ORIGINAL RESEARCH PAPER

Volume-7 | Issue-12 | December-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARATIVE STUDY BETWEEN LAPAROSCOPIC CHOLECYSTECTOMY BY ULTRASONIC SCALPEL VERSUS CONVENTIONAL METHOD: A PROSPECTIVE RANDOMIZED STUDY

General Surgery

Dr. Mohammed Najm Mohammed Tameemi M. B. Ch. B.D.S, General surgeon

Safauldeen Salim* Assistant professor F. I. C. M. S. Department of surgery l Collage of medicine/ University of Kufa *Corresponding Author

ABSTRACT

The ultrasonically activated scalpel has proven to be an effective, efficient, and safe instrument for dissection and haemostasis in both open and laparoscopic surgical procedures. This ultrasonic scalpel work on the tissue's cutting and coagulating very effectively with the replacement of high frequency current, which connected with diverse complications. The principle is transforming of the electric power into mechanical movement of the working part of the instrument, by piezoelectrical transducer situated in the hand piece. The primary use of the ultrasonic scalpel in laparoscopic cholecystectomies has been for the division of the cystic artery and gallbladder bed dissection.

AIM OF THE STUDY: Aim of this study is a comparison between the use of ultrasonic scalpel and conventional electrocautery in laparoscopic cholecystectomy, as a regard of safety and efficacy.

PATIENTS AND METHODS: A Prospective study done for (428) patients underwent laparoscopic cholecystectomy. (254) performed by using conventional electrocautery and (174) using ultrasonic scalpel (LOTUS). From January 2010 to November 2010 in Al-Sader Teaching Hospital, and Al-Gadeer Private Hospitals in Najaf city, different surgeons operated all these patients.

RESULT: Four hundred and twenty eight patients underwent laparoscopic cholecystectomy, with regarding to intraoperative bleeding the results (16.5% vs. 2.3%), and to gallbladder perforation (10.5% vs. 8%), and to need for drain (90.5% vs. 3.4), and to the need for proximal clipping of cystic artery (90.5% vs. 63.2%).

CONCLUSION: The application of ultrasonic energy to endoscopic surgery makes procedures safer, easier, and efficient dissection and haemostasis.

KEYWORDS

Laparoscopic cholecystectomy, ultrasonic scalpel (LOTUS), conventional electrocautery.

INTRODUCTION

Electro surgery has become a common energy modality in laparoscopic surgery. It is, however, associated with certain specific hazards, such as bowel injury that can lead to significant morbidity or even mortality from fecal peritonitis[1,2]. The tissue temperature generated by ultrasound is less than 80 C, much lower than that associated with electro surgery, which can be as high as 200 C. thermal spread is therefore expected could be less with ultrasound sources .[3]

In animal experiments ,the extent of thermal spread is 4 times less with ultrasound compared with electro surgery ,which is Associated with charring and smoke formation[4,5]. charring may also lead to the coagulum becoming detached , resulting in problems with bleeding . first ultrasonic scalpel was introduced in 1991 traditionally, the older shears such as the harmonic scalpel have applied longitudinal ultrasonic waves down the shaft of the instrument .this invariably concentrates the energy at the tip of the instrument instead of between the blades ,thereby producing efficacy.[6,7]

Ultrasonic scalpel designed as a safe alternative to electrocautery for the haemostatic dissection of tissue, this innovative method of cutting tissue based upon the coagulating and cavitational effects provided by a rapidly vibrating blade contacting various tissues. [8, 9] The resulting decrease in temperatures, smoke, and lateral tissue damage placed the ultrasonic scalpel in contrast to the effects seen with the more traditional electrosurgery / cautery.[10]In addition, the elimination of inadvertent, sometimes unrecognized, electrical arcing injuries with their potentially hazardous sequelae supported the role of the ultrasonic scalpel as a potentially safer instrument for tissue dissection. Since its inception, the harmonic scalpel has gained significant clinician acceptance and applications. Uses now range widely to include surgery of the head and neck, chest, liver, spleen, kidney, adrenal glands, colon, rectum, gastroesophageal junction, and others. [10]

Ultrasonic Generators:

The ultrasonically activated scalpel has proved its efficacy and is, efficient, and safe instrument for dissection and haemostasis in both open and laparoscopic surgical procedures.

