Original Research Article

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In vitro comparison of ultrasonic shear versus ligating clip application in closure of cystic duct in cholecystectomy

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ABSTRACT

Background: Cholecystectomy is one of the most commonly performed surgery overall. One of the most important steps in the operation of cholecystectomy whether open or laparoscopic, is the closure of cystic duct which if not done properly can lead to disastrous postoperative outcome. This study was conducted with an aim to do *in vitro* comparison of ultrasonic shear and standard titanium ligating clips in closure of cystic duct with respect to their ability to withstand the pressure generated inside the gall bladder by pneumatic tourniquet device.

Methods: A total 148 patients underwent open or laparoscopic cholecystectomy Between August 2016 to October 2017 at Sir Sayajirao Gaekwad Hospital, Baroda, were eligible for this prospective randomized study. A total of 16 cases were excluded from the study and specimens from 132 patients were included in the study. The eligible patients were randomized into two groups using sealed envelopes. The two groups were as follows: A) ligating titanium clips, and B) ultrasonic shear. Independent assessors were assigned to obtain cystic duct bursting pressure.

Results: A comparison of the mean cystic duct bursting pressure between both the groups indicated the superiority of ultrasonic shear group over ligating titanium clip group.

Conclusions: The mean cystic duct bursting pressure was higher in the ultrasonic shears group than in ligating clips group, higher than the maximum cystic duct bursting pressure (195 mmHg). The ultrasonic shear provides safe alternative to standard titanium ligating clip for cystic duct closure.

Keywords: Cholecystectomy, Cystic duct, Laparoscopy, Pneumatic tourniquet device, Titanium clip, Ultrasonic shear

INTRODUCTION

Gallstone disease is common and cholecystectomy is the treatment of choice for symptomatic disease. Cholecystectomy is one of the most commonly performed surgery overall. One of the most important steps in the operation of cholecystectomy whether open or laparoscopic, is the closure of cystic duct which if not done properly can lead to disastrous postoperative outcome.

There are many methods for closure of cystic duct. Commonly used methods are silk suture, ligating clip application, ultrasonic shear etc. Simple metal clips have been used by most surgeons to close the cystic duct since Professor Muhe reported the first successful laparoscopic cholecystectomy in 1985.²

However these ligating clips have been known to migrate into adjacent structures, lead to stricture due to a foreign body response, serve as a nidus for stone formation, and occasionally fall of and result in substantial morbidity.³

One problem with laparoscopic cholecystectomy is the occurrence of post-operative biliary leakage which may be related to insufficient closure of cystic duct after standard closure with two metal clips. 4 Consequently, different techniques have been proposed for closure of

cystic duct including using of resorbable clips and performing ultrasonic dissection.

Efficacy and ability of these methods in closure of cystic duct should be evaluated first before we use it in vivo. Therefore this study proposes to do *in vitro* comparison of closure of cystic duct with ultrasonic shear and standard titanium clips with respect to the ability of the closure to withstand the pressure generated inside the Gall bladder by pneumatic tourniquet device before giving way or at the bursting pressure generated.

Contraction of sphincter of oddi is the major cause of common bile duct pressure. The mean basic common bile duct pressure is 15 mmHg (range 5-35 mmHg) and increases up to 135 mmHg (range 95-195 mmHg) during phasic contraction of the sphincter (4 times/min). Therefore, any sealing method that leads to bursting pressure of the cystic duct >195 mmHg could be reasonable. ⁵

METHODS

Between August 2016 to October 2017, a total 148 patients who underwent open or laparoscopic cholecystectomy at Sir Sayajirao Gaekwad Hospital, Baroda, were eligible for this prospective randomized study. A total of 16 cases were excluded from the study due to perforation of the gall bladder during dissection (n=10) and contracted gall bladder (n=4). Two cases were excluded from the study during pressure management studies (n=2). Thus specimens from 132 patients were eligible.

Patients having symptomatic cholelithiasis (diagnosed by ultrasound) were subjected to laparoscopic or open cholecystectomy and were included in this study. And patients having Intraoperative leakage of bile from gall bladder, suspected perforation of gall bladder (by either visualization of bile or stone), Fibrous and complete contracted gall bladder or acute cholecystitis were excluded from the study.

The eligible patients were randomized into two groups using sealed envelopes. The envelopes were drawn and opened by an assistant who was not involved in the study before the operation. The two groups were as follows: A) ligating titanium clips and B) ultrasonic shear.

