A comparative study of harmonic versus electrocautery in the dissection of gallbladder in laparoscopic cholecystectomy

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Abstract

Background: Laparoscopic cholecystectomy is considered the "gold standard" in the surgical treatment of symptomatic gallstones, gallbladder adenomas and acute cholecystitis. Among the alternative energy sources proposed (monopolar, bipolar electric scalpel, and radiofrequency sealers) with the aim to dissect and/or seal, the ultrasonic energy has been frequently adopted, however without a widespread acceptance among surgeons for routine or emergency laparoscopic cholecystectomy. This study investigates the possible beneficial aspects of ultrasonic dissection and its efficacy in the complete dissection of gallbladder from the liver bed and haemostasis

Methods: Patients were divided into 2 groups according to the instruments used for dissection of the gall bladder from the liver bed. 32 patients in whom dissection and coagulation was performed using monopolar coagulation and 28 patients who were all treated with the ultrasonically activated scalpel harmonic ACE (Ethicon Endo-Surgery) for the dissection of gallbladder and for coagulating cystic artery.

Results: The mean operative time, was significantly shorter in the harmonic group than in the mono polar group $(33.64 + 6.61 \text{ min vs. } 49.15+129.08 \text{ respectively; } \mathbf{p} < 0.0001$). The Intra operative volume blood loss was significantly more in the Ec group than in the HS group $(60+34.05 \text{ vs. } 38.6+22.02; \mathbf{p} < 0.0001)$. The post operative pain is significantly less with the harmonic scalpel. The mean amount of postoperative drainage was not significantly different among the two groups $(117.18 \text{ vs. } 108.92 \text{ ml}, \mathbf{p} > 0.05)$. No considerable visceral injury has been recorded in either group. The hospital stay was not significantly shorter in harmonic group (48.15+4.29 vs. 49.06+2.94 h. (p > 0.05).

Conclusions: Ultrasonic dissection is safe and effective, and it improves the operative course of laparoscopic cholecystectomy. It provides a superior alternative to the currently used high frequency monopolar technology in terms of a lower incidence of gallbladder perforation, especially in patients with complicated gallbladder disease, and a shorter duration of surgery. Harmonic has a greater precision near vital structures and it produces minimal smoke with improved visibility in the surgical field

Keywords: Laparoscopic cholecystectomy, Ultrasonic scalpel, Monopolar coagulation

Date of Submission: 20-08-2021 Date of Acceptance: 05-09-2021

I. Introduction

Laparoscopic cholecystectomy is the gold standard for treatment of symptomatic gall stone disease. **1-6** Gallbladder perforation during dissection from the liver bed with spillage of bile and loss of stones in the peritoneal cavity is a common operative problem during laparoscopic cholecystectomy**7**. The incidence of gallbladder perforation during laparoscopic chole cystectomy has been reported to be 20%–40%. During surgery, gallbladder perforation with spillage of bile and loss of stones disrupts the flow of surgery and prolongs its duration. At present, monopolar electrocautery is the main cutting method used for gallbladder dissection from the liver bed. It is associated with local thermal and distant tissue damage, which might cause inadvertent perforation of the gallbladder during gallbladder bed dissection.**8-10** Ultrasonic dissection generates less thermal injury, produces a smaller zone of tissue damage and more precise dissection, and has been suggested as an alternative to monopolar electrocautery in laparoscopic cholecystectomy. The incidence of gallbladder perforation also has been reported to be low with ultrasonic dissection compared to monopolar electrocautery during laparoscopic cholecystectomy. **11-15** Ultrasonic dissection of the gallbladder bed during laparoscopic chole cystectomy.

chole cystectomy has the potential to improve the quality of surgery by decreasing the incidence of gallbladder perforation and its intra operative consequences. The primary use of the Harmonic scalpel in laparoscopic cholecystectomy has been used for the division of the cystic artery and liver bed dissection. This innovative method of cutting tissues was based upon the coagulating and cavitational effects provided by a rapidly vibrating blade contacting various tissues16. The resulting decrease in temperature, smoke, and lateral tissue damage by using the Harmonic scalpel a better alternative to more traditional electrocautery. In addition, the elimination of inadvertent, sometimes unrecognized, electrical arcing injuries with their potentially hazardous squeal supported the role of the Harmonic scalpel as a potentially safer instrument for tissue dissection17.