A- Mechanism of action:

The Ultrasonic Generator system consists of different parts, which comprise of a current generator, a hand piece that houses an ultrasonic transducer, an instrument which has end effecter (specific types include blade or shears) used to cut tissue and a hand switching adaptor.

The ultrasonic generator cuts and coagulates by using low temperatures, lower than those used by electro surgery coagulate. Ultrasonic technology controls bleeding by coaptive coagulation at low temperatures, which ranges from 50 ◌̊C to 80 ◌̊C. Vessels, are coapted (tamponaded) and sealed by a protein coagulum. Coagulation occurs by means of protein denaturation when the blade couples with protein, denaturing it to form a coagulum, which finally contracts to seal small coapted vessels. When the effect is prolonged, secondary heat produced that seals larger vessels. By contrast, electro surgery and lasers provides the technique of obliterative coagulation, i.e. coagulation by burning at higher temperatures (150 ◌̊C to 400 ◌̊C). Blood and tissue are desiccated and oxidized (charred), forming escher that covers and seals the bleeding area. Re-bleeding can be hazardous when blades removed during electro surgery and they stick to tissue disrupting the escher. Surgeons need to control the ultrasonic scalpels coagulation rate and cutting speed by applying appropriate time and force to the tissue by the end effecter, and by the selected excursion level of the end-effecter. At the tip of the end-effecter, energy delivered to tissue where it creates several effects within the tissue. Conversion of mechanical energy to heat from friction at the blade tissue interface occurs along with bulk heating due to tissue's viscoelastic nature. [11,12]

The ultrasonic Scalpel uses ultrasonic technology, and energy that allows both cutting and coagulation at the point of impact. It used for those surgical procedures in which soft-tissue incisions can be made and in which bleeding control and minimal lateral thermal damage to tissue are desired.[13,14]

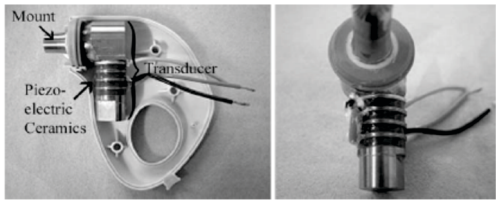

Fig. 1. Transducer housed within the opened hand piece of the LOTUS (left) and front view of the transducer (right) showing the stack of

ceramic being placed perpendicularly at the side and offset from the axis of the main metal cylinder.

B-Advantages:

1. the procedure has advantages in that it utilizes a single instrument for the operation.
2. Avoidance of repeated instrument change during surgery.
3. Selection of different instruments in between breaks the natural flow of the operation and may result in distraction.
4. The retrograde (top to bottom) dissection suites the instrument naturally and helps to minimize confusion regarding the vitally important anatomy in this area of the body.
5. It tackles the concerns regarding smoke production and inadvertent injuries to the abdominal organs and structures.
6. High vessel sealing capacity (5mm) makes it ideal for coagulation Purpose.
7. The maximum temperature achieved is 80 C and the spread of necrosis from the point of contact is < .05mm, hence less collateral damage seen*
8. The dangers of coupling and tissue charring necessarily obviated.