The surgeries were performed by Consultant Surgeons from all surgical units. In both groups, laparoscopic cholecystectomy was performed using the traditional method, which involved dissection of Calot's triangle using a monopolar hook and then isolation of the cystic duct and cystic artery using curved dissecting forceps. Closure of the cystic duct was performed using (medium/large) 10 mm titanium ligating clips (Ethicon Endo-Surgery, Cincinnati, OH), with two clips on the CBD side and one clip on the gallbladder side and then dividing it in between. The cystic artery was also clipped

with two metal clips and divided in between. Mobilization of the gallbladder from the liver bed was completed using a monopolar hook. The gallbladder was retrieved with the ligating clips in situ after widening of the 10-mm port. Once the gallbladder is removed, it was prepared for *in vitro* bursting pressure measurement.

Cystic duct bursting pressure

It is the pressure at which the gall bladder burst at the cystic duct closure site which is generated inside gall bladder by pneumatic tourniquet device.

In group A, the ligating clip was removed and two fresh clips were placed to ensure that the fresh clips are competent.

In group B, the ligating clip was removed and ultrasonic shear was applied which was set at level 2(less cutting and more coagulation) at the site of cystic duct until the duct is cut completely.

Then a k-19 catheter was inserted from the fundus of gall bladder after putting a stab incision at the fundus and fixed it with two rings of purse string suture. The catheter was then connected with a pneumatic tourniquet device. The gall bladder was then immersed in a saline filled kidney tray. The pressure emerging from tourniquet device was increased very slowly and steadily until air leakage (bubbling) was observed from sealed cystic duct. At this point the pressure in the tourniquet device was recorded as the cystic duct bursting pressure. We excluded the cases in which bubbling occurred from places other than the stump of cystic duct.⁶ In one specimen (n=1) bubbling occure at the fundus site and in one specimen (n=1) while incision was made at fundus perforation occurred at body of gall bladder, so these two specimens were excluded.

Materials used

Gall bladder specimen, pneumatic tourniquet device, K-19 catheter, suture material with basic surgical instruments, ligating clip and its applicator, ultrasonic shear instrument



Figure 1: Material used.



Figure 2: Pneumatic tourniquet device.

Statistical analysis

Data analysis was performed using MedCalc version 17.9.5 software. Continuous variables were analyzed with 't' test. Values were reported as mean±2 standard deviation or median or percentages as and when required. P value of less than 0.05 was considered significant.

RESULTS

A prospective study was carried out in the Department of General Surgery, from August 2016 to October 2017, in 132 patients undergoing laparoscopic or open cholecystectomy and divided into two groups using sealed envelopes. Adequacy of randomization was evident from similarity in patient characteristics in both the groups (Table 1 and 2). No protocol violations were recorded during the study.

Table 1: Comparison of age in titanium clip group and ultrasonic shear group.

Number of patients					
Age (in years)	Titanium clip group A	Ultrason ic shear group B	Total	(%)	
21 to 30	11	18	29	21.96	
31 to 40	18	13	31	23.48	
41 to 50	16	18	34	25.75	
51 to 60	13	8	21	15.90	
61 to 70	7	8	15	11.36	
71 to 80	1	1	2	1.51	

Out of the 132 patients who underwent successful laparoscopic cholecystectomy, 32 (24%) were males and 100 (76%) were females. The ratio of males to females was 1:3. The above sex distribution shows that the gall bladder diseases have a higher frequency in females than in males (Table 2).

Table 2: Comparison of sex in titanium clip group and ultrasonic shear group.

	Number of patients			
Sex	Titanium Clip Group A	Ultrasonic Shear Group B	Total	
Male	17	15	32	
Female	49	51	100	
Total	66	66	132	

The cystic duct bursting pressure was significantly higher in the ultrasonic shears group compared with the ligating titanium clip group (p value <0.0001). The mean cystic duct bursting pressure was 252.24 \pm 32.50 mmHg in the ligating titanium clip group and it was 330.50 \pm 32.20 mmHg in ultrasonic shears group. A comparison of the mean cystic duct bursting pressure between both the groups indicated the superiority of ultrasonic shear group over ligating titanium clip group (Table 3 and Figure 3).

Table 3: Comparison of mean cystic duct bursting pressure in titanium clip group and ultrasonic shear group.

	Titanium clip group A	Ultrason ic shear group B	P value
Mean pressure (mmHg)	252.24	330.50	
Mean pressure (mmHg)±2SD	252.24± 32.50	330.50± 32.20	0.0001

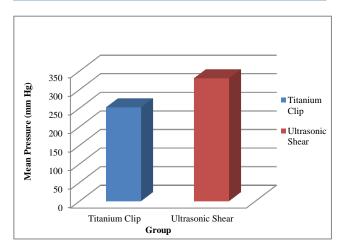


Figure 3: Mean cystic duct bursting pressure in titanium clip group and ultrasonic shear group.