This study is undertaken to demonstrate the efficacy and safety of the harmonic scalpel to achieve complete dissection and haemostasis at laparoscopic cholecystectomy in comparison with the traditional electro cautery at St. Theresa hospital, Sanathnagar, Hyderabad.

II. Materials And Methods

Study Setting:

St Theresa's General Hospital, Sanathnagar, Hyderabad

Study Duration:

January 2019 to December 2020

Study population: The patients who underwent laparoscopic cholecystectomy in St Theresahospital during my study period i.e. January 2019 To December 2020.

This prospective study was conducted after the approval from the Ethical Committee of theinstitution.

Inclusion criteria:

- 1. Patients > 18 years of age.
- 2. Patients with simple gall stones.
- 3. Patients with clinical or ultrasound evidence of cholecystitis.
- 4. Patients with normal body wt. with American society of anesthesiologists class 1-3.
- 5. Informed consent.

Exclusion criteria:

- 1. Patients with age < 18yrs.
- 2. Informed consent refusal.
- 3. Choledocholithiasis.
- 4. Generalized peritonitis.
- 5. Previous abdominal surgical procedures.
- 6. Patients with other synchronous surgical pathologies.
- 7. Cases which were converted to open cholecystectomy due to any intra operative difficulties.

Sample size:

Present prospective study comprises of **60** patients who underwent laparoscopic cholecystectomy filling the inclusion criteria. For calculating sample size following formulawas used.

 $N = \frac{2(Za+Z1-\beta)2\sigma^2}{2}$

 Δ

N= sample sizeZ is a constant

Za is set by convention according to accepted a error of 5% as 1.649

Z1- β is set by convention according to accepted 1- β or power of study of 80% as 0.8416 Σ is standard deviation estimated

 Δ is difference in the effect between two interventions (estimated effect size)According to following study by

Fausto Catena et al²³

Standard deviation in the duration of surgery with harmonic scalpel was 10.1 Difference in the intra operative time between the LC with electro cautery and harmonicscalpel was 5.1 min

$$N = \frac{2(1.649+0.8416)^2 10.1^2}{5.1^2}$$

$$N = 49$$

Sampling procedure:

An estimated number of 60 patients fulfilling the inclusion criteria and admitted to St. Theresa's hospital during my study period were included in the study. The patients were divided into two groups according to the instrument used for dissection of gall bladder from its bed, the first group with electrocautery comprises of 32 members and the second group with harmonic scalpel which includes 28 members.

III. Methodology:

Screening of cases by clinical examination in OPD and by investigations such as USG Abdomen, LFT and when necessary CT Abdomen and ERCP were done. Patients were admitted in St. Theresa's Hospital during January 2015 To December 2015 were studied and analyzed in detail with regard to:

- History
- Clinical examination
- Pre operative investigations like CBP, CUE, RBS, Serum creatinine, Chest X ray and ECG.

Following the diagnosis patients were subjected to laparoscopic cholecystectomy under general anaesthesia under aseptic conditions with traditional four port technique of

LC using electrocautery or harmonic scalpel and they were analyzed in both groups based on:

- Duration of surgery
- Intra operative bleeding and complications
- Post operative pain
- Post operative drain
- Duration of hospital stay

Surgical technique:

In all cases the surgical procedure is carried out with patients under general anesthesia. They are supine with their legs extended in an Anti trendelenberg position and inclined laterally to the left at an angle of 30 degrees to facilitate exposure of the hepatic region. A nasogastric tube was placed into the stomach at the beginning of the procedure. Prophylactic intravenous antibiotics were administered before surgery.

The first surgeon stands left to the patient and another two assistants stand on patient's left and right. The laparoscopic equipment was placed on the cranial right side of the operating table. A 10mm trocar was introduced into the peritoneal cavity and placed in the periumbilical site with an open technique and pneumo peritoneum to a pressure of 10 mm Hg was created.

A 30 degree laparoscope was introduced through the umbilical trocar (#1), and three operative trocars are inserted near the xiphisternum, 10mm (#2), mid clavicular line 5mm trocar (#3) mid axillary line 5 mm trocar (#4) under video guidance.