Gall bladder surgeries performed with the ultrasonic scalpel is rather feasible and effective. Operating time and blood loss are minimal, and there is a drop in conversion rate (3.9%). No bile duct injuries observed. Use of the ultrasonic generators makes dissection easier, with the reduction in the operative time and in the need for conversion to open surgery. The Ultrasonic generator provides complete haemobiliary stasis for most of the patients and is often a safe alternative to Monopolar current.[15]

C-Safe in less experienced hands

Janssen etal conducted a randomized clinical trial of ultrasonic versus electrocautery dissection of the gallbladder in laparoscopic cholecystectomy on 200 patients. He reported that with the use of ultrasonic generators in laparoscopic cholecystectomy, the incidence of gallbladder perforation dropped down drastically and the operation progressed more smoothly. **The surgeons with less experience benefited the most from ultrasonic dissection, particularly in daunting and complicated Intraoperative circumstances.[16]**

D-Effect on Postoperative immunity

A study on the Intraoperative and postoperative immune status of the patient conducted using Ultrasonic Generators for surgery and it proved that the devices using Ultrasonic technology and those with Monopolar electrosurgery are equally traumatic in terms of activation of mediators for the systemic immune response. [7]

E- Effect on postoperative pain.

Retrieval of data on postoperative pain after laparoscopic cholecystectomy was not possible due to insufficient literatures available but its effect on those undergoing haemorrhoidectomy recorded. There was significantly reduced postoperative pain with ultrasonic scalpel haemorrhoidectomy compared with those of electrocautery controls. The diminished pain in the postoperative period using ultrasonic generator most likely resulted from the avoidance of lateral thermal injury.[17]

F-Effect on wound healing.

Histological examination of the tissues revealed that segments divided with the ultrasonic techniques retained more or near normal tissue architecture at the site of anastomosis two weeks after the surgery. There results show that with use of ultrasonic generators, the wound healing was rapid and complete than with electrocautery .[18,19,20]

G- Surgical Smoke

Ultrasonic scalpel generated plume contained Large quantities of cellular debris (>1x107particles/ml) almost approximated to be one-quarter the amount of particle concentration when compared with the plume generated by dissection of a similar amount of tissue with electrocautery.[21,22,23]The liquid (blood or serum) aerosol concentration was in a directional spray pattern with the use of hook or ball-tip. These easily detected up to the level of 40cm from point of production. [24,25] In addition, fatty tissues almost generate 17–23times more particulate matter than those generated by lean tissue. The ultrasonic scalpel produces a 'vapour,' and not the smoke, the manufacturers have aptly described the process as low-temperature vaporisation.[26] This is more of the matter of concern because cool aerosols in general harness a higher chance of carrying infectious and rather viable material than higher-temperature aerosols.[24, 25] One study stated that the particles created by the ultrasonic (harmonic) scalpel are composed of tissue blood and blood by-products.

H- Disadvantage of HS.

The only Great disadvantage with Harmonic Scalpel is that it is very costly.

The acronym LOTUS stands for laparoscopic operation by tortional ultra -sound. The LOTUS shears are the first ultrasonic scalpel to use tortional rather than longitudinal mode ultrasound to produce a cutting and haemostatic effect. They achieve focused energy transmission into the target; tortional waves applied directly to the target tissues, thereby enhancing the efficacy of the shears.

The tortional mode is a rotational oscillation whereby the tip (and equally spaced points along the wave-guide) vibrates back and forth in a short arc around the wave-guide axis.

It generated by applying a harmonic torque about the proximal end of the wave-guide axis. The unique blade comprises two grooves side by side in the edge of the wave-guide, at the distal end.

The sides of the grooves are in fact planar, near-radial facets that lie normal to the direction of tortional vibration. Any tissue contacting these facets experiences a direct mechanical force.

The waves cause denaturation of protein by the breakage of hydrogen bonds in tissue, cutting and coagulating them with maximum efficiency. [27]

PATIENTS AND METHODS

This study designed for prospective evaluation of patients having cholecystitis submitted to laparoscopic cholecystectomy, the control had formal laparoscopic cholecystectomy while the other group had laparoscopic cholecystectomy using ultrasonic scalpel, the comparison include the following parameters; intraoperative blood loss, gallbladder perforation, the need for drain, and proximal cystic artery clipping.

