

ORIGINAL RESEARCH

Efficacy And Safety Of Titanium Clips During Laproscopic Cholecystectomy**¹Dr P K Pandove, ²Dr Arvinth K, ³Dr Sanjeev Gupta**

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Abstract

Introduction - The National institute of health consensus committee stated that laparoscopic cholecystectomy provided safe and effective treatment for most patients with symptomatic gall stones. Cystic artery haemostasis is considered a crucial step in completion of laparoscopic cholecystectomy. For this major step various methods are used like intra-corporeal suture ligation, titanium clip ligation, absorbable clip ligation and the novel electro-surgical devices like harmonic, bipolar device and the latest device known as vessel sealer.

Material and method - The study includes 100 patients admitted in Government Medical college and Rajindra hospital. Patients with diagnosis of **cholelithiasis** were posted for laparoscopic cholecystectomy. Patients are divided into two groups on a randomized basis.

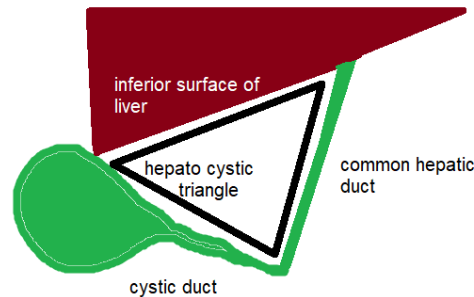
Result- The average time taken to complete the process of haemostasis in patients for whom titanium clips (group A) were used was 52.5 seconds with S.D +5.27secs. This includes application of three clips at appropriate distances and division of the cystic artery. The average time taken to complete haemostasis in patients chosen for vessel sealer device was 36.3 seconds with S.D \pm 5.51 secs. P value on comparing the time taken for haemostasis of cystic artery was <0.01 and it was statistically highly significant.

Conclusion - The vessel sealer device was found to be a better device with respect to less time consumption in completion of haemostasis.

Introduction

Advent of laparoscopy has fastened the recovery of the patient. The National institute of health consensus committee stated that laparoscopic cholecystectomy provided safe and effective treatment for most patients with symptomatic gall stones.¹ The usage of minimally invasive technique of laparoscopy has reduced the surgical stress on patients and also on the surgeon.² It has reduced the incidence of open cholecystectomy which in turn will end up in a larger scar and an increased duration of hospital stay. Haemostasis of cystic artery is an important step in laparoscopic cholecystectomy. The cystic artery is located in the hepatocystic triangle, the area bounded by cystic duct, common hepatic duct and the liver margin. The identification of hepatocystic triangle and its contents helps the surgeon to locate the pedicle of gallbladder and ligate it. The errors in gallbladder surgery often occur from failure to appreciate the common variations of the extrahepatic biliary system. This occurs especially when the right hepatic artery gets inadvertently clamped or ligated along with cystic pedicle or injured leading to profuse bleeding.³The concept of Calot's triangle was

described by Jean Francois Calot in the year 1891.(10). As described by him, Calot's triangle is bounded by inferior surface of liver, cystic duct and common hepatic duct.⁴. But in late 20th century, the concept of Calot's triangle(described by J.F.Calot) was changed. According to the new concept, Calot's triangle is a relatively smaller triangle situated within the hepatocystic triangle and is formed by cystic artery, cystic duct and common hepatic duct.



schematic representation of hepato cystic triangle

Cystic artery is usually ligated before ligating the cystic duct owing to prevention of traction of cystic artery which might lead to avulsion and retraction of cystic artery that may result in haemorrhage.²⁻⁴ Hence cystic artery haemostasis is considered a crucial step in completion of laparoscopic cholecystectomy. For this major step various methods are used like intra-corporeal suture ligation, titanium clip ligation, absorbable clip ligation and the novel electro-surgical devices like harmonic, bipolar device and the latest device known as vessel sealer (tissue response electro-surgical generator). Titanium clips are important clamping devices which employ the pressure energy to achieve haemostasis. They are made up of titanium which makes the clips biocompatible. The titanium clips have both outer and inner surreys which enable proper affixing to the clip applicator and proper grip on the tissues respectively. The vessel sealer device, also known as the tissue response electro-surgical generator is a novel electro-surgical device which employs the pressure energy and electrical energy. The electrical energy generates heat which in turn ends up in the following reactions.⁵

Temperature Biological reaction Effects 55 -

- 80°C- Coagulation of proteins Shrinkage of lumen
- 100°C - Liquefaction of elastic and collagen, Approximate and occlude the lumen
- >100°C- Burning of elastin and collagen Charring of tissues.

