**Comparative study between Clip Laparoscopic Cholecystectomy Versus Cholecystectomy Using Energy Sealing Devices**

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**Abctract:**

LC is the gold standard treatment of gall stones. Ultrasonic scalpel causing three effects that act synergically: cavitation, coaptation/coagulation, and cutting**.** to Compare between Clipless laparoscopic cholecystectomy and conventional laparoscopic cholecystectomy as regard the post-operative complications (pain, infection, leakage, . etc ) , early post-operative recovery , hospital stay etc. This was prospective study, that was conducted in General Surgery Department of Benha University Hospital after an approval from the research ethics committee in Benha Faculty of Medicine and all patients signed informed consents that they was involved in this study.As regard our study in Group A mean Hospital stay (in days) was (2.21), while in Group B mean Hospital stay (in days) was (2.24), There’s no statically significant difference between two groups in respect of Hospital stay. In Group A: post-operative infection was in one case, while in Group B post-operative infection was in 2 cases, and there was no post-operative bile leak in both groups.The energy sealing devices provides complete hemobiliary stasis for all patients and is a safe alternative to stander clip of cystic duct and artery. It provides a shorter operative duration, , and less blood loss and less rate of conversion to open cholecystectomy.

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

**1. Introduction**:

The advantages of laparoscopic cholecystectomy (LC) have been published extensively, and LC has become the gold standard in treating benign gallbladder diseases. LC has largely replaced conventional open cholecystectomy (**1)**

The traditional LC is commonly performed by means of dissector, the electrosurgical hook, spatula, and/or scissors, and this method has been used in most centers. Simple metal clips are frequently used to achieve cystic duct and artery closure. Alternative technique using sutures for cystic duct closure is infrequently used.**(2)**

Although the surgical clip was known to be a safe closure method, bile leakage due to clip displacement from the cystic duct stump is a potential complication of laparoscopic cholecystectomy. There are many other complications that have been found to be associated with the use of the clips like accidental clipping of common bile duct leading to obstruction, strictures, slippage of clips etc **(3)**.

Therefore, various new methods are now used to control the cystic artery like absorbable or non-absorbable sutures; Monopolar or Bipolar electro coagulation and Energy sealing devices have also been used for this purpose but due to its high cost Energy sealing devices has been used less frequently **(4)**

Designed as a safe alternative to electro cautery for the haemostatic dissection of tissue, the ultrasonically activated Energy sealing devices was introduced into clinical use nearly a decade ago. Several studies have described the use of ultrasound dissection technology in the LC, which concluded that ultrasonic dissection was safe and easy to use. **(5)**

The Energy sealing devices is also an effective tool for closure of biliary ducts and vessels whose diameter is 4mm to 5mm (as certified by the FDA in 2006). This study was undertaken to demonstrate the efficacy and safety of the Energy sealing devices as the sole instrument to achieve complete hemobiliary stasis in the performance of Laparoscopic cholecystectomy. Moreover, the use of a single instrument during the whole procedure averts or decreases the risk of distant organ injuries **(6)**

**2. Subjects and Methods:**

This was prospective study, that was conducted in General Surgery Department of Benha University Hospital after an approval from the research ethics committee in Benha Faculty of Medicine and all patients signed informed consents that they was involved in this study.

A total of 40 patients with a history of Chronic Calcular Cholecystitis were recruited to our study with post-operative follow up plan for 6 months.

**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 and mirizzi syndrome.

All patients meeting the inclusion criteria were subjected to our study after proper history taking, full clinical examination, and required preoperative investigations.

By computer assisted randomization or card system our patients was randomized into two groups:

* **Group A:** (20 patients) underwent clipless laparoscopic cholecystectomy.
* **Group B:** (20 patients) underwent conventional laparoscopic cholecystectomy.

**Procedures:** All patients were subjected to thorough history and clinical examination focused on manifestation of gallstone disease and chronic liver disease. The following investigations were performed [whole blood picture, liver function tests (serum albumin, ALT, AST, and prothrombin time “INR”), HCV and HBV markers, and abdominal ultrasound] to show the state of the liver, portal vein, gallbladder, and CBD. Patients were placed in the supine position on operation table. After giving general anesthesia, pneumo-peritoneum was created using a Veress needle inserted through a small skin incision in infraumblical region.

In (Group-B), the fold of peritoneum covering the cystic artery, cystic duct and lymph node were dissected and the junction between gallbladder and the cystic duct was defined and the cystic duct was dissected towards the common bile duct.

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

Extraction of gallbladder was similar in both groups.. Postoperative pain was evaluated at 12, 24, and 48 h and 1 week after the operation using a visual analogue scale (VAS); postoperative analgesia in the form of a NSAID was administered intramuscularly when required. If the patients still complained of pain, a strong analgesic (1 mg/kg pethidine intramuscularly) was administered and the total doses of this medication were recorded

All intraoperative variants as operative time, type of anaethesia 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 following surgery and the average length of 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 from the research ethics committee in Benha Faculty of Medicine was obtained.