From January 2010 to November 2010 in Al-Sader Teaching Hospital, and Al-Gadeer Private Hospitals in Najaf city, different surgeons operated all these patients.

The ultrasonic scalpel used is (LOTUS G3),which utilize torsion of blades oscillating 3500/ second in dissecting Calot,s triangle, bisecting the cystic artery and dissecting the gallbladder from it's bed.

The parameters evaluated subjectively and compared with laparoscopic cholecystectomy used conventional electrocautery prospectively by the operator surgeon himself.

The operations carried out by different surgeons and all patients admitted for laparoscopic cholecystectomy included without exempt (empyema, mucocel, acute and chronic cholecystitis).

The additional equipments used in this study are:

1- Ultrasonic scalpel: tortional mode device (LOTUS G3), laparoscopic handpeice.
2- Conventional electrocautery: storz laparoscopic electrocautery autocon 200 .lap. Hook.

RESULTS

Four hundred and twenty eight patients underwent laparoscopic cholecystectomy; 361 of them were female and 67 were male (F: M=5.3:1) median age of 47 yr, (range, 19 - 79). (254) patients performed by using conventional electrocautery in the dissection of the gallbladder bed and (174) using ultrasonic scalpel (LOTUS) in this dissection.

The results in regard to parameters as follows: [table1]

***Table 1:* Comparative parameters between conventional electrocautery and ultrasonic scalpel in laparoscopic cholecystectomy.**

*chi-square test applied at level of significance α=0.05 to test the categorical association.

1- Intraoperative bleeding, it occur in 42 patients of total 254 (16.5%)

	Intraoperative bleeding		Gallbladder perforation		drain		Cystic artery clipping	
	NO.	%	N0.	%	NO.	%	NO.	%
Conventional electrocautery	42	16.5	27	10.5	230	90.5	230	90.5
Ultrasonic scalpel	4	2.3	14	8	6	3.4	110	63.2
P value	0.00003		0.372		0.00001		0.0003	

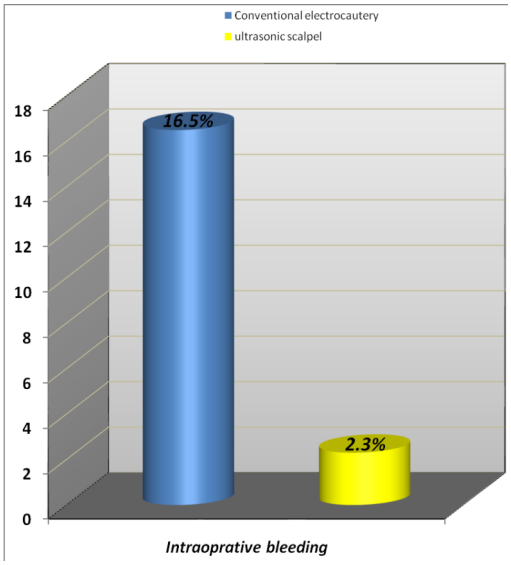

Figure 1: ***Intraoperative bleeding comparison between ultrasonic scalpel and conventional electrocautery in laparoscopic cholecystectomy.***

2- Gallbladder perforation which happened in 27 patients of total 254 (10.5%) by using conventional electrocautery and 14 patients of total 174 (8%) by using ultrasonic scalpel (LOTUS) which is statically insignificant P=0.372. [Fig.2]