A grasper forceps was inserted through trocar #4 to grasp the fundus of the gall bladder and drawn towards the right axilla. A second grasper was introduced through the trocar #3 to apply gentle rightward traction on the infundibulum, thus improving the exposure of Calot's triangle.

GROUP 1: (Monopolar coagulation plus clips)

The Maryland dissector and dissector forceps were used to dissect the Calot's triangle to release the adhesions with the help of monopolar electrocautery. Cystic duct and cystic artery were clipped separately and they were divided with scissors. Gall bladder was dissected from the bed with the help of monopolar hook. Any antecedent bleeding was controlled with monopolar hook or bipolar cautery.

GROUP 2 (Harmonic scalpel):

The harmonic scissors were inserted through trocar #2 and used as a dissector for dissection of Calot's triangle. When both artery and duct were visualized and isolated, cystic duct is clipped and divided with harmonic and cystic artery section is performed with a single application of ultrasonically activated scissors on minimum position. The gall bladder dissection was carried out using harmonic in the maximum position from theinfundibulum to the fundus taking advantage of positive effects of ultrasound cavitation and coagulation.

In both groups, gall bladder was extracted in a bag through the xiphisternal port. Thorough wash wash given and drain was kept for selective patients who had gall bladder perforation, bile leak or acute cholecystitis or in cases of excess intra operative bleeding.

Post operative care:

All the cases were monitored in the post operative ward and managed with individualized IV antibiotics and IV fluids and analgesics. For cases where drain was kept was retained for 24 to 48 hours. Post operative pain is assessed on day 0,1,2 with universal pain assessment tool. Post op drain was noted at the time of removal.

Follow up:

The post op follow up was advised 4 weeks after surgery. Three months later the patients were followed up with ultra sonography of the abdomen.

STATISTICAL TOOLS EMPLOYED:

To analyze the data following statistical methods were employed.

Frequencies

The Frequencies procedure provides statistics and graphical displays that are useful fordescribing many types of variables.

Independent-Samples T Test

The Independent-Samples T Test procedure compares means for two groups of cases. Ideally, for this test, the subjects should be randomly assigned to two groups, so that any difference in observation is due to the intervention (or lack of intervention) and not to other factors.

Mean

To obtain the mean, the individual observations were first added together and then divided by the number of observation. The operation of adding together or summation is

denoted by the sign \Box .

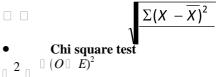
If the individual observation is denoted by the sign X, total number of observations denoted by n and the mean by X, then

X \square X

- п
- **Standard Deviation**

SD is denoted by the Greek letter \Box . If the sample size is more than 30 then

 $\Box \qquad \sum \sum (X - \overline{X})^2$ When sample set is smaller than 30 then



Ε

Where O = Observed frequency E = Expected frequency

ANOVA test:

Analysis of variance (ANOVA) is a collection of statistical models used to analyzed the difference between group means and their associated procedures (such as variation among and between groups). In ANOVA setting, the observed variance in a particular variable is partitioned into components attributable to different sources of variation. In its simple form ANOVA provides a statistical test of whether or not the means of several groups are equal and therefore generalizes the t-test to more than two groups.

For this reason, ANOVA are useful in comparing three or more means for statistical significance.

Probability value

"p" is level of significance of an occurrence of an event. Probability value is a measure of how much evidence

we have gained against the null hypothesis i.e., the likelihood of occurrence of an event, expressed as a number between 0 and 1.

In the present study, a probability value of ≤ 0.05 is taken as a limit to define a value whether statistically significant or not.

All the analysis was done by windostat version 9.2

IV. Results

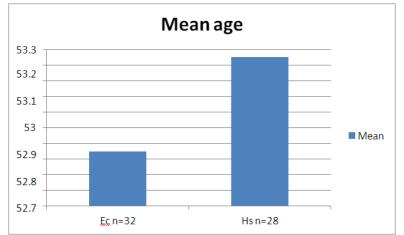
This study entitled "A comparative study of harmonic versus electrocautery in the dissection of gallbladder in laparoscopic cholecystectomy" was an institutional based Prospective study and was conducted in the Department of General Surgery, ST Theresa's General Hospital, Hyderabad, from January 2014 To December 2015.

