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Comparative study of Harmonic Scalpel Assisted Clip Less Laparoscopic Cholecystectomy v/s Clipped Laparoscopic Cholecystectomy

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Abstract: ***Objective:*** *To compare both modalities in terms of operative time, no. of times instruments changed, post-operative pain, post-operative drainage, complications and hospital stay (recovery time). To assess and compare the cost-effectiveness of the harmonic scalpel assisted clip less laparoscopic cholecystectomy and clipped laparoscopic cholecystectomy.* ***Methods:*** *The patients were prospectively randomized into two groups- Group-A (study group) - includes all cases that were treated by using harmonic scalpel. Group-B (control group) - includes all cases that were treated by using monopolar electrocautery and titanium clips.* ***Results:*** *Post-operative pain was measured with visual analogue scale (VAS) graded between 110 according to the patient's perception. Mean post-operative pain in study group was 3.88 (range 1 to 8) and in control group was 3.98 (range 1 to 7). Mean operative time in study group was 40.40 min (range 28 to 60 min) and in control group was 49.90 min (range 30 to 70 min). On Statistical analysis, significant difference was found in operative time of both the groups. Mean drainage in study group was 46.83 ml (range 20 to 80 ml) and in control group was 48.16 ml (range 20 to 180 ml). On Statistical analysis no significant difference was found in drainage of both the groups.* ***Conclusion:*** *On the basis of our study we conclude that use of harmonic scalpel for dissection, isolation, sealing and cutting of cystic duct and artery is safe, effective, and without any complication. We recommend use of harmonic ACE for laparoscopic cholecystectomy especially when cystic duct diameter is less than 5 mm.*

Keywords: Harmonic scalpel, Clipless laparoscopic cholecystectomy

1. Introduction

Laparoscopic cholecystectomy is regarded as "gold standard" in the surgical management of symptomatic cholelithiasis and cholecystitis because it is convenient in comparison with the open cholecystectomy.

The standard laparoscopic cholecystectomy involves using a monopolar electrosurgical hook for dissection and clips for clamping of the cystic duct and cystic artery. Alternatively one can use linear stapler, endoloops, or sutures, which are, however, rarely used.

Earlier, during Laparoscopic cholecystectomy, titanium clips have been used for sealing the cystic duct and the cystic artery before dividing them which may lead to clip dislodgement, which is associated with an increased risk of bile leakage [1-3]. Electrocautery causes excess smoke production and an increased risk of tissue damage. Due to energy conduction through the titanium clips, there is also an increased risk of gallbladder (GB) perforation. Slipped titanium clips also act as a source for stone formation [1, 4]. The harmonic scalpel can occlude vessels of up to 5 mm thickness without an increased leakage risk [5-6].

Harmonic scalpel in Laparoscopic cholecystectomy has been accepted by many surgeons. It is mainly used for the dissection of Calot's triangle and the separation of the GB from the liver bed. The harmonic scalpel, which occludes up to 5 mm thickness of luminal structures, is used to divide cystic duct and artery and has been found comparatively safe [7-10].

The Harmonic scalpel was introduced into surgical patients more than a decade ago. This technology involves use of ultrasound within the harmonic frequency range to tissues and allows 3 effects that act synergistically: coagulation, cutting, and cavitation.

Harmonic scalpel cuts via vibration. The scalpel surface cuts through tissue by vibrating in the range of more than 20 kHz which seals it using protein denaturation, instead of heat.

This study is done to compare the efficacy, safety, risk and cost effectiveness of the harmonic scalpel for dividing cystic artery and duct and dissection from the liver bed versus conservative clip and cautery dissection.

2. Materials and Method

Total numbers of patients in study were 60.

Inclusion Criteria

- Age between 17 to 80 years.
- All patients with proven cholelithiasis on Ultrasonography of abdomen & fit for general anesthesia.

Exclusion Criteria

- Choledocholithiasis
- Previous hepatobiliary surgery
- Carcinoma Gall Bladder
- Acute cholangitis
- Stricture of bile duct
- Carcinoma of Ampulla of Vater
- Known coagulopathy or hematological disorder
- Any functional disorder / psychiatric patient
- Any patient not fit for surgery OR not giving consent.

