

Comparitive Study between Conventional Laparoscopic Cholecystectomy Versus Cholecystectomy Utilizing Energy Sealing Devices

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Abstract

LC is the gold standard treatment for gallstones. Ultrasonic scalpel, which causes three synergically acting effects: cavitation, coaptation / coagulation and cutting. to Compare between laparoscopic cholecystectomy utilizing energy sealing devices (clipless) and conventional laparoscopic cholecystectomy as regard operative time, pain, infection, bile leakage ,early post-operative recovery , hospital stay ,the need for drain etc. This was a prospective study, which was performed at the General Surgery Department of Benha University Hospital after approval by the Benha Faculty of Medicine Research Ethical Committee, and all patients signed informed consent to be included in this study.As far as our analysis in Group A was concerned, mean hospital stay (in days) was (2.21) while mean hospital stay (in days) was (2.24) in Group B, there is no statistically significant difference in hospital stay between the two groups. In Group A: postoperative infection occurred in one case, in Group B postoperative infection occurred in 2 cases, and in both groups there was no postoperative bile leakage. The energy sealing system offers full hemobiliar stasis to all patients and is a healthier alternative to traditional cystic duct and artery video. It has a shorter processing time, decreased blood loss and decreased transfer rate for open cholecystectomy.

Keywords: Laparoscopic, Conventional, Ultrasonic Scalpel, Operative, Hemobiliary.

1. Introduction

The modern LC is usually performed with dissecting, electro-surgical instruments as spatula, and/or scissors, and this procedure has been used in most of the centres. Clear metal clips are also used for the closing of cystic ducts and arteries. Alternative technique with sutures to close cyst ducts is rarely used [1].

While the surgical clip was considered a safe form of closure, bile leakage is a potential risk of laparoscopic cholecystectomy due to the displacement of the clip from the stump in the cystic duct. There are also other dangers involved with the use of clips, such as unintended cutting of typical bile duct, leading to blocking, stretching, slicing, etc [2].

As a result, many conventional methods are often used to control the cystic artery, such as absorbable or non-absorbable sutures; monopolar or bipolar electro coagulation and energy sealing devices have also been used for this purpose, but energy sealing devices have been used less commonly due to their high cost [3].

Ultrasound-activated energy sealing systems, developed as a safe alternative to haemostatic tissue dissection electrocautery, were put into clinical use nearly a decade ago.it is stated that ultrasound dissection is efficient and easy to implement [4].

Energy sealing systems are also an important means of closing cystic ducts and vessels with a diameter less than 4 mm (as FDA certified in 2006). This research was conducted to show the effectiveness and safety of energy sealing devices as the only tool for the laparoscopic cholecystectomy procedure to achieve complete hemobiliary stasis. In addition, the use of a single instrument [5].

2. patient and methods

A prospective study, which was performed at the General Surgery Department of Benha University Hospital after approval by the Scientific Ethics

Committee of the Faculty of Medicine in Benha, and all patients signed informed consent to be included in it research.

A total of 42 patients with history of Chronic Calcular Cholecystitis have been enrolled in our post-operative follow-up study from January 2018 to December 2018.

Inclusion criteria

All patients with history of Chronic Calcular Cholecystitis and Patients from 18-60 years old.

Exclusion criteria

Age less than 18 or more than 60 years and wide cystic duct, mirizzi syndrome and patients with history of obstructive jaundice .

All patients meeting the inclusion criteria were subjected to our study after proper history taking, full clinical examination, and required preoperative laboratory investigations as whole blood image, liver function test, HCV and HBV markers and also imaging as abdominal ultrasound and MRCP .

Closed envelop randomization or card system our patients was randomized into two groups:

- **Group A:** (22 patients) underwent clipless laparoscopic cholecystectomy.
- **Group B:** (20 patients) underwent conventional laparoscopic cholecystectomy.
- **N.B:** 2 patients from group A underwent clipless laparoscopic cholecystectomy but intraoperative bile leak noted from gallbladder stump so metal clip was applied on cystic duct to ensure safety and for that those tow patient were excluded from the study .

Procedures

Both groups underwent the same procedure with the tow different technique.

Patients were placed in the supine position on operation table. After giving general anesthesia, pneumo-peritoneum was created using a verses needle inserted through a small skin incision in infraumbilical region.

In (Group-B), 4 ports were placed then the fold of peritoneum covering the cystic artery, cystic duct and lymph node were dissected and the junction between the gallbladder and the cystic duct was established and the cystic duct was dissected to the common bile duct.