The optimal temperature for dividing the vessel is 80°C where the lumen is fully occluded and there is no damage or charring of adjacent tissues.⁶ All the above-mentioned methods do have their own advantages and limitations with respect to efficacy, safety, postoperative events. The aim of this study was to evaluate the efficacy, safety and complications of titanium clips and vessel sealer device (tissue response electro surgical generator) for cystic artery haemostasis.

Material and method

The study includes 100 patients admitted in Government Medical college and Rajindra hospital. Patients with cholelithiasis or chronic cholecystitis due to cholelithiasis were included in the study. Patients with choledocholithiasis /cholangitis/ acute pancreatitis /who underwent ERCP and CBD stenting were excluded from the study.

Patients with the diagnosis of **cholelithiasis** posted for laparoscopic cholecystectomy. Patients are divided into two groups on a randomized basis.

- **Group A** - which includes patients for whom **titanium clips** are used for cystic artery haemostasis
- **Group B** - which includes patients for whom **vessel sealer device** is used for cystic artery haemostasis.

The patients were preoperatively assessed by history taking, clinical examination, blood investigations including complete hemogram, bleeding time, clotting time, renal function tests, liver function tests, coagulation profile, screening for HIV, HBsAg, HCV; ultrasonography of abdomen with a detailed description of the biliary tree and any other investigations required. An informed consent was taken from all the patients before surgery. Following evaluation, the patients were subjected to a standard 4 port laparoscopic cholecystectomy and the time taken for achieving critical view of safety is noted. This time includes the time taken for access to peritoneal cavity, localisation of the infundibulum of gall bladder, adhesiolysis (if adhesions are present) and skeletonization of cystic pedicle till visualization of only two skeletonized structures (cystic artery and cystic duct) were seen entering the gall bladder. The efficacy of the above mentioned methods can be assessed intra-operatively on the basis of time taken to achieve haemostasis, total time required for procedure, incidence of intra-operative complications. All these findings were tabulated and a comparative analysis of all these data was done.

Observations and results

Time taken to achieve critical view of safety

The time taken to reach critical view of safety was calculated starting from the placement for first incision till the achievement of critical view of safety.

Table 1: Time for critical view of safety (in mins)

Time for critical view of safety (mins)	Titanium clips (group A)		Vessel sealer device (group B)	
	Number of patients	Percentage	Number of patients	Percentage
1-10	1	2%	1	2%
11-20	32	64%	21	42%
21-30	12	24%	22	44%
31-40	3	6%	5	10%
41-50	1	2%	1	2%
Total	50	100%	50	100%
Fisher Exact Test	6.154			
P Value	0.133			
Significance	Not significant			

Incidence of intraoperative difficulties

The difficulties encountered during surgery were adhesions, Edema of the Gall bladder and difficult Calot's triangle dissection and subsequent difficulty in skeletonizing the structures of cystic pedicle.

Table 2: Intra- Operative Difficulties

Intraop Difficulties	Titanium clips (group A)		Vessel sealer device (group B)	
	Number of patients	Percentage	Number of patients	Percentage
Adhesions	6	12%	16	32%
Edematous GB	4	8%	4	8%
Difficult Calot's	2	4%	2	4%
No difficulty	38	76%	28	56%
Total	50	100%	50	100%

Chi square	4.4563
P value	0.05
Significance	Significant

Table 2 shows that in 6(12%) patients in group A and 16(32%) patients in group B had adhesions, 4(8%) in group A and 4(8%) in group B had edematous gall bladder and 2(4%) in group A and 2(4%) in group B had difficulty in dissecting Calot's triangle. Total 12 (24%) patients in group A and 22(44%) patients in group B had intra operative difficulties. Total 12 patients(24%) in group A and 22 patients(44%) in group B had intraoperative difficulties. The P value was found to be 0.05 and was statistically significant.

Time taken for haemostasis of cystic artery (in secs)

The time taken for haemostasis of cystic artery was calculated starting from the time of approach of the respective device to the cystic artery till the completion of division of cystic artery.

Table 3 - Time taken for haemostasis of cystic artery (in secs)

Time taken for haemostasis of cystic artery(seconds)	Titanium clips (Group A)		Vessel Sealer device (Group B)	
	Number of patients	Percentage	Number of patients	Percentage
30-35	0	0 %	27	54 %
36-40	1	2 %	14	28 %
41-45	7	14 %	8	16 %
46-50	19	38 %	0	0 %
51-55	12	24 %	1	2 %
56-60	11	22 %	0	0 %
Total	50	100 %	50	100 %
Fisher Exact Value	77.641			
P Value	<0 01			
Significance	Highly significant			

Table 3 shows that in group A (titanium clips), the time taken to complete haemostasis of cystic artery was between 36- 40 secs in 1 patient (2%), 41 – 50secs in 7 patients(14%), 46 – 50secs in 19 patients(38%), 51-55secs in 12 patients (24%) and 56 – 60% in 11 patients(22%).

