Randomized control trial. **Setting:** Unit 1, Department of Surgery, Jinnah hospital, Lahore. **Duration:** It was conducted for a period of six months from July 2016 to January 2017. **Data collection:** A total of 130 patients were included in the study using nonprobability consecutive sampling and were randomly divided in two groups by using lottery method. In group A, clip-less Harmonic scalpel was used along with Ultrasonic shear. In group B, the conventional instruments were used with the application of clips. Patients were called for follow-up in OPD after 1 week to assess biliary leakage through MRCP. All the data was collected through a pre-designed proforma. The data was entered and analyzed in SPSS version 20. **Results:** The mean age of patients was 42.97±10.77 years with 68 (52.31%) patients were male and 62 (47.69%) patients were females. The biliary leakage was noted in 29 cases i.e. 9 from clipless group and 20 were from clipped group and the difference was statistically significant (p-value=0.020) **Conclusion:** It can be concluded from this study that the frequency of biliary leakage is significantly higher in the clipped LC for management of Cholecystitis. Thus it is encouraging to use clipless method to avoid such complication and improve surgical outcomes.

Key words: Cholecystitis, Laparoscopic, Cholecystectomy, Biliary, Leakage

Article Citation: Akhtar HS, Farooq Z, Rathore H, Farooq MU, Ahmad A. Clipped or clipless cholecystectomy; which option to choose to prevent postoperative biliary leakage in patients of cholecystitis. Professional Med J 2018; 25(6):805-809. **DOI:**10.29309/TPMJ/18.4791

INTRODUCTION

Gallstone-related diseases present commonly in the surgical department with a diverse clinical spectrum which may take form of mild biliary colic which can be managed conservatively to serious conditions like gall stone pancreatitis needing lifesaving urgent surgery.[1] Now a days laproscopic cholecystectomy is usually the procedure of choice to manage gall stone related cholecystitis. It is simple, less invasive procedure for the treatment of gall stone as compared to open cholecystectomy and usually involves usage of titanium clip to secure cystic artery and cystic duct. However, it is also associated with drawbacks as most studies reported separate and multiple ligations of cystic duct and artery a technically demanding and time consuming procedure. Similarly the incidence of biliary leakage, which is one of the most severe early complication after cholecystectomy, has increased upto 3% after the use of the clips in the laproscopic surgery as compared to 0.5% after an open procedure.[2] Moreover, its management need further sophisticated procedure like magnetic resonance retrograde cholangiopancreatography (MRCP) or drainage which not only prolongs the hospital stay but also increases the morbidity and financial pressure on patient, his family and health care settings.[3]

The harmonic scalpel was an option of 'clipless' surgery and was considered as a safe alternate choice to secure the cystic artery without increasing the hazard of biliary leakage with

clipped surgery.[4,5] Bessa et al. also supported clipless surgery by the results of their study in which it was reported that the incidence of gallbladder perforation (biliary leakage) was statistically significantly higher in the clipped group, compared to the clipless group (30 vs. 10%, respectively; P=0.002).[6] however, controversial results were reported by another study in which it was seen that the use of the clipless harmonic scalpel had a compareable rate of biliary leakage as 1.75% as compared to a rate of 0.66% with clip placement.[7] Similarly, another study conducted in Rawalpindi also reported same frequency of biliary leakage in both groups (2 [3.4%] vs. 2 [3.6] respectively with P-value=0.972).[8] the results of the study conducted by Hassan et al. also endorsed these findings by reporting the rate of biliary as 1.7% with clipless method and 3.3% with clipped method which was not statistically significant (p = 0.45).[9]

The aim of this study was to compare the frequency of biliary leakage with clipless versus clipped Laparoscopic Cholecystectomy for management of Cholecystitis. It has been observed through literature that clipless laparoscopic cholecystectomy by using harmonic scalpel is safe and better management approach as compared to traditional laparoscopic cholecystectomy with clips but controversial results has been reported. Thus this study was designed to determine the more effective technique to avoid complications according to our local setup which may help us to improve the practice and evidence based implementation of more effective procedure.

METHODOLOGY

This was a randomized control trial undertaken after the approval from ethical review board of Jinnah hospital Lahore. The study was conducted in the department of Surgery, Jinnah Hospital Lahore during six months time period i.e. July 2016 to January 2017. About 130 patients aged 25 to 60 years, presenting with symptoms suggestive of cholecystitis during past 6 weeks along with evidence of stones on ultrasonography were approached through non probability consecutive sampling technique. A detailed evaluation was done by the consultant surgeon for eligibility of laproscopic surgery and patients fulfilling the selection criteria were included in the study after taking an informed consent. Patients with deranged clotting profile or having diabetes mellitus were excluded from the study.

All the patients were randomly divided into Group A: clip-less Harmonic scalpel in which ultrasonic shear (Olympus KeymedSmonosurg version G2 220-240 V 3A. 50/60 Hz.) was used for removal of gall bladder while in group B: conventional instruments were applied for laproscopic cholecystectomy. Patients were allocated in each group using lottery method. Surgery was done using standard protocol and procedure by the consultant surgeon. Patients was kept under observation for 24 hours following surgery to check any oozing of blood or fluid in catheter drain and was shifted to the ward later after removal of the drain. Patients were discharged on first post-operative day and advised for follow-up on OPD basis after 1 week. Assessment of biliary leakage was done by MRCP performed by consultant radiologist and pre-designed proforma was used as data collection tool.