This study includes 60 patients who underwent laparoscopic cholecystectomywith harmonic scalpel or traditional monopolar electrocautery during my study period in our institution. Among them 32 patients underwent LC with monopolar electrocautery and 28 with harmonic scalpel. This study of LC with different energy sources was performed to look for the advantages of the harmonic scalpel over the traditional monopolar electrocautery in a gallbladder in laparoscopic cholecystectomy. The subjects who underwent this study were distributed randomly to avoid bias.

V. Data Analysis And Results:-

Table-1: Distribution of cases by age:

the Distribution of custs by uget		
	Ec n=32	Hs n=28
Range	28-78	28-76
Mean	52.65	53.25
SD	± 13.2	±12.97

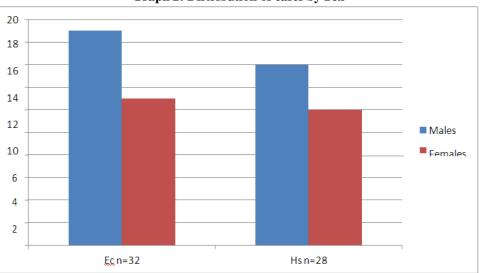


Graph 1: Distribution of cases by Age

The age distribution of the patients undergoing laparoscopic cholecystectomy by both electro cautery and harmonic scalpel were comparable. The mean age in Ec group was 52.65 (n=32) in Hs group was 53.25 (n=28).

Table-2: I	Distribution	of ca	ses by sex:
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Sex	Ec n=32	Hs n=28
Males	19 (59.3%)	16 (57.1%)
Females	13 (40.7%)	12 (42.9%)

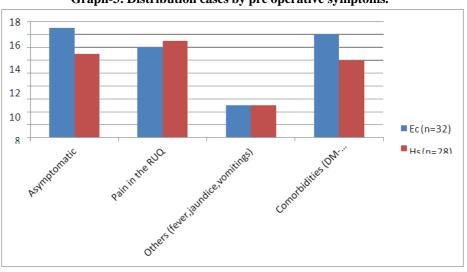


Graph 2: Distribution of cases by Sex

The sex distribution in the both groups was comparable. Among the Ec (n=32) group 59.3% were males and 40.7% were females. Among the Hs (n=28) group 57.1% were males and 42.9% were females.

Table-3: Distribution cases by pre operative symptoms.			
Pre op symptoms	Ec (n=32)	Hs (n=28)	
Asymptomatic	17 (53%)	13 (46.4%)	
Pain in the RUQ	14 (43.7%)	15 (53.5%)	
Others (fever, jaundice, vomiting)	5 (15.6%)	5 (18%)	
Co morbidities (DM-II, HTN, Obesity)	16 (50%)	12 (43%)	





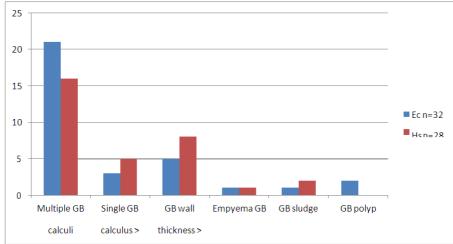
Graph-3: Distribution cases by pre operative symptoms.

The distribution of pre op symptoms in both groups was comparable. Asymptomatic patients with incidental gall stones found in usg in Ec group (n=32) were 53% and in Hs group (n=28) are46.4%. Patients with pain in the right upper quadrant of abdomen in Ec group (n=32) were 43.7% where in Hs group (n=28) are 53.5%. Patients with other symptoms like fever, jaundice, vomitings were present in 15.6% in Ec group and 18% in Hs group. Patients with other co morbidities like diabetes mellitus type 2, hypertension and BMI more than 29 were 50% in Ec group and 43% in Hs group. There was no significant difference in distribution of symptoms in both groups.