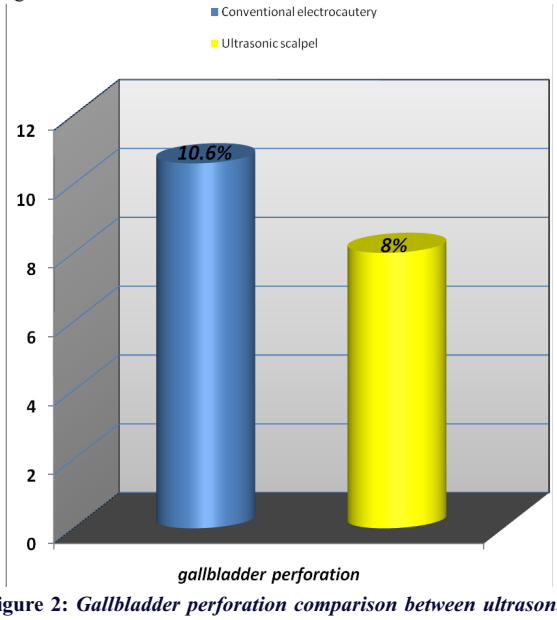

Figure 2: ***Gallbladder perforation comparison between ultrasonic scalpel and conventional electrocautery in laparoscopic cholecystectomy.***

3-Regarding the need for drain in 230 patients of total 254 (90.5%) by using conventional electrocautery and in 6 of total 174 (3.4%) by using ultrasonic scalpel (LOTUS) which is statically significant P=0.00001. [Fig.3]

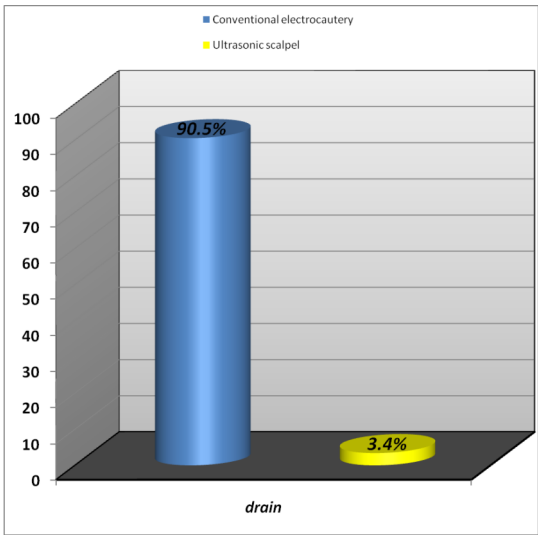

Figure 3: Drain placement comparison between ultrasonic scalpel and conventional electrocautery in laparoscopic cholecystectomy

4- The need for proximal clipping of cystic artery in 230 patients of total 254(95.5%) by using conventional electrocautery and in 110 of total 174 (63.2%) by using ultrasonic scalpel (LOTUS) which is statically significant P=0.00003. [Fig.4]

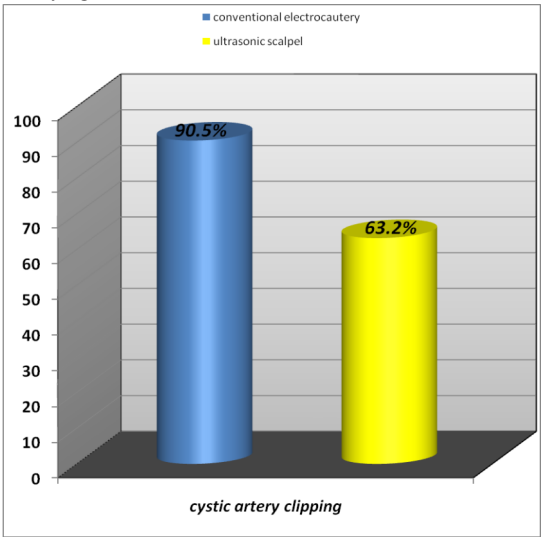

Figure 4: Cystic artery clipping comparison between ultrasonic scalpel and conventional electrocautery in laparoscopic cholecystectomy

This randomized multicenter trial compared results of dissection of gall bladder bed for patients underwent laparoscopic cholecystectomy using ultrasonic scalpel starting dissection at the triangle of Calot and comparing the results with conventional method of electrocautery.