Data was entered and analyzed in the SPSS version 21.0. The quantitative variable were presented in the form of mean and standard deviation. Qualitative variables like age duration, gender, duration of symptoms and biliary leakage in the post-operative period were presented as frequency and percentage. Statistically significant difference between two groups regarding frequency of biliary leakage was determined by applying Chi square test of homogeneity and value of $p < 0.05$ was considered as statistically significant.

RESULTS

In this study total 130 cases participated. The mean age of the patients was 42.97±10.77 years with minimum and maximum ages of 25 & 60 years respectively. 68(52.31%) patients were male and 62 (47.69%) patients were females. The male to female ratio of the patients was 1.09:1. A comparison of characteristics of patients in two groups is shown in Table-I.

Effect modifier		Type of technique		Total
		CLIPLESS	CLIPPED	
Age	< 45 years	43	32	75
	> 45 years	22	33	55
Sex	Male	33	35	68
	Female	32	30	62
Duration of cholecystitis	12 days	31	37	68
	> 12 days	34	28	62

Table-I. Comparison of characteristics of two groups

Out of 130 cases the biliary leakage was noted in 29(22.31%) patients in which 9 were from clipless group and 20 were from clipped group. (Fig I) Statistically significant difference was found between the study groups i.e. p-value=0.020. (Table II)

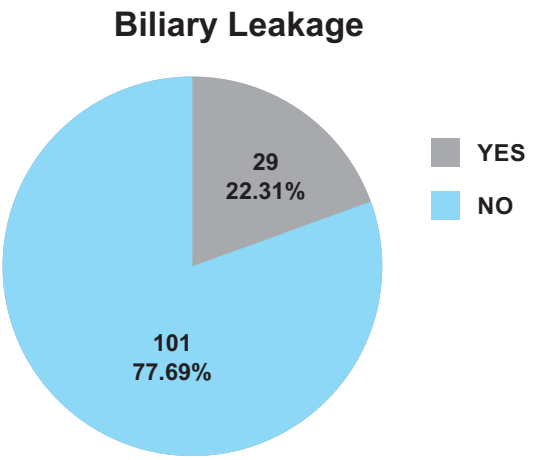

Figure-1. Frequency distribution of biliary leakage

Biliary Leakage	Study Groups		Total
	Clipless	Clipped	
Yes	9	20	29
No	56	45	101
Total	65	65	130

Table-II. Comparison of biliary leakage in study groups
Chi value=5.37 p-value=0.020 (Significant)

DISCUSSION

Laproscopic cholecystectomy (LC) is simple, safe and economical choice as compared to the open cholecystectomy.[10] The main procedure involved in includes the removal of the gall bladder and securing the cystic duct and artery which can be secured using clips by either intracorporeal or extra corporeal ligation.[11] But the complication of biliary leakage hampers its use as a safe procedure demanding a clipless surgery in which Harmonic scalpel and "LigaSure" came up as a recent advancement.[12,13]

According to the present study the Clipless group showed significantly less biliary leakage as compared to the clipped group patients i. e p-value=0.020. Similar results were reported by PK Saha, Ratna Rani Roy et al in a study conducted in Bangladesh in which it was concluded that Clipless LC is a safe and effective method with no bile leak or other complications related to ligature.[14] Similarly, in another study it has been reported that the incidence of biliary leakage was statistically significantly higher in the clipped group, compared to the clipless group (30 vs. 10%, respectively; P=0.002) with a lesser median operative time in the HS group than in the Clips group (32 vs. 40 minutes, respectively; P=0.000).[6] A study by Tharwat Kandil et al concluded that clipless surgery is an effective and safe method for hemobiliary with less operative time along with decreased risk of biliary leakage and the further complications and management related with gall bladder perforation.[12]

However, controversial results were reported in another study which reported a lower incidence of gall bladder perforation with the use of the clipless harmonic scalpel but comparable rates of bile leak i.e. 1.7% with clipless method and 3.3% with clipped method (p = 0.45) with none of the technique being superior to other in terms of biliary leakage.[9] similarly, inconsistent results were reported by another study conducted in Rawalpindi in which it was seen that the frequency of gall bladder perforation was same in both groups (2 [3.4%] vs. 2 [3.6] respectively with P-value=0.972).[8] These variations in the literature makes the evidence based use of harmonic scalpel a controversy during laproscopic surgery.

A study by Roberta Gelmini et al. presented that the mean operative time was significantly shorter in patients treated with the Harmonic scalpel.[15] But the main constraint in use of this technique is the expertise required and expensive instrumentation which is difficult to achieve in a resource depleted county. Therefore, in resource limited setting Harmonic scalpel can be introduced in tertiary care set up atleast which can provide a reliable and efficient alternative to clipped surgery in reducing the operative time, postoperative pain and incidence of gall bladder perforation resulting in subsequent decrease in the rate of conversion of laproscopic cholecystectomy to an open procedure. This will lead to decrease morbidity and mortality and improved outcome in most frequently encountered gall stone related diseases in the emergency.

CONCLUSION

It can be concluded in the light of the results of this study that clipless surgery is superior over conventional laproscopic technique in terms of gall bladder perforation. Thus it can be used safely in patients without any fear of complications reducing the morbidity and mortality.

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Thinking is difficult,
that's why most people judge.

– Carl Jung –

AUTHORSHIP AND CONTRIBUTION DECLARATION

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4	Muhammad Umar Farooq	Data analysis, introduction, Manuscript writing.	
5	Arooj Ahmad	Proof reading, Biostatic analysis.