This prospective study namely "***Comparative study of Harmonic scalpel assisted Clipless Laparoscopic Cholecystectomy V/s Clipped Laparoscopic Cholecystectomy"*** was conducted in ***Department of***

Surgery, Sarojini Naidu Medical College & Hospital, Agra from November 2019 to June 2021 in 60 patients undergoing elective laparoscopic cholecystectomy for gallstones. 60 patients were included in this study who were randomized in two groups of 30 patients each in study group and control group respectively.

3. Results

Age both the groups are age and sex matched. Among cases males were 9 and females were 21 and among controls males were 6 and females were 24.

Table 1: Demographic and clinical data of cases and controls

S. no	Clinical feature	Cases (n=30)	Controls (n=30)	P at .05
1	Age distribution	38.26	38.9	
2	Sex distribution	3:7	1:4	
3	Post-Operative Pain	3.88	3.98	.38
4	Operative time (min)	40.40	49.90	0.000081
5	Drainage (ml)	46.83	48.16	0.67
6	Duration of Hospital Stay (days)	2.0	2.13	0.25

Post-operative pain (POP): POP was determined and quantified on Visual analogue scale from 1 to 10 where 1 indicates minimum and 10 indicates extreme pain. Average severity of pain among cases was 3.8 (SD ± 2.3). Maximum pain with score of 10 was experienced by two females aged 42 and 43 years respectively. Minimum pain with score of 1 was experienced by four subjects 3 females aged 37yrs, 43yrs, 49yrs and 1 male aged25 yrs.

Controls: POP was evaluated between the two techniques and results show that there is no statistical difference between them. (The t-value is -0.29081. The p-value is .386119. The result is not significant at $p < .05$).

Table 4: Showing Statistical analysis of Post operative Pain

	Post operative Pain (Mean) on VAS (1- 10)	SD	t Value	p Value
Study Cases	3.88	0.51	0.76	NS
Control Cases	3.98	0.37		

Operative timing: Mean operative time was determined ranging between 28 minutes and 60 minutes. Average operative time was 40.4 minutes (SD±5.7). Maximum operative time was 52 minutes in a 59 year old female. Minimum operative time was 31 minutes in 39 year old female subject.

Controls: Operative time was evaluated between the two techniques and results show that there is significant statistical difference between them. (The t-value is -4.05807. The p-value is .000075. The result is significant at $p < .05$).

Table 3: Showing Statistical analysis of Operative Time

	Operative Time (Mean)	SD	t Value	p Value
Study Cases	40.40min	9.10	4.24	0.000081
Control Cases	49.90min	8.21		

Drainage: Drainage was measured ranging from 20ml to 80ml. Average drainage was 46.8ml (SD±6.0). Maximum drainage was 59ml in a 30 year old female. Minimum drainage was 31ml in 42 year old female subject.

Controls**:** Drainage was evaluated between the two techniques and results show that there is no significant statistical difference between them. (The t-value is -0.18054. The p-value is .428681. The result is not significant at $p < .05$).

Table 4: Showing Statistical analysis of drainage

	Drainage (Mean)	SD	t Value	p Value
Study Cases	46.83ml	14.35	0.43	0.67
Control Cases	48.16ml	9.05		

Duration of Hospital Stay: Duration of hospital stay was evaluated between 1.5 to 3 days. Average duration of hospital stay was 2 days (SD±0.5). Maximum duration of hospital stay was 3 days in a 22 year old female and 53 year old male subject. Minimum duration of hospital stay was 1.5 days in 10 subjects who were 27, 29, 30,32,33,49,50,59 year old females and 20 and 31 year old male subject.

Controls: Duration of hospital stay was evaluated between the two techniques and results show that there is no significant statistical difference between them. (The t-value is -0.37942. The p-value is .35288. The result is not significant at $p < .05$).

