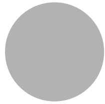
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THE BETTER SURGICAL OPTION FOR CHRONIC CHOLECYSTITITS;

HARMONIC SCALPEL OR CONVENTIONAL LAPROSCOPIC CHOLECYSTECTOMY?

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ABSTRACT… Introduction: Laparoscopic cholecystectomy is a standard and widely used procedure in the treatment of chronic cholecystitis for quite a long time now but there is a recent development in technique because of advent of harmonic scalpel (HS). Thus this study was conducted with an objective to compare frequency of post-operative complications in patients undergoing laparoscopic cholecystectomy by conventional versus harmonic technique. **Data Source:** Primary data based on patients presenting with chronic cholecystitis to the surgical department at tertiary care hospital. **Study Design:** Randomized Control Trial. **Study Setting:** The study was conducted in surgical unit-I, Jinnah Hospital Lahore. **Duration of Study:** Study was conducted in duration of one year i.e. January 2015 to December 2015. **Subjects & Methods:** After approval from the hospital ethical review board, 400 patients of either sex with age from 16 to 60 years and a diagnosis of chronic cholecystitis were included using purposive non-probability sampling technique. They were then randomly assigned to either conventional or harmonic group for laparoscopic cholecystectomy using lottery method at a ratio 1:1. . Information regarding their demographic characteristics and frequency of gall bladder perforation during surgery along with readmission in patients was noted in a structured proforma and data was analyzed using SPSS version 21.0. **Results:** The mean age of patients was 48.19 ± 6.484 years with about 156 (39%) male patients while 244 patients (61%) were female. About 15 (7.5%) patients in harmonic group and 16 (8%) patients in conventional group of laparoscopic cholecystectomy had gall bladder perforation during the procedure while 20 (10%) patients of harmonic group and 27 (13.5%) patients in conventional group were readmitted. On application of chi square test it was seen that the differences were statistically insignificant in both groups for the complications related to the procedure. **Conclusion:** It can be concluded from this study that both treatments are equally effective in terms of gall bladder perforation and rate of readmission. Thus, any of the techniques can be selected without much fear of complications depending upon the health care facility and financial constraints of health system in a resource depleted developing country.

Key words: Laparoscopic Cholecystectomy, Harmonic Scalpel, Gall Bladder Perforation, Electrocautry.

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INTRODUCTION

Chronic cholecystitis is one of the commonest conditions encountered by the surgeons in outpatient department. For long time, open cholecystectomy was used for the removal of gall bladder which had been replaced widely by Laparoscopic cholecystectomy (LC) during the last decade because of its major advantages over the former.[1,2] Laparoscopic technique is based upon use of surgical clips, electric scalpel and cautery for dissection and coagulation resulting in much lesser complications and short in-hospital stay as compared to open cholecystectomy.[3] However, recently harmonic scalpel (HS) has been introduced as an alternative for conventional laproscopic technique in which ultrasonically activated gadgets are utilized to perform dissection and coagulation without using electrocoagulation and minimum tissue injury and wandering currents.[4] This results in a clean and clear field of operation making it a more attractive option over electrocautery but it comes with a

disadvantage of difficult maneuvering technique and overall cost.[5]

Literature has shown that the selection of either of the two methodologies as a superior dissection, in terms of post-operative complications, is contradictory. In a retrospective study, rates of bile leak in Harmonic scalpel versus clip placement were 5.26% and 0.66%, (p value= .0322) and readmission rates were 10.53% and 0.66% (p value=0.005) respectively.[3] While in a local study HS was labeled equivalent in terms of post-operative complications (leakage and perforation).[6] Kandil et al. reported that no postoperative bile leak was encountered in HS but it occurred in 2.9% of patients along with a significantly less incidence of gallbladder perforation (7.1% vs. 18.6%, p = 0.04) in conventional method.[7] El Mallah and colleagues suggested the use of HS for sealing of the cystic artery and cystic duct less than 6 mm in size in laparoscopic cholecystectomy but its use is limited because of the cost effectiveness of the procedure and equipment.[8]

The current study was designed with an aim to find which one is a better dissection and cautery method for gallbladder dissection from liver bed in laparoscopic cholecystectomy. Harmonic scalpel seems to be a better option as compared to the conventional laproscopic surgery but the high cost of the procedure puts a question mark over its use in a resource limited settings.[9] Thus this study was an attempt to compare the outcome of the two procedure so that evidence based technology can be implemented considering a balance between the clinical advantage and financial burden on the health system.

