SEALING OF CYSTIC DUCT USING ULTRASONIC GENERATOR AND ITS COMPARISON WITH THE APPLICATION OF CLIPS - A REVIEW

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PROJECT TO BE SUBMITTED IN PARTIAL FULFILLMENT OF DIPLOMA IN MINIMAL ACESS SURGERY

ABSTRACT

Ever since the beginning of laparoscopic Cholecystectomy, in 1985 by Erich Mühe in Germany followed by Harry Reich and Eddie Joe Reddick an American in 1989, the technique has seen many areas of refinements. Initially popularized techniques were turned down by the pioneers on the account of incredible and awful complications substantiated by controlled trials. The dissection of the cystic pedicle (which entails cystic duct division and the sealing of cystic artery), a crucial step in Gall Bladder surgery, has undergone revolutionary change since the introduction of harmonic Scalpel.

The issue with clipping (absorbable & nonabsorbable) is that there is the complication of clips being dislodged. With the advent and use of ultrasonically activated scalpel a new chapter is re-written for tissue cutting and co-agulation with potential replacement of electrosurgery by virtue of its complications. The safety profile of Harmonic Scalpel (HS) in other surgeries has been already demonstrated and documented. It's use in Gall Bladder surgery in particular cholecystectomy needs more to be emphasized over the application of clips on cystic duct and the artery which underlines the aim of this study.

KEYWORDS

Laparoscopic cholecystectomy (LC), Ultrasonic Generator (UG), Clipless cholecystectomy, Sealing of Cystic Duct and artery.

INTRODUCTION

Laparoscopic Cholecystectomy is the "Gold Standard "for the treatment of cholelithiasis and acute cholecystitis. But, still the problem of cystic duct leak leading to biloma, an infrequent but one of the most dreaded complications mandates the need to review the efficacy of the use of Clips comparing with the Harmonic Scalpel in sealing of Cystic Duct and artery. Technological advances have set new standards for different indications keeping in view the patient's comfort at its utmost. This document reviews the issue of harmonic scalpel as a new technique applicable to laparoscopic cholecystectomy, examines the causes, indications, complications with proper use and rewrites the literature, refuting the use of clips and advocating the use of harmonic scalpel on the cystic duct and the artery.

AIM

The aim of this study is to compare the use of harmonic scalpel in sealing the duct and the artery with all its Advantages and Disadvantages over clipping of the cystic duct and artery. This review is based on the following parameters.

1. Patient selection on the basis of Age, Sex, Duration and indication of Lap Cholecystectomy.
2. Technique of surgery- Fundus First, Duct First
3. Duration of surgery
4. Complications- Intraoperative, Post operative
5. Quality / Intensity of post operative pain
6. Post operative recovery
7. Post operative morbidity
8. Cost effectiveness
9. Quality of life post operatively
10. Patient satisfaction

MATERIALS AND METHODS

A thorough search of literatures which included controlled trials, original articles and reviews was conducted using Google, Highwire, Springerlink as the respective search engines. Articles of different surgical disciplines, giving vivid details of the effect of Harmonic Scalpel and clipping were also incorporated. Research materials conducted on animals in various Labs across the Globe were used for reference. The following key words were used: "laparoscopic Cholecystectomy", "Clips", "Harmonic Scalpel", and "Ultrasonic dissection". More than 500 citations were found in total. Following protocol was fixed for the selection of literature.

1. Articles based on studies conducted in the Hospital Based setup or Laboratory set up where advanced laparoscopic procedures were performed.
2. Literatures published in renowned journals. (After 2001)
3. Studies conducted on large number of subjects. (More than 15)
4. Globally accepted method of statistical analysis was followed.

CONTENTS:

1. **Essential Steps of LC.**

A. Placement of ports.
B. Evaluation of Laparoscopic anatomy
C. Exposure of gallbladder and cystic pedicle
D. Adhesiolysis (if required)
E. Dissection of cystic pedicle (clipping or sealing of cystic duct and artery)
F. Dissection of Gall bladder from the liver bed.
G. Extraction of gall bladder with closure of the ports.