Table 5: Duration of Hospital Stay

	Hospital Stay (Mean)	SD	t Value	p Value
Study Cases	2.0 days	0.51	1.16	0.25
Control Cases	2.13 days	0.37		

Relation between operative time and post-operative pain: Among cases operative time is correlated with post-operative pain and it is found that there is negative but weak correlation exists between the two variables. The value of R is -0.141.The P-Value is .460591. The result is not significant at $p < .05$.Among controls operative time is correlated with post-operative pain and it is found that there is negative but weak correlation exist between the two variables. The value of R is -0.0939.The P-Value is .624984. The result is not significant at $p < .05$.

4. Discussion

The current study was performed to determine the possible role of ultrasonically activated scissors in laparoscopic cholecystectomy, mainly focusing on the reduction of operation time, bile duct injuries and biliary complications. It was observed in the study that male: female ratio was 1: 2.33 and 1: 4 respectively in study and control group. This goes in accordance with the well-known saying Fat, Fertile, Fair, Female, Forty'.

It has been reported that with ultrasonic energy, there is a minimal lateral spread of vibration current in the surrounding tissues minimizing the risk of injury compared with monopolar electrocautery, which is associated with 90% of visceral injuries and 15% of biliary tract injuries during laparoscopic cholecystectomy[11]. Conversion rate reported in the literature is 1.2-8.2% [12,13], in our study none of the patient was required to convert to open

cholecystectomy and all gall bladders were dissected intact from liver bed.

In a study done by Tsimoyiannis et al[14] (1998) mean length of hospital stay is statistically shorter with patient with ultrasonic dissection as compared to electrocautery (1.60 days in ultrasonic group and 1.90 days in electrocautery group) but in our study there was no significant difference (mean hospital stay -study group 2 days, control group 2.13).

Two crucial aspects regarding the use of ultrasonically activated devices during laparoscopic cholecystectomies are the modality of application of ultrasonic scissors and the presence of severe adhesions. The surgeon must become familiar with the instrument and avoid maneuvers such as pointing the tip toward delicate structures or touching them with the active blade immediately after use. Cavitation could cause injuries to organs, vessels, and ducts ahead of the instrument's tipand the active blade (which becomes hot after use) could endanger the bile duct, the gallbladder, or the bowel. Correct application of the ultrasonically activated shears onto the cystic duct is mandatory to avoid subsequent leakage. However in our study group no such complication occurred.

Visual analogue scale (VAS) was used to measure postoperative pain in both the groups. Postoperative analgesia used was same in both the groups. Postoperative pain scores studied by Cengiz et al trial (2005) (mean 1.50 in ultrasonic group and 2.60 in electrocautery group) were statistically lower with ultrasonic dissection. In our study mean pain on VAS was 3.88 and 3.98 respectively in study and control group. So we see that there is no significant difference in postoperative pain in both the groups.

In our study drain was placed in all the patients of both the groups. Mean drainage was 46.83 ml and 48.16 ml in study and control group respectively. This shows there was no significant difference in both the groups. Ultrasound abdomen was done in all the patients in postoperative period to see any collection which also did not show any significant collection in both the groups.

In Europe, Huscher et [15] (1999) estimated the cost for a disposable LCS Harmonic scalpel to be lower compared with the combined cost for one scissors and one clipper (346.03 Euro vs. 397.67 Euro).

In our study total cost of operation was Rs 9200 In study group and Rs 5550 in control group. This difference in cost was because clips were not used in study group. One harmonic scalpel was used for 30 patients which costed about Rs 27000 i.e. Rs 900 per patient. Cost of liga clip used in control group was about Rs 550. So we find significant difference of cost was found between both the groups.

However, the cost issue is relevant only on the assumption that disposable technology is used for monopolar electrocautery. By knowing that both ultrasonic and monopolar electrosurgery are now reusable instruments, making cost comparisons would be more difficult.

5. Conclusion

The use of harmonic scalpel eases the dissection manoeuvres and avoids the use of clips to seal the cystic duct and artery. The harmonic scalpel is a safe, efficient and practical instrument to use during laparoscopic cholecystectomies. No significant difference was found in our study regarding post-operative pain, biliary complications, hospital stay and post-operative drainage. However, operative time and no. of times camera lens cleaned during surgery was significantly lower in patient undergoing clip less laparoscopic cholecystectomy. This improves ease of operation.

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