Gall bladder was separated from its bed using spatula or electro-hooks. In study group (Group-A), 3 ports only were placed the fold of peritoneum covering the cystic artery, cystic duct and lymph node were dissected using a harmonic scalpel as an energy sealing devices.

Gallbladder extraction was similar in both groups. Postoperative pain was assessed at 12, 24 , and 48 h and 1 week after visual analog scale (VAS) surgery; postoperative analgesia (NSAID) was administered intramuscularly, if necessary. When patients were already affected by pain, a potent analgesic (1 mg / kg of intramuscular pethidine) was prescribed and cumulative doses of this medicine were given.

All intraoperative variants as operative time, type of anaesthesia learning curve and intraoperative variants as analgesics requirement, hospital stay, postoperative complications (as hemorrhage, biliary fistula, infection) postoperative complication i.e.-cystic duct leak, cystic artery bleed or any other collection subsequent surgery and average hospital stay.

Regular follow-up was performed for all patients at the outpatient clinic every week up to 6 month for follow up to assess the postoperative complications.

Ethical consideration

All patients had informed consent that they were involved in the study. An approval was obtained from the Committee on Research Ethics at the Faculty of Medicine in Benha.

2.1 Statistical analysis

Table (1) Operative time and Intraoperative blood loss in both group.

| Operative time | Group A (N=20) | Group B (N=20) | Total (N=40) | P-value |
|--------------------------------|----------------|----------------|--------------|---------|
| Mean duration (min) | 37.28 | 49.5 | 43.28 | <0.001 |
| Minimum duration (min) | 32 | 52 | 32 | |
| Maximum Duration (min) | 61 | 72 | 72 | |
| Standard deviation | 7.86 | 8.053 | 10.01 | |
| Intraoperative blood loss (ml) | | | | |
| Mean | 33 | 73 | 43.28 | <0.02 |
| Minimum | 20 | 32 | 20 | |
| Maximum | 56 | 70 | 70 | |

Table (2) Intraoperative pile spillage and Cases converted to open surgery in both group in both group.

| Groups | Pile spillage | % |
|----------------|---------------|---|
| Group A (N=20) | 0 | 0 |
| Group B (N=20) | 1 | 5 |

The data gathered were tabulated and presented in appropriate figures. While quantitative data is summarized using mean and standard deviation, qualitative data has been summarized using frequency and percentage. Data was analyzed by the aid of software package of SPSS using suitable statistical tests. For this study the agreed degree of importance was 0.05 (P<0.05 was considered significant).

3. Results

In Group A mean Intraoperative blood loss (ml) was (33), while in Group B mean Intraoperative blood loss (ml) was (73). There is statically significant in intraoperative blood loss between two types. In Group A Intraoperative pile spillage was no case, while in Group B Intraoperative pile spillage was in one case Table (1).

One case occurred in group cases converted to open surgery, and in group B cases converted to open surgery there was a mean postoperative pain score in group A (2.172), and in group B there was a mean postoperative pain percentage (2.18) (using VAS percentage). There is no statistically significant difference between the two groups in the Post-Operation Pain Ratings Table (2).

In Group A mean Amount of drainage was [31], while in Group B mean Amount of drainage was [43]. There is a dynamically significant difference between the two groups with regard to the Postoperative Drainage Level Table (3).

The mean hospital stay in Group A (days) was (2.21) while the median hospital stay in Group B was (2.21). (Days) was (2.24). There is no statistically significant difference between two categories between hospital stays. Table (4).

In Group A post-operative infection was in one case, while in Group B post-operative infection was in 2 cases Table (5).

There was no post-operative bile leak in both groups Table (6).

Table (2) Continue

| Groups | Cases converted | % |
|----------------|-----------------|----|
| Group A (N=20) | 1 | 5 |
| Group B (N=20) | 2 | 10 |

Table (3) Post-operative pain Score in both group (using VAS score).

| Score | Group A (N=20) | Group B (N=20) | P-Value |
|--------------------|----------------|----------------|---------|
| Mean pain score | 1.772 | 2.18 | 0.09 |
| Minimum pain score | 1 | 2 | |
| Maximum pain score | 3 | 4 | |
| Standard deviation | 0.548 | 0.54 | |

Table (4) Amount of drainage in both group.

| Amount of drainage | Group A (N=20) | Group B (N=20) | Total (N=40) | P-Value |
|--------------------|----------------|----------------|--------------|---------|
| Mean | 31 | 43 | 43.28 | <0.03 |
| Min. | 23 | 30 | 23 | |
| Max. | 60 | 73 | 73 | |

Table (5) Hospital stay (in days) in both group.