Table-4: Distribution of cases by pre-op-usg/ cect findings.			
USG/CECT Findings	Ec n=32	Hs n=28	
Multiple GB calculi	21 (66%)	16 (57%)	
Single GB calculus > 10mm	3 (0.1%)	5 (18%)	
GB wall thickness > 3mm	5 (16%)	8 (28.5%)	
Empyema GB	1	1	
GB sludge	1	2	
GB polyp	2	0	

Table-4: Distribution of cases by pre op usg/ cect findings.

Graph-4: Distribution of cases by pre op USG/ CECT findings.

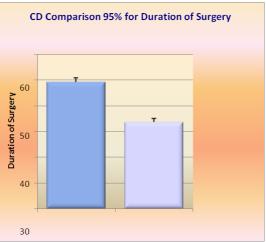


The various radiological abnormalities among the cases studied in both groups were comparable. Multiple gallbladder calculi were present in 66% in Ec group (n=32) and 57% in Hs group (n=28). Single GB calculus of size > 10 mm seen in 3 cases in Ec group, 5 cases in Hs group. GB wall thickness of > 3 mm seen in 16% in Ec group and 28.5% in Hs group.

Table -5: Duration of surgery			
Operating time in min	Ec (n=32)	Hs (n=28)	
Maximum	70	50	
Minimum	35	25	
Mean time	49.15	33.64	
SD	±9.08	±6.61	

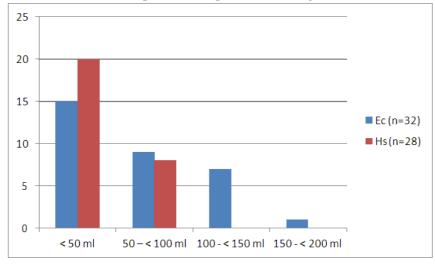
P value – 0.00001 significant	P value –	0.00001	significant
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Graph -5: Duration of surgery



There was significant difference in the duration of surgery in both groups. The mean operating time in cases of lap cholecystectomy with Ec was 49.15 min (SD +- 9.08) and with Hs was 33.64 min (SD +- 6.61). The p value is 0.0001 and is significant.

Table-6: Intra operative bleeding:				
Amount of bleeding	Ec (n=32)	Hs (n=28)		
< 50 ml	15	20		
50 – < 100 ml	9	8		
100 - < 150 ml	7	0		
150 - < 200 ml	01	0		



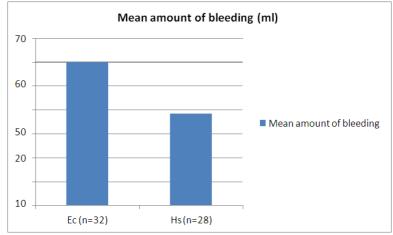
Graph-6: Intra operative bleeding:

The intra operative bleeding was assessed by measuring the amount of suction drain excluding the irrigation fluid used while surgery. There was significant difference in the intra operative bleeding between the both groups. The bleeding is more in the Ec group compared to Hs group. The p value is 0.0068 and is significant.

Table-7: Mean intra operative bleeding:

	Ec (n=32)	Hs (n=28)
Mean amount of bleeding(ml)	60	38.6
SD	±34.05	±22.02

Graph-7: Mean intra operative bleeding:

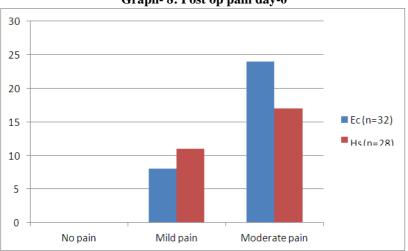


Post operative pain:

Pain in post operative period is attributed to the dissection and lateral thermal damageduring surgery. In the post operative period all the patients in both groups were given analgesia by combination of NSAID and Opioid analgesics. Severity of the post operative pain was recorded on day 0, 1 and 2 by universal pain assessment tool and they were sub divided into no pain, mild pain and moderate pain. None of the patient in both groups complained severe pain.

Table 8: Post on pain day 0

	Ec (n=32)	Ec (n=32) Hs (n=28)			
No pain	0	0			
Mild pain	8	11			
Moderate pain	24	17			



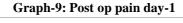
Granh-	8:	Post on	nain	dav-0	

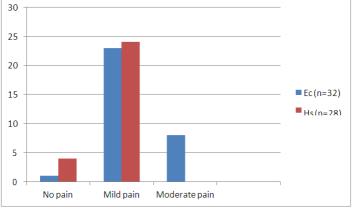
There was no significant difference in the post operative pain on day-0 between both groups.p value was 0.24 Hence not significant.