METHODOLOGY

This was a randomized control trial conducted in department of Surgery, Jinnah Hospital Lahore during January 2015 to December 2015. After approval from Ethical Review Board, about 400 patients aged 16 to 60 years, presenting to surgical outpatients department with Pain in right hypochondrium with on and off symptoms of nausea or vomiting for at least 6 week along with presence of one or more stones in gall bladder determined by ultrasonography were evaluated by consultant. Patients fulfilling the selection criteria were included in the study after taking an informed consent using non-probability consecutive sampling technique. Obese, Immune compromised patients, Patients suffering from any connective tissue disorder e.g. SLE, RA or having any suspicion of carcinoma of gall bladder determined by sonography were excluded from the study.

All the patients were randomly divided into two equal group by lottery method i.e. one group in which conventional laproscopic method were used and in second group harmonic scalpels were used for standard three port laparoscopic cholecystectomy. All the operations were carried out by same consultant under general anesthesia using standard operative procedure. Gall bladder perforation was defined as leakage of bile from gall bladder while dissecting it from its bed during laparoscopic cholecystectomy determined by an independent evaluator during surgery by direct observation and verified after removal. Readmission was defined as appearance of the patients in hospital within one month after laparoscopic cholecystectomy with presence of either a bilioma (was labeled if there is collection of fluid in subhepatic area more than 10mm3 determined by ultrasonography), persistent pain (was labeled if the patient has to take NSAID at least once daily to relieve the right hypochondrial pain for at least 2 weeks) or Persistent vomiting (was defined as more than 2 episodes/day for at least 2 weeks). Data was collected on a structured proforma containing variables of interest like age, sex and type of surgery. Current history of smoking and diabetic status was recorded additionally as effect modifier.

All the data from the proforma was entered and analyzed in the SPSS version 21.0. The quantitative statistics like age were presented in the form of mean and standard deviation while qualitative variables were presented as frequency and percentage. Chi square test of homogeneity was applied to determine statistical difference in both groups regarding frequency of complications. A value of $p \leq 0.05$ was considered as statistically

significant.

RESULTS

About 400 patients included in this study had mean age of 48.19 ± 6.484 years. Among them, 156 (39%) were male patients while 244 patients (61%) were female. Out of 400 patients only 158 patients (39.5%) had history of diabetes however remaining 242 patients (39.5%) were non-diabetic while 129 patients (32.3%) showed history of smoking. A comparison of characteristics of patients in two groups is shown in Table-I.

Overall, 31 patients (7.8%) had gall bladder perforation during surgical procedure while 47 patients (11.8%) were re-admitted during the first postoperative month. On cross tabulating treatment group with gall bladder perforation, 15 patients of harmonic group and 16 patients of conventional group of treatment groups had gall bladder perforation. In terms of re-admission, 20 patients of harmonic group and 27 patients of conventional group presented within first postoperative month with a need of re-admission. (Table-II)

Effect modifier		Type of technique		Total	P value
		Harmonic Scalpel n = 200	Conventional n = 200		
Age	< 40 years	26	22	48	0.53
	≥ 40 years	174	178	352	
Sex	Male	72	84	156	0.21
	Female	128	116	244	
Smoking	Smoker	66	63	129	0.74
	Non-smoker	134	137	271	
Diabetic status	Diabetic	73	85	158	0.22
	Non-diabetic	127	115	242	

Table I. Stratification for effect modifiers for the two groups

		Development of Complications		Total	P value
		Yes	No		
Gall Bladder Perforation					
Group	HS	185	15	200	0.85
	Conventional	184	16	200	
Total		369	31	400	
Readmission During First Postoperative Month					
Group	HS	180	20	200	0.27
	Conventional	173	27	200	
Total		353	47	400	

Table-II. Development of complications with harmonic scalpel VS conventional laproscopic

DISCUSSION

Since the introduction of laparoscopic cholecystectomy, it is commonly performed procedure and has widely replaced the years old open cholecystectomy technique. It is based upon three ports technique and uses monopolar electrosurgery and metallic clips to perform cystic duct and artery closure.[10] A new avenue has opened in this aspect since the introduction of ultrasonic dissection technology in laparoscopic cholecystectomy considering it safe and easy to use.[11,12] The primary use of a harmonic scalpel in laparoscopic cholecystectomy has been for division of the cystic artery and liver bed dissection with minimum injury to the local tissue.[13] The major drawback to this technique is the expertise needed and cost which adds to its limitation.

The current study was designed to evaluate the two techniques in terms of complications. To ensure the uniformity of our randomization process, stratification of age was done which showed age was uniformly distributed between the two groups and no statistical difference was observed between the two groups. Moreover, it was seen that 156 (39%) were male patients while

244 patients (61%) were female. Cholecystitis is more common in female population as generally observed and similar are results of our study. More female underwent cholecystectomy during our study period but their distribution in the two groups was uniform. Similarly on stratification for diabetes and smoking it was seen that they were equally distributed in both groups hence ensuring the control of effect modifiers on results and uniformity of the two groups.

