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Surgery

COMPARATIVE STUDY OF HARMONIC SCALPEL ASSISTED CLIPLESS LAPAROSCOPIC CHOLECYSTECTOMY V/S CLIPPED LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT Laparoscopic cholecystectomy is considered worldwide the "gold standard" in the surgical treatment of symptomatic gallstones and acute cholecystitis because it offers well-known and more definite advantages in comparison with the open procedure. The standard laparoscopic cholecystectomy is usually performed using a monopolar electrosurgical hook for dissection and clips for occlusion of the cystic duct and cystic artery. Some pitfalls are associated with the use of the monopolar electric scalpel, such as the high risk of thermal injuries and significantly more common postoperative biliary complications such as bile leakage due to slippage of the clips. The ultrasonically activated scalpel (Harmonic) was introduced into surgical patients more than a decade ago. This technology relies on the application of ultrasound within the harmonic frequency range to tissues. We compare Harmonic scalpel assisted Clipless Laparoscopic Cholecystectomy with Clipped Laparoscopic Cholecystectomy in 60 patients undergoing elective laparoscopic cholecystectomy for gallstones, 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.

Both the approaches are acceptable modalities for laparoscopic cholecystectomy and the results are comparable in terms of patient outcome. The final choice is surgeon specific and dependent on his/her expertise and learning curve.

KEYWORDS

INTRODUCTION:

Cholecystectomy is the universal standard for the treatment of symptomatic cholelithiasis and acute cholecystitis, because it offers well-known and more definite advantages in comparison with the laparotomic procedure.[1]

The advantages of this surgical approach have been reported by a number of authors, showing both the positive impact of this method on the postoperative quality of the patient's life and its optimal short- and long term results[2] .The standard laparoscopic cholecystectomies commonly performed by means of specialized instruments. For gallbladder dissection, the electrosurgical hook, spatula, and or scissors, using high frequency monopolar technology, have been used in most centres. Occlusion by simple metal clips is the most frequently used technique to achieve both cystic artery and duct closure.

Alternative techniques for cystic duct closure have included sutures, a three-throw reef knot, or Roeder slip knot. However these alternatives are technically more difficult and, therefore, were not used frequently [3] .Although the laparascopic cholecystectomy is a safe technique, several reports have pointed out special injuries and postoperative complications inherent in the current technology and technique.

The ultrasonically activated (Harmonic) scalpel was designed as a safe alternative to electrocautery for the hemostatic dissection of the tissues and was introduced into clinical use nearly a decade ago. This innovative method of cutting tissues was based upon the coagulating and cavitational effects provided by a rapidly vibrating blade contacting various tissues[4,5]. The resulting decrease in temperature, smoke, and lateral tissue damage placed the Harmonic scalpel in contrast to the effects seen with the more traditional electro surgery/cautery. In addition the elimination of inadvertent, sometimes unrecognized electric arcing injuries with their potentially hazardous outcome supported the role of the Harmonic scalpel as a potentially safer instrument for tissue dissection. The replacement of scissors, dissectors and clips applicator with the harmonic scalpel gives the opportunity to use a single instrument during the whole surgical procedure, limiting the number of passage through the trocars and consequently reducing the possibility of causing lesions to the intraabdominal organs.

This study was undertaken to evaluate the safety and efficacy of harmonic scalpel in laparoscopic cholecystectomy in comparison to standard clip application to ligate and divide cyst artery and duct.

MATERIALAND METHODS:

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 Jan. 2015 to Jul. 2016 in 60 patients undergoing elective laparoscopic cholecystectomy for gallstones, who were randomized in two groups of 30 patients each in study group and control group respectively.

INCLUSION CRITERIA:

- 1. Age between 17 to 80 years.
- 2. Symptomatic cholelithiasis (biliary colic, acute cholecystitis).
- 3. Choledocholithiasis (Gallstone pancreatitis).

EXCLUSION CRITERIA:

- 1. Unable to tolerate general anesthesia.
- 2. Refractory coagulopathy.
- 3. Suspicion of carcinoma.
- 4. Previous multiple upper abdominal surgery.
- 5. Cholangitis
- 6. Diffuse peritonitis.
- 7. Cirrhosis or portal hypertension.
- 8. Chronic obstructive pulmonary disease.
- 9. Cholecysto-enteric fistula.
- 10. Morbid obesity.
- 11. Pregnancy.

The patients were prospectively randomized into two groups:

GroupA (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 coagulation and titanium clips.