Table-9: Post op pain day-1

	Ec (n=32)	Hs (n=28)
No pain	01	04
Mild pain	23	24
Moderate pain	08	0

p value – 0.0028. Significant



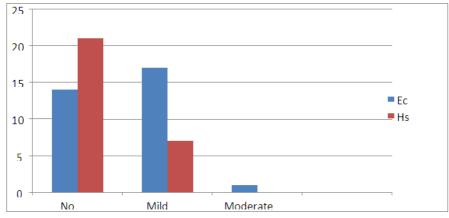


On post op day-1 pain was not complained by 4 cases in Hs group and 1 patient in Ec group. Mild pain was complained by 23 in Ec and 24 in Hs group. Moderate pain was complained by 8 patients in Ec group and none in Hs group. Hence there was significant difference in the post operative pain in both groups on post op day-1.

Table-10: Post op pain day-2				
	Ec (n=32)	Hs (n=28)		
No pain	14	21		
Mild pain	17	7		
Moderate pain	01	0		

Table-10:	Post o	op pai	n dav-2

P value - 0.011. Significant



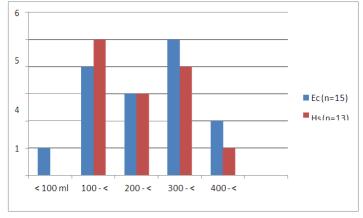
Graph-10: Post op pain day-2

Post op pain recordings on day-2 reveal no pain by 14 cases in Ec group and 21 cases in Hs group. Mild pain was complained by 17 patients in Ec group and 7 patients in Hs group. Moderate pain was complained by 1 in Ec group and none in Hs group. Hence there was significant difference in post operative pain on day-2 between two groups.

	Ec (n=15)	Hs (n=13)
< 100 ml	01	0
100 - < 200 ml	04	05
200 - < 300 ml	03	03
300 - < 400 ml	05	04
400 - < 500 ml	02	01

p value - 0.825. Not significant

Graph -11 Post operative drains:



Drain was kept in selected patients in the setting of acute cholecystitis or difficult gall bladderdissection or intra operative bile leak or excess intra operative bleeding. Drain was left for 48 hrs in and was removed on post op day-2

Table-12: Duration of stay in days				
	Ec (n=32)	Hs (n=28)		
Mean	2.66	2.64		

p value- 0.937. Not significant

VI. Discussion

Gallstones are one of the common surgical problem encountered and are operated for in the primary setting. They are the most common cause of pain in right hypochondrium and are a considerable cause of morbidity and disability. Traditional treatment methods for gallstone disease depend on the stage of the disease and the presentation. Acute gallbladder disease like acute cholecystitis can be managed with conservative management though surgery within first 48-72 hrs is the choice in recent era.

The surgery stands the best with laparoscopic cholecystectomy; gold standard in the modern era for symptomatic gallstones.1-6

Electro surgery has taken a steep curve with the advent of Harmonic scalpel, ultrasound dissector; the surgery is more comfortable, less painful, and post operative pain is minimal and so are the complications with harmonic.

The harmonic scalpel possess the unique advantage of causing very little lateral thermal damage40. The rationale for using the harmonic scalpel in performing cholecystectomy was the concept that a decreased lateral thermal damage (1-1.5mm deep)at the surgical site may translate into decreased post operative pain. Studies examining the depth of thermal injury reported a lateral thermal injury up to 240 micron to 15 mm deep, using monopolar cautery, whereas unipolar cautery caused tissue injury from 120 micron to 9 mm deep, CO2 laser caused 60 micron to 4mm deep and Nd:YAG laser creates 300 micron to 4.2 mm deep(Mc Carus, 1996). On contrast, with electrocautery cholecystectomy, very little smoke is generated by harmonic scalpel. A local water vapour is generated, which is easily removed in adjacent suction and does not permeate as far as electrocautery smoke.