**2.1.Statistical Analysis** The collected data was tabulated and presented in suitable figures. Quantitative data was summarized using mean and standard deviation, while, qualitative data by using frequency and percentage. Data was analyzed by the aid of software package of SPSS using suitable statistical tests. The accepted level of significance in this work 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’s a statically significant difference between two groups in respect of Intraoperative blood loss. In Group A Intraoperative pile spillage was no case, while in Group B Intraoperative pile spillage was in one case. **(Table 1)**

In Group Cases converted to open surgery was one case, while in Group B Cases converted to open surgery was in two cases, In Group A mean Post-operative pain Score was (2.172 ), while in Group B mean Post-operative pain Score was (2.18) (using VAS score). There’s no statically significant difference between two groups in respect of Post-operative pain Score. **(Table 2)**

In Group A mean Amount of drainage was (31), while in Group B mean Amount of drainage was (43). There’s statically significant difference between two groups in respect of Post-operative Amount of drainage. **(Table 3)**

In Group A mean Hospital stay (in days) was (2.21), while in Group B mean Hospital stay (in days) was (2.24). There’s no statically significant difference between two groups in respect of Hospital stay. **(Table 4)**

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

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

## 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 |
| Mean duration (min) | 37.28 | 49.5 | 43.28 | <0.001 |
| Min. duration (min) | 32 | 52 | 32 |  |
| Max. Duration (min) | 61 | 72 | 72 |  |
| Std. deviation | 7.86 | 8.053 | 10.01 |  |
| Intraoperative blood loss (ml) |  |  |  |  |
| Mean | 33 | 73 | 43.28 | <0.02 |
| Min. | 20 | 32 | 20 |  |
| Max. | 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 | |
| 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 |
| Mean pain score | 1.772 | 2.18 | 0.09 |
| Minimum pain score | 1 | 2 |  |
| Maximum pain score | 3 | 4 |  |
| Std. 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 |
| 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 |
| 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

LC is the gold standard treatment of gall stones. Ultrasonic scalpel causing three effects that act synergically: cavitation, coaptation/coagulation, and cutting. The lateral energy spread is minimal, and the risk of distant tissue damage is lower than that of electrosurgery. **(7)**

In our study, the mean operative time was significantly shorter in the harmonic group than in the traditional group (37.28 min vs. 49.5, respectively, p=0.0001). **Samer et al. (8)** reported that statistically significant shorter mean operative time in the A group can be attributed to several factors; the harmonic ACE is a multifunctional instrument. It replaces four instruments routinely used in the LC, namely, the dissector, clip applier, scissors, and electrosurgical hook or spatula. Finally, the activation of the harmonic ACE does not form smoke, therefore allowing the surgeon to work in a clear operative field throughout the operation.

**Tebala et al (9)** demonstrated that because the energy sealing devices can replace 4 Instruments owing to the multiple functions of the energy sealing devices. It thus eliminates the need for instrument change, making operative time short, whereas in the classical technique using electrocautery frequent change (extraction and reinsertion) of instruments can increase the risk of tissue injury such as bowel or liver.

In our study, intraoperative blood loss was significantly more in the traditional group than is in the A group (73 ml vs. 33 ml p = 0.0001). **Huscher et al. (10)** reported that energy sealing devices has been proven to be an effective and safe instrument for dissection and hemostasis.

This is in accordance with the studies conducted by **Mahabaleshwar et al (11)** and **Gelmini et al (12)** There was no incidence of any significant intra-operative or post-operative hemorrhage (bleeding) in any of the groups

The main finding of the present study is the absence of either minor or major bile leaks from the cystic-duct stump in the A group, denoting that the harmonic shears are as safe and efficient as simple metal clips in achieving the closure of the cystic-duct stump in the LC. **Samer et al. (8)** reported the same result about the absence of either minor or major bile leaks from the cystic-duct stump**.**

**Huscher et al. (10)** found that bile leaks were encountered in seven of the 331 patients (2.1%), in whom the closure and division of the cystic duct was achieved by the harmonic shears alone. This 2.1% cystic-duct leakage rate is comparable to the 2% rate reported in the literature when using other cystic-duct closure techniques.22–24

Various examples of cystic-duct leakage are due to inadequate closure of the duct caused by mismatch of the clip arms, necrosis of the duct at the site of clipping, or slippage of the clips off the end of the duct and migration into the biliary tract. **(13)**

The use of ultracision was associated with a statistically significant lower incidence of gallbladder perforation compared to electrocautery (7.1% vs. 18.6%, respectively; p=0.04) as reported in **(14)** study

**Samer et al. (8)** reported that the use of the harmonic ACE was associated with a statistically signifi-cant lower incidence of gallbladder perforation, compared to electrocautery (10% vs. 30%, respectively; p=0.002.

In our study In Group A mean **Post-operative pain Score** was (1.772), while in Group B mean **Post-operative pain Score** was (2.18) **(using VAS score).** There’s no **statically significant difference between two groups in respect of Post-operative pain Score.**

In a study carried out by **Kandil et al.** **(15)** who reported that the incidence of pain was significantly more in the traditional group. This statistical difference may be attributed to several factors such as shorter duration of operation, so we use less amount of gases and less incidence of perforation of gall bladder perforation in harmonic group so less escape of bile in the peritoneum.

In our study The mean amount of postoperative drainage was more in the traditional group than in the group (43 vs. 31 ml) The hospital stay was shorter in the A group (2.21 vs. 2.24 day)

This is in agreement with the result of a study carried out by **Kandil et al. (15)**, who reported that the mean amount of postoperative drainage was significantly more in the traditional cholecystectomy group than in the energy sealing devices group. In our study, the hospital stay was shorter in group B 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)** who reported that the hospital stay was shorter in the energy sealing devices group than in the traditional cholecystectomy. This is in agreement with the result of a study carried out by **Kandil et al. (15)**, who reported that the hospital stay was shorter in the energy sealing devices group.

**5.Conclusion:**

## The energy sealing devices provides complete hemobiliary stasis for all patients and is a safe alternative to stander clip of cystic duct and artery. It provides a shorter operative duration, , and less blood loss and less rate of conversion to open cholecystectomy.

## 6.References

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