Regarding intraoperative bleeding ultrasonic scalpel produce less blood loss compared to conventional method, 4 patients (2.3%) versus 42 patient(16.5%) respectively ; $p<0.05$(0.00003) similar results shown in study done by Cengiz shows decreased blood loss comparing both methods (12 vs.53 or 36 ml; $p<0.001$). [28]

Ayman shows in his study that intraoperative blood loss was significantly more with conventional electrocautery (133 ± 131.13 ml vs. 70.13 ± 80.79 ml; p = 0.002). [29] Ultrasonic scalpel sealed vessels by a protein coagulum, denaturing it to form a coagulum, which finally contracts to seal small coapted vessels. When the effect is prolonged, secondary heat produced that seals larger vessels. So ultrasonic scalpel

is safer in the dissection by sealing blood vessels firmly and so decreasing intraoperative bleeding in contrast with conventional electrocautery provides the technique of obliterative coagulation, i.e. coagulation by burning at higher temperatures, re-bleeding can be hazardous when blades removed during electro surgery and they stick to tissue disrupting the escher.

Cengiz shows fewer gallbladder perforations (26% vs. 46%; p = 0.001) [28], in other study done by Kandil etal shows significant less incidence of gallbladder peroration (7.1% vs. 18.6, p = 0.04). [30] In a study done by Bessa etal, the incidence of gallbladder perforation was statistically higher in the conventional group, compared to the ultrasonic scalpel group (30 vs. 10%, respectively; P=0.002).[31] While in our study the results was insignificant 14 patients (8%) vs. 27 patients (10.5%); p>0.05 (0.372).our study shows higher resultsbecause 6 cases were empyema of the gall bladder operated on by ultrasonic scalpel.

The tissue temperature generated by ultrasound is much lower than that associated with electro surgery, thermal spread is therefore expected could be less with ultrasound sources. The ultrasonic Scalpel uses ultrasonic technology, and energy that allows both cutting and coagulation at the point of impact. It used for different surgical procedures in which soft-tissue incisions can make and in which bleeding control and minimal lateral thermal damage to tissue are desired.

Regarding postoperative drainage our study shows the use of drain in 230 patients (90.5%) using conventional electrocautery and in 6 patients (3.4%) by using ultrasonic scalpel (LOTUS) which is statically significant P=0.00001.Similar results shown in a study done by Kandil etal, the amount of postoperative drainage is significantly less in ultrasonic scalpel (29 vs. 47.7 , p = 0.001). [30]

The decreased amount of intraoperative bleeding, less perforation of gallbladder, and less injuries to the adjacent tissues with ultrasonic scalpel reducing the need for postoperative drainage.

Regarding proximal clipping of cystic artery in 230 patients (90.5%) require clipping by using conventional electrocautery while clipping is used in 110 patients (63.2%) by using ultrasonic scalpel (LOTUS) which is statically significant P=0.0003. In other study done by Westervelt, no patients developed intraoperative or postoperative hemorrhage after cystic artery division by ultrasonic scalpel.[32]

Conventional electrocautery is, however, associated with certain specific hazards, such as bowel injury that can lead to significant morbidity or even mortality, grounding pad failures, or electrical injury to the operator, while with ultrasonic scalpel there is much less such hazards, in addition to it's safety and efficacy becoming more popular and widely used.

CONCLUSION

The application of ultrasonic energy to endoscopic surgery offers many advantages over the use of electrocautery, without giving up the cut and coagulated with efficacy equal to that of electrocautery. However, unlike electrocautery, there are less intraoperative bleeding, less gallbladder perforation, greatly decreasing use of drain, and effectively provide haemostasis and sealing vessels, so no need for clipping of cystic artery. In addition, because of lower heat generation, ultrasonic energy produces minimal tissue charring and desiccation, leaving tissue planes and operative fields better visualized. You do not have destroyed tissue to stop bleeding.

Recommendation

The ultrasonic scalpel is safe and effective to use in laparoscopic cholecystectomy and extend it is use in many other surgical operations such as thyroidectomy, haemorrhoidectomy, colorectal, and other abdominal and pelvic surgery.

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