On comparing the two techniques it was found that 20 patients of harmonic group and 27 patients in conventional group were readmitted and the difference was statistically non-significant. Furthermore, on cross tabulating treatment group with gall bladder perforation, 15 patients in harmonic group and 16 patients in conventional group of laparoscopic cholecystectomy had gall bladder perforation which was also statistically non-significant. These results imply that both treatments are equally effective in terms of gall bladder perforation and rate of readmission. Similar results were reported by Khan et al.[6] who observed insignificant difference between two groups in terms of gall bladder perforation and readmission. The only significant difference reported by Khan et al. was the duration of operative procedure with HS having short median operative time as compared to the conventional technique. However, different studies conducted all over the world have shown HS to be superior over the conventional technique in terms of complication related to the procedure. Willis et al. reported the use of the Harmonic scalpel as safe and comparable to clip placement especially for the bile leakage.[3] Similarly, another study reported HS as a better procedure with a shorter operative duration, less incidence of gallbladder perforation, postoperative pain, and rate of conversion to open cholecystectomy as compared to the conventional laproscopic cholecystectom.[7] However, one major limitation of these studies as compared to the current study is a smaller sample size of patients included in them. El Mallah et al. observed two major drawbacks of HS technique.[8] They reported it to be safe for sealing of the cystic artery and cystic duct less than 6 mm in size in laparoscopic cholecystectomy but recommended the use of clips technique for a larger diameter. Moreover, it was much expensive constraining its wide use and availability.

In short, this study provides an insight into the two techniques of laproscopic surgery but one major limitation of this study is shorter follow up period. Thus, further comprehensive studies are needed to explore further complications and long term outcomes of the two procedures.

CONCLUSION

It can be concluded from the study that none of the technique is superior over other in terms of gall bladder perforation and readmission. Thus, conventional laproscopic surgery can be used effectively for the treatment of chronic cholecystitis without much disadvantage to the patients. Harmonic scalpel seems to be an attractive alternative for the conventional laproscopic technique but the indifferent effectiveness and major difference in terms of cost should be considered. However, further extensive and long term studies should be conducted to help surgeons developing evidence based practices for the treatment of cholecystitis maintaining a balance between the effectiveness and cost-effectiveness in a resource depleted and overburdened health system of the country.

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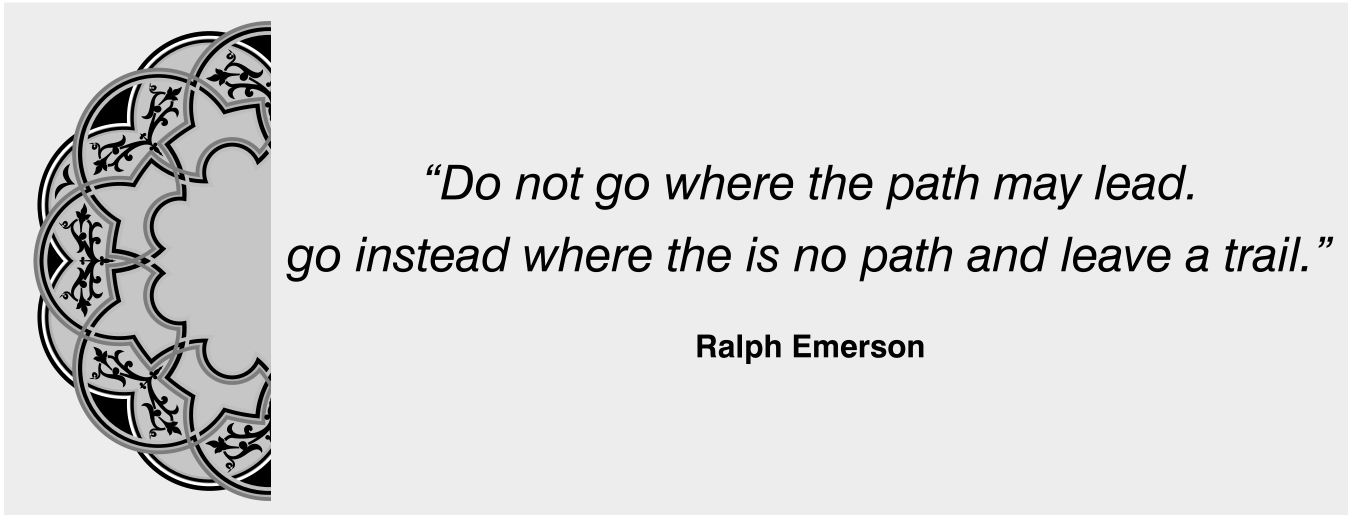

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
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2	Akhtar Mahboob	Data collection, manuscript writing proof reading.	
3	Hasnat Hassan	Data analysis, references, proof reading.	
4	Shabbir H. Chaudhry	Manuscript, writing, analysis, Proof reading	