Pre-operative data:

- A. Age of Patient (17-80 age)
- B. Gall bladder pathology on ultrasonography abdomen
- C. Any other relevant finding

The assessment were done under the following heads:

Infra-operative assessment -

- (a) Mean Operative time
- (b) Blood Loss

- (c) Mean duration no. Of time lens cleaned
- (e) Lateral tissue damage

Post-operative assessment -

- (a) Post operative pain
- (b) Mean drainage
- (c) Mean duration of hospital stay

OPERATIVE TECHNIQUE-

60 subjects were divided randomly into two groups of 30 each. One group underwent traditional laparoscopic cholecystectomy using clips and whole dissection was done by Maryland dissector, whereas other group underwent clipless laparoscopic cholecystectomy using harmonic scalpel.

First cystic artery was identified and dissected. It was inserted between jaws of harmonic ACE. Then it was divided by activation of harmonic ACE. Then it was ascertained that there was no micro-calculi in the lumen of the cystic duct by moving the jaws of the harmonic ACE up and down. The duct was inserted between the jaws at a safe distance from common bile duct to avoid damage to it then the jaws were closed. The harmonic was activated to power level 3 and during this phase, great care was taken to avoid stretching or rotating cystic duct rather to keep it still until the gall bladder was detached from the cystic duct. Then the cutting point of the cystic duct was checked for any bile leakage. Irrigation was done with normal saline and hemostasis was achieved. Finally intra-abdominal drain was inserted in hepatorenal pouch in all patients of both the groups.

The analysts included -

The operative time, number of times the lens cleaned during surgery, inlra operative difficulties, gall bladder perforation with or without spillage of stones in peritoneal cavity and any spillage of bile in the peritoneal cavity were recorded.

Post operative follow-up included -

- Repeated clinical examinations till discharge.
- Drain output, nature of output (serous, bilious or hemorrhagic).
- Post operative pain was recorded on visual analogue scale (VAS) at 1,4 and 24 hrs after the surgery.
- Post operative investigations in the form of abdominal ultrasound on day 2 with special attention to the presence or absence of any subhepatic collection, full blood count, assessment of liver functions and renal functions were recorded. Drain was removed when it was not draining. Patient were discharged once they were tolerating oral feeds and there was no abnormality on clinical examination. Follow up was done upto 3 months.

Data was analyzed statistically using 't' test. 't' value was 1.98. Test was significant when calculated 't' value is greater than table 't' i.e. p< .05.

Then conclusion were drawn after analysis.

OBSERVATIONS AND RESULTS

In the present study " Comparative study of Harmonic scalpel assisted Clipless Laparoscopic Cholecystectomy V/s Clipped Laparoscopic Cholecystectomy".

The observations noted were as follows:

There were 21 (70 %) females and 9 (30%) males in group A (study group) and 24 females(80 %) and 6 males(20 %) in group B (control group). The age range for group 1 was 20-60 years, and that for group 2 was 20-70 years. Mean age for study group was 37.9 yrs and mean age for control group was 39.5 yrs.

SUMMARY & CONCLUSION

- There were 21 (70 %) females and 9 (30%) males in Group A (Study Group) and 24 females (80%) and 6 males (20%) in Group B (Control Group).
- The age range for Group A (Study Group) was 20-60 years (mean 37.90 yrs), and that for Group B (Control Group) was 20-70 years (mean 39.50 yrs).
- Post operative pain was measured with visual analogue scale (VAS) graded between 1-10 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). On statistical analysis no significant difference was found in both these group.
- Mean operative time in study group was 40.40 minutes (range 28

- to 60 mins) and in control group was 49.90 minutes (range 30 to 70 mins). On Statistical analysis, significant difference was found in operative time of both the groups.
- Mean drainage in study group was 46.83 ml (range 25 to 80 ml) and in control group was 48.16 ml (range 30 to 70 ml). On Statistical analysis no significant difference was found in drainage of both the groups.
- Mean duration no. of times lens cleaned during surgery in study group was 1.43 and in control group was 2.57.On Statistical analysis, significant difference was found in both these groups.
- In our study cases none of the patient had bile duct injury. In control group there was single patient who had minor bile duct injury which was managed conservatively. All patients demonstrated no clinical evidence of bile leakage or bleeding.
- Mean duration of hospital stay in study group was 2 days (range 1.5 to 3 days) and in control group was 2.13 days (range 1.5 to 3.5 days). On Statistical analysis no significant difference was found in both these groups.
- Harmonic shear was used in study group that costed Rs. 27000 (Rs 900 per patient). In control group liga clip of 300and 400 sizes were brought by the patient which costed about Rs 550 per patient. So we found that there was significant difference of cost in both the groups.

The use of harmonic scalpel eases the dissection maneuvers 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 clipless laparoscopic cholecystectomy. This improves ease and maneuversbility of operation. Hence 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.

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