Erich Mühe (1985) of Germany first performed Laparoscopic Cholecystectomy and today it is the "Gold standard" for almost all the Gallbladder diseases. Apart from all the steps of surgery it is the Dissection of cystic pedicle (clipping or sealing of cystic duct and artery) which is the most crucial. Most of the complications directly or indirectly are pertaining to this crucial step of surgery.

Dissection of Cystic Pedicle [1]

The cystic pedicle is nothing but a fold (triangular) of peritoneum which contains the cystic duct and artery, the cystic node and a variable amount of fat. It has two leaves one superior and the other inferior leaf which are continuous over the anterior edge formed by the cystic duct. It is the frequent anomaly of the structures contained between the two leaves (15 -20%) which needs to be remembered. Normally there is an anterior cystic duct with the cystic artery situated postero-superiorly and arising from the right hepatic artery usually behind the common bile duct. The various anomalies are to be memorized to encounter the unforeseen complications. It is the skeletonized cystic duct and the cystic artery which has to be clipped or sealed.

Use of Clips:

Non-absorbable titanium clips are the one which are most widely used for the tissue approximation used by laparoscopic surgeons [2]. The first version of clip appliers used to deliver a single clip and have to be withdrawn for reloading. Multiple fire clip applicators are now available from disposable instrument manufactures. It is also that the clips made of biodegradable materials such as polydioxanone (PDS) are available.

The correct size of clip for the vessel needs to be selected. The distance between first two clips should not exceed 3mm and those between second and third should be 6mm.The risk of slippage is high if the clip.

- Is selected too small for the vessel
- Does not project beyond the whole width of the vessel
- Is not applied at right angles to the vessel
- Is subjected to traction
- Includes fat or adventitial tissue around the vessel.

The correctly applied clips generally offer a pressure between 450 and 700 mbar. Clips with pressure less than 100 mbar are never tight and inadvertently fall off. [3]
Most of the surgeons have been using simple clips to close the cystic duct since Professor Muhe reported the first successful laparoscopic cholecystectomy in 1985[4-10] Cystic duct leak though an infrequent but is potentially a serious complication of laparoscopic cholecystectomy which cannot be overlooked [11]

A Retrospective Comparative Evaluation of Titanium versus Absorbable Clips was conducted by Lapo Bencini et.al[12] Their aim was to determine any differences in outcome and costs of the clips. From January 1999 to February 2002, 690 patients were selected who had successfully undergone a laparoscopic cholecystectomy and were reviewed. According to the type (absorbable and nonabsorbable) of clip, they retrospectively identified two groups of patients: 199 of those in which the surgeons had used absorbable clips (absorbable clip group, ACG) and 491 of those in which the surgeons had used titanium nonabsorbable clips (titanium clip group, TCG). Data about demographics, operation, results, complications, and follow-up were collected and matched in between the two groups. The difficulty score of the operation was lower (6.3 vs. 7.0, $P = .03$) and the operative time was shorter (44 vs. 61 minutes, $P < .0001$) in the ACG than in the TCG. The complications, hospital stay, and long-term results were satisfactory and comparable between the two groups. Correlation was not found between clip type and the incidence of biliary tree injuries, bleeding, wound infection, or readmission. There was slight variation as far as respective price was concerned (90 euros for each procedure). Inspite of the fact mentioned that the absorbable clips are theoretically less likely to cause complications than

metallic ones; the study did not demonstrate any clinical advantage during laparoscopic cholecystectomy [12].

Complications:

1. **Duct leakage**

Inspite of the best applications, clipping suffers a huge drawback, somewhat more in the hands of surgeon-in-training. Several studies have been conducted to prove the superiority of non absorbable clips over and above the absorbable ones but went futile.
In significant number of cases more cystic duct leaks were recorded when simple clips were used than those with the use of absorbable locking clips. [11] It was seen that the incidence of cystic duct leak using simple clips was (0.11–2%) [4, 5, 8, 13, 14].The incidence of bilomas and bile leaks associated with metallic clips is five times greater than those associated with locking absorbable clips.