In our study out of 60 cases studied 28 patients underwent laparoscopic chole cystectomy with harmonic scalpel and 32 patients with mono polar electro cautery. Both groups were comparable in age, sex and pre operative symptom distribution.

The present study demonstrates a significant difference in duration of surgery in both groups. The mean operative time in Ec group is 49.15+9.08 sec and in Hc group is 33.64+6.61 sec. (P- value is 0.00001). This was in coherence with the other studies conducted by A.ZANGHI41 et al and Varun mahabaleswar42 et al which shows duration of surgery with harmonic scalpel is significantly lower than the electro cautery.

The operative times varied depending on the degree of peri cholecystic and cholecystic and/or associated intra peritoneal adhesions. The shorter operative time with harmonic is attributed to multi functional ability. As it coagulate, cut and dissect between the tissue planes it can replace 3 instruments i.e. Maryland forceps, monopolar hook, bipolar cautery. The time needed for change of multiple instruments through various ports can be avoided rendering short duration of surgery with harmonic.

The present study demonstrated that intra operative bleeding was far less in Hc group than Ec group .The mean amount of bleeding in Ec group is 60+34.05 ml, where in Hc group is 38.6+22 ml. p- value is 0.0068. This is in agreement with prospective study conducted by A.ZANGHI41 et al and V.MINUTOLO43 et al. An attractive feature of harmonic scalpel cholecystectomy is excellent haemostasis during procedure Haemostasis is accomplished by coaptation of blood vessels which are sealed by denatured proteins. During cholecystectomy hemostasis was readily established by blunt edge of the blade and the variable power mode. This combination was generally used for the cystic artery, this being the most important part of the vascular dissection in cholecystectomy The sharp blade was used for the adhesion components to afford cutting ability through the thicker adhesions. The excellent haemostasis offered by harmonic scalpel permits an excellent excision of the peri gall bladder tissues without the need to establish haemostasis from multiple sites. The dissection of the gall bladder from the liver bed being the hardest part in laparoscopic and open cholecystectomy after Calot's, is best fared by harmonic dissector as the lateral damage to the liver bed is minimal and the smoke production is less. So the visual obliteration of field is less and so less complications. During the course of evaluation of our work, several distinct advantages and disadvantages became evident. One of the main advantages was less post operative pain after harmonic cholecystectomy compared to electro cautery group on post operative days 1 and 2.

In this respect the study is in agreement with studies conducted by WALID Sasi, Msc44 in 2010 and HAC trial conducted by the Fausto Catena45 et al in 2009 where the study comprised of patients with

laparoscopic chole cystectomy with harmonic scalpel had very less pain than compared to electrocautery. This is attributed to the less lateral thermal damage caused by the harmonic than the electrocautery. The disadvantage of monopolar coagulation, the limits of the bipolar coagulation and the frequent changes of instruments during laparoscopic procedures, are three elements that make the harmonic dissectors very useful in laparoscopic surgery. Westervelt J46 from Clark Memorial Hospital. Have the similar views on usage of harmonic scalpel in cholecystectomy and broadening the role of the harmonic scalpel even to closing of the cystic duct with harmonic. Our study revealed the mean amount of post operative drainage was not significantly different among the two groups.

The post operative stay was not significantly different in the both groups.

Acknowledgement

To put emotions on paper is an incredibly difficult task. Words perhaps would fail to express my deep sense of gratitude and indebtedness to my esteemed teacher, my guide **Dr. Kilambi Srinivas, M.S Gen.Surgery** Head of the departmentOf General Surgery, ST. Theresa's hospitals for his encouragement and continuous support in carrying out this whole study at each and every step.

I am extremely thankful to for his understanding, encouragement and personal attention for carrying on my thesis.

I am thankful to my colleagues **Dr. Bhaskar**, **Dr. Hima soumya madasu** for their help and support in carrying out the study.

I appreciate the help of our **Technical staff** for their help and support throughout. However, I shall not be able to put into words my appreciation for my family and friends whoare close to my heart as without their moral support it would not be possible for me to complete this thesis.

My sincere thanks to all the patients who participated in this study as without their consent, this study would not have reached its destination.

In the end, I express my gratitude to the Almighty God for helping me in each and every step of my life.

DECLARATIONS

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