In group B(Vessel Sealer Device), the time taken to complete haemostasis of cystic artery was between 30 – 35 secs in 27 patients (54%) 36- 40 secs in 14 patient(28%), 41 – 50secs in 8 patients(16%), 51-55 secsin 1patient (2%).

Table 4 - Mean time taken for cystic artery haemostasis(seconds)

Groups	Mean time taken for cystic artery haemostasis(seconds)	S.D (seconds)	P value	Significance
titanium clips(Group A)	52.5	5.27	<0 01	Highly significant
Vessel sealer device (Group B)	36.3	5.51		

Table 4 shows that the average time taken to complete the process of haemostasis in patients for whom titanium clips (group A) were used was 52.5 seconds with S.D +5.27secs. This includes application of three clips at appropriate distances and division of the cystic artery. The average time taken to complete haemostasis in patients chosen for vessel sealer device was 36.3 seconds with S.D ± 5.51 secs. P value on comparing the time taken for haemostasis of cystic artery was <0 01 and it was statistically highly significant.

Discussion

The time taken for haemostasis was more in patients for whom time taken to achieve CVS was more. The average time taken for haemostasis in group A (titanium clips) was 52.5seconds and group B(vessel sealer device) was 36.3seconds. Comparing both the data, the p value was found out to be less than 0.01 and was statistically a highly significant parameter.

Study done by	Inference of the study	Inference in the present study
Albert K Chin et al	Titanium clips are better choice for haemostasis in areas with difficult access	Usage of vessel sealer device took lesser time when compared to titaniumclips ⁷
Bimal Kumar Sah et al	Vessel sealer device has advantages of less time requirement.	Vessel sealer device consumed less time in completing haemostasis ⁸
M Imran et al	Devices employing energy sources take less time in achieving haemostasis	Vessel sealer device (energy-based) took less time in achievinghaemostasis ⁹

In our study, the difficulties encountered were adhesions, oedematous gall bladder and difficulty in dissection of Calot's triangle. In both the groups, most of the patients had adhesions. In group B, there were 16 patients with adhesions and total 22 patients had difficulties versus 12 patients in group A. The handling of difficulties in group B required more time which in turn resulted in higher duration of surgery. Vessel sealer device, an energy-based device proved helpful in handling adhesions and other difficulties enabling minimal bleeding during adhesiolysis. This advantage of vessel sealer device got reflected in the volume of drain output fluid and haemoglobin content of drain output fluid being significantly lesser than the same in patients for whom titanium clips were used. **Bimal kumar shah et al** conducted a pilot study in October 2007 and presented the advantages of vessel sealer device as avoidance of bleeding, less time consumption, relatively more safe in haemostasis of vessels in pedicles where the creation of space between 2 vessels or 2 structures remain difficult and can be applied more safely and more easily in tight or deep spaces.⁸ After completing haemostasis of cystic artery, surgery was continued and the total duration of surgery was computed. The steps of surgery after haemostasis of cystic artery were division of cystic duct, dissection of gall bladder out of the GB fossa, extraction of the gall bladder out of abdomen, placement of drain and closure of port sites. Time taken for haemostasis of cystic artery is a part of total duration of surgery which is also dependent on the other steps of surgery as well.⁹

In our study, there was a highly significant difference in duration of surgery between patients for whom titanium clips were used and patients for whom vessel sealer device was used. The P value was <0.01.

In a study conducted by Jahangir Sarwar Khan et al on 144 patients, patients for whom energy-based device harmonic was used had a shorter duration of surgery when compared to the patients for whom titanium clips were used. The P value was found to be less than 0.001 and it was a highly significant difference¹⁰.

The significant difference in the total duration of surgery between energy-based devices and titanium clips can be explained by

- Lesser time requirement for energy-based devices owing to the working mechanism of the devices.
- Energy-based devices can be used for the subsequent steps of dissection as well.
- Application of titanium clips require extra time owing to the practice of application of 3 clips and time requirement for loading and applying clips individually.

Conclusion

In this study comparing titanium clips and vessel sealer device with respect to haemostasis of cystic artery, the vessel sealer device was found to be a better device with respect to less time consumption in completion of haemostasis and duration of surgery.

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