A. Rohatgi and A.L. Widdison had reviewed the cholecystectomies performed at the Royal Cornwall Hospital on the patients over a 5-year period and reported similar results when the two varieties of clips were compared [11].
The cause of duct leakage can be attributed to slipping of the clips, loose clips, sloughing of the duct due to improper clip placement or improper size of the clips. Slipping of the clips from cystic artery can lead to hemorrhages beyond control.

1. **Migration of the clips.-**

A case presented with recurrence of common bile duct stones 2 years post laparoscopic cholecystectomy in whom laparoscopic common bile duct exploration. Was performed at a later date [15].
Mouzas IA et al reported a case of a 31-year-old woman; 6 years post laparoscopic cholecystectomy, which eventually developed acute abdomen and choleperitoneum resulting from the rupture of a secondary bile duct with bile leakage. This complication was thought due to a common bile duct calculous. The calculous was formed around a surgical clip which in the due course of time had migrated from the cystic duct remnant to the common bile duct [16]. The patient was subjected to investigative laparotomy and, subsequently, an ERCP with extraction o the calculous and clearance of the common bile duct after which she recovered completely.
Migrated endoclip and stone formation after cholecystectomy though an extremely rare but can create a new danger of acute pancreatitis. Dolay K et al [17] reported a case presenting with obstructive jaundice and acute biliary pancreatitis due to choledocholithiasis caused by a long migrated endoclip after six months of LC. The patient was subjected to an early endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy and stone extraction.

Tsumura H et al reported an extremely rare complication, migration of an endoclip into the common bile duct, following few months after laparoscopic cholecystectomy, in a 57-year-old man. He underwent laparoscopic cholecystectomy, but was confronted by postoperative bile leakage that occurred from the cystic duct stump and was treated by conservative drainage for 1 month. It was that again after Five years, he came with the complain of vomiting and pain in the right hypochondrium, and was admitted for investigations of jaundice and liver dysfunction. Computerized tomography scanning of the abdomen and endoscopic retrograde cholangiography

revealed the fact that several calculi, formed around six endo-clips acting as the nidus, had migrated into the biliary tract.

Many other reports have substantiated the migration of clips in the hepatic duct after laparoscopic cholecystectomy, as cause of late recurrent gallstones. Choledochal stenosis and lithiasis caused by penetration and migration of surgical metal clips has also been documented**.**

The translocation of surgical pins to distant sites may be a sign of impending doom if not rectified.

Wasserberg N et al describes two cases in which there was an incorporated surgical clip into a duodenal ulcer post laparoscopic cholecystectomy. The patients presented with were acute gastrointestinal bleeding. Both were treated endoscopically, and the bleeding stopped after the removal of the clip from the ulcer base. [19]

Eighteen months after cholecystectomy a patient complained of dyspnea. Plain radiograph and computed tomography of the thorax was advised which showed a metallic clip in the branch of the left pulmonary artery supplying the posterior basal segment of the left inferior lobe. This is a case of Embolism of a metallic clip following laparoscopic cholecystectomy reported by Ammann K et al from Austria. The clip was applied to control bleeding from the Gall Bladder bed which was the cause of disaster. Hence, the use of clips on Gall Bladder bed should be strictly condemned.

There are studies which have shown migration of clips to distant locations like intervertebral discs and other awfully incredible sites. Hence, most of the researchers have condemned their use though it is rampantly used by the developing world.