DISCUSSION

Although rare, using clips in laparoscopic cholecystectomy is associated with several complications such as ulcerating through the duodenum causing severe hemorrhage, embolism of clips, internalization of clips into the Common Bile Duct, bile leak secondary to clip displacement, and clip-induced biliary stone. Leak from the cystic duct after using clips may be due to slippage of

the clips and migration of clips into the biliary tract, necrosis of the duct at the site of clipping, or inadequate closure of the duct due to mismatch of the clip arms. Besides the common use of clips, various other techniques for securing the cystic duct and arteries have been introduced including ligature, ultrasonic shears, and ligasure.

Shah and Maharjan used intracorporeal suturing for securing the cystic duct and artery in 80 patients undergoing laparoscopic cholecystectomy. The authors stated that intracorporeal suturing is simple, safe and economical with no cases of bile leak. Several recent reports had demonstrated that ultrasonic shears is a safe alternative to standard clipping of the cystic duct in laparoscopic cholecystectomy. Some studies also documented the safety of ultrasonic shears that was associated with shorter operative time, less incidence of gallbladder perforation, and less postoperative pain. 9,10

One of the advantages in laparoscopic cholecystectomy is the efficacy, efficiency and advantage of ultrasonic device to occlude cystic duct intraoperatively.

The use of ultrasonically activated shears for both dissection and closure-division of the cystic duct and artery was first reported in 1999. The use of ultrasonic shear in laparoscopic removal of the gall bladder was first reported by Geidie. The Harmonic scalpel is also an effective tool for closure of biliary ducts and vessels in laproscopic cholecystectomy (as certified by the FDA in 2006). Out of all ultrasonic shear application has gained significant clinical acceptance and application. It is an ultrasonically activated scalpel and its technology relies on application of ultrasound within the harmonic frequency range on tissue and allows 3 effects synergistically.

- Ultrasonic coagulation,
- · Cutting and
- Cavitation.

The temperature obtained and the lateral energy spread are lower than those detected when monopolar hook is used, thus reducing the risk of tissue damage.

The efficacy and safety of ultrasonic device for gallbladder dissection are concurred by numerous randomized studies.

Since its early introduction in 1999, reports have demonstrated the positives of the surgical manipulation (dissection, coagulation, division, and closure of the cystic duct) using ultrasonic shear.

Ultrasonic device denatures protein by means of ultrasonic vibrations at a frequency of 55500 Hz with a vibratory excursion of 50–100 $\mu m.$ The vibration transfers mechanical energy to the tissue, resulting in simultaneous cutting and coagulation. The vibrating

ultrasonic dissector produces a coagulum of denatured protein and blood clot that occludes adjacent blood vessels and reduces bleeding.

Vibration of the dissector scalpel blade does not generate as much heat as monopolar cautery or laser cautery, and the vibration in potential spaces results in cavitations, which may facilitate tissue dissection.

The ability to perform all the key steps in the procedure using the same instrument can reduce the operative time by reducing the number of times instruments were changed, prevents dissipation of heat, arcing of electrical current, thermal injuries to surrounding structures especially in the Calot's triangle.

Other benefits include prevention of injuries related to ligating clips including its slippage, inadvertent application on the common bile duct or the common hepatic duct.

In a study conducted in Egypt by Abdallah et al for in vitro comparison of cystic duct bursting pressure in 420 patients which were divided into three groups of ultrasonic shear, ligating clip and ligasure group, mean cystic duct bursting pressure was 329.7±38.8 mmHg in ligating titanium clip group, 358.0±33.1 mmHg in ultrasonic shear group and 219.7±41.2 mmHg in the ligasure group. Cystic duct bursting pressure was significantly higher in the ligating clips group compared with the ligasure group (p<0.001). Ultrasonic shears and ligating clips were found to be safe sealers as their mean Cystic duct bursting pressure was found to be higher (>195 mmHg) than the maximum common bile duct pressure, whereas for ligasure the Cystic duct bursting pressure range was 150-297 mmHg, indicating that it is not safe for sealing.6

In our study of 132 patients undergoing laparoscopic or open cholecystectomy, the mean cystic duct bursting pressure was 252.24 mmHg in ligating titanium clip group and 330.5 mmHg in ultrasonic shears group, which was higher than the maximum cystic duct bursting pressure (195 mmHg), which means that they are safe for cystic duct sealing.

In our study, in ultrasonic shears group, cystic duct bursting pressure was significantly higher than ligating titanium clip group (p value <0.0001).

CONCLUSION

The mean cystic duct bursting pressure was higher in the ultrasonic shears group than in ligating clips group, higher than the maximum cystic duct bursting pressure (195 mmHg). The ultrasonic shear provides safe alternative to standard titanium ligating clip for cystic duct closure. Thus, we can safely use ultrasonic shear in vivo for cystic duct closure in laparoscopic cholecystectomy.

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Institutional Ethics Committee

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