| Hospital stay (in days) | Group A (N=20) | Group B (N=20) | P-Value |
|-------------------------|----------------|----------------|---------|
| Mean (days) | 2.21 | 2.24 | 0 |
| Minimum (days) | 1 | 1 | |
| Maximum (days) | 4 | 7 | |
| Std. deviation | 0.876 | 1.154 | |

Table (6) Post-operative infection and post-Operative bile leak in both group.

| Groups | Infection | % |
|----------------|-----------|----|
| Group A (N=20) | 1 | 5 |
| Group B (N=20) | 2 | 10 |
| Groups | Bile leak | % |
| Group A (N=20) | 0 | 0 |
| Group B (N=20) | 0 | 0 |

4. Discussion

In our analysis, the mean working time for the harmonic group was significantly shorter than for the regular group (37.28 min vs. 49.5, $p=0.0001$). Samer et al. [8] concluded that statistically significant shorter average running time in Group A may be due to many factors; ACE is a multi-functional device. Replaces four instruments that are widely used in the LC, In other terms, a dissecting device, a clip package, a scissor and an electrosurgery hook or a spatula. Finally, the activation of the harmonic ACE does not produce smoke, which allows the surgeon to perform in a direct field of action during surgery.

Tebala et al [9] have shown that, due to the various functions of energy sealing devices, 4 instruments can be replaced by energy sealing devices. It reduces the need for instrument adaptation, shortening the time of operation, whereas in conventional electrocautery techniques repeated adjustments (extraction and

reinsertion) of instruments may increase the risk of tissue injury, such as the intestine or the liver.

In our study, intraoperative blood loss was significantly higher in the conventional group than in the A group (73 ml vs. 33 ml $p = 0.0001$). Huscher et al. [10] argued that energy sealing systems have been shown to be effective and safe for dissection and haemostasis.

This is consistent with studies performed by Mahabaleshwar et al [11] and Gelmini et al [12] that no major intraoperative or postoperative bleeding (blinding) has occurred in either class.

The main finding of this analysis is the absence of any minor or substantial leakage of bile from the cystic duct stump in Group A, which means that the harmonic shears are as stable and as successful as the simple metal clips to cover the stump in the LC. Samer et al. (8) recorded the same result in the absence of either minor or significant bile leaks from the cystic duct stump.

Huscher et al. [10] found Bile leakage was found in seven of the 331 patients (2.1 per cent) in whom only harmonic shears were able to close and isolate the cystic duct. This rate of cystic-duct leakage is similar to the 2% rate recorded in the literature by the use of other cystic-duct closing techniques [22–24].

Different forms of cystic-duct leakage are caused by an improper closing of the duct due to the dislocation of the clip muscles, the necrosis of the duct at the clip point, or the sliding of the clips from the end of the duct and the migration to the biliary duct [13].

Ultracision was associated with a statistically significant lower incidence of perforation of the gallbladder compared to electrocautery (7.1 percent vs. 18.6 percent, respectively; $p=0.04$) as reported in [14] studies.

Samer et al. [8] stated the use of harmonic ACE was correlated with a statistically marginally lower frequency of perforation of the gallbladder relative to electrocautery (10 percent vs. 30 percent).

In our group A sample, the mean post-operative pain score was (1,772), while the mean post-operative pain score was [2,18] in group B (using VAS score). There is no statically significant difference in Post-Operative Pain Score between two groups.

In a study conducted by Kandil et al. [15] who reported a substantially higher incidence of pain in the average population. This statistical difference may be attributed to many factors, such as shorter time of operation, as we use less gas and less gale bladder perforation in the harmonic group and less bile leakage in the peritoneum.

The mean amount of postoperative drainage in our sample was more in the conventional group than in the group (43 vs. 31 ml) the hospital stay in group A was shorter (2.21 vs. 2.24 days).

This is consistent with the result of a study conducted by Kandil et al. [15] who reported that the mean volume of postoperative drainage in the conventional cholecystectomy group was significantly higher than in the energy sealing group. In our sample the hospital stay in group B was shorter than group A (20.15 ± 5.65 vs. 24.65 ± 6.22 , $P = 0.006$). This is in agreement with the result of a study carried out by Huscher et al. [10] indicated that the hospital stay was shorter in the energy sealing category than in conventional cholecystectomy. It is in line with the findings of the analysis carried out by Kandil et al. [15] who reported that the hospital stay in the Energy sealing devices category was shorter.

5. Conclusion

Energy sealing devices can be used safely in laparoscopic cholecystectomy for control of cystic duct and cystic artery with less operative time and less intraoperative bleeding.

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