Ultrasonic Generators

The dissection of the cystic pedicle in Gall Bladder surgery has undergone revolutionary change since the introduction of harmonic Scalpel. The ultrasonically activated (Harmonic) scalpel has proved its efficacy and is, efficient, and safe instrument for dissection and hemostasis in both open and laparoscopic surgical procedures.
To date, the ultra sonic technology embraces Laparoscopic cholecystectomies for its use in the division of the cystic artery and liver bed dissection. A refinement in the blade tips of the Harmonic scalpel provides us with the most reliable ultrasonic division techniques for closure of the cystic duct. [21]

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 effector (specific types include blade or shears) used to cut tissue, a foot pedal, and a hand

switching adaptor.
Ultrasound technology is the basis for an efficient surgical instrument: the ultrasonic generator cuts and coagulates by using low temperatures, lower than those used by electro surgery or lasers. Ultrasonic technology controls bleeding by coaptive coagulation at low temperatures which ranges from 50 degrees Celsius to 100 degrees Celsius: 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 is produced that seals larger vessels. By contrast, electro surgery and lasers provides the technique of obliterative coagulation, e.i. coagulation by burning at higher temperatures (150 Degrees C to 400 Degrees 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 are removed during electro surgery and they stick to tissue disrupting the Escher. Surgeons need to control the harmonic Scalpels coagulation rate and cutting speed by applying appropriate time and force to the tissue by the end effector, and by the selected excursion level of the end-effector. At the tip of the end-effector, energy is 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. The Harmonic Scalpel uses ultrasonic technology, and energy that allows both cutting and coagulation at the point of impact. It is 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.

Advantages:

1. The procedure has advantages in that it utilizes a single instrument for performing 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 100.C and the spread of necrosis from the point Of contact is < .05mm, hence less collateral damage is seen.
8. The dangers of coupling and tissue charring are necessarily obviated.

Gall bladder surgeries performed with the UG 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 were observed. Use of the ultrasonic generators makes dissection easier, with the reduction in the operative time and also in the need for conversion to open surgery.[22]

The Ultrasonic generator provides complete hemobiliary stasis for most of the patients and is often a safe alternative to Monopolar current, standard clip or ligature closure of the cystic duct. [21]

Tebala GD[23] Performed three-port laparoscopic cholecystectomy by harmonic dissection without using the standard clips for sealing cystic duct and artery on 100 patients and

documented that the risk of tissue injury caused by repeatedly blind extraction and insertion maneuvers of various instruments in the abdomen was decreased by the use of the multipurpose ultrasonic dissector.
Apart from LC the prowess of duct sealing capacity of HS has been adjudged in various documented proofs from surgeries on Breasts, Pancreatic surgeries and those conducted over thyroid. The beauty of the instrument lies in being more target oriented and causing less collateral damage.

Safe in less experienced hands

A randomized clinical trial of ultrasonic *versus* electrocautery dissection of the gallbladder in laparoscopic cholecystectomy was conducted by I. M. C. Janssen et al [24]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. T**he surgeons with less experience benefited the most from ultrasonic dissection, particularly in daunting and complicated Intraoperative circumstances.**

Effect on Post operative immunity

A study on the Intraoperative and post operative immune status of the patient was conducted using Ultrasonic Generators for surgery and it was 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 [25].

Effect on post operative pain.

Retrieval of data on post operative pain after LC was not possible due to insufficient literatures available but its effect on those undergoing hemorrhoidectomy was recorded. There was significantly reduced postoperative pain with U.G. hemorrhoidectomy 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**. [26]

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 [27]

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.[28] The liquid (blood or serum) aerosol concentration
was in a directional spray pattern with the use of hook or ball-tip. These were easily detected up

to the level of 40cm from point of production. [28] 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 process has been aptly described by the manufacturers as low-temperature vapourisation.[29] 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.[30] One study stated that the particles created by the ultrasonic (harmonic) scalpel are composed of tissue blood and blood by-products.

Disadvantage of HS

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

Conclusion

Harmonic scalpel has a definite edge over clips used for laparoscopic cholecystectomy. The advantages lie unparalleled when it comes to sealing of cystic duct and arteries. Least collateral damage and better tissue healing perspective makes it a valuable surgical tool. Low complication rates, safety in hands of less experienced surgeons, speedy recovery and better patient compliance are some of the milestones which has been achieved with the use of Harmonic scalpel making Laparoscopic Cholecystectomy the true 'Gold standard' for Gall bladder diseases.

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