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Randomized clinical trial of torsional versus linear mode ultrasonically activated devices for laparoscopic cholecystectomy

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Abstract
Background Conventional ultrasonically activated devices use linear mode vibration. Torsional mode ultrasonically activated device (TM) that oscillate around an arc have been recently introduced in the hope that the design may result in faster cutting and better hemostasis.
Methods Patients undergoing elective laparoscopic cholecystectomy were randomized to TM or linear mode ultrasonically activated device (LM). Intraoperative events were recorded. Postoperatively, a sample of suction fluid was analyzed for hemoglobin concentration to calculate intraoperative blood loss.
Results Seventy-five patients were randomized to TM and 76 patients to LM. Median blood loss was 5 (interquartile range (IQR), 1–19.7) ml with TM and 10.5 (IQR, 2.3–23) ml with LM ($p = 0.105$). The 95% confidence interval for the difference in median operative blood loss was −1.3 to +9.5 ml. Median gallbladder dissection time was similar in both groups (17 (IQR 11–29) minutes for TM vs. 21 (IQR, 12–29) minutes for LM; $p = 0.248$). Other modalities of hemostasis were required in 14 patients (19%) in the TM group compared with 21 patients (28%) in the LM group. One patient in the LM group developed postoperative hemoperitoneum and required urgent laparoscopic exploration. No patient required blood transfusion or suffered any other significant complication.
Conclusion TM has similar effectiveness to LM for laparoscopic cholecystectomy. Registration number: ISRCTN87527062 (http://www.controlled-trials.com).

Keywords Randomized clinical trial · Ultrasonic coagulating shears · Ultrasonically activated device · Torsional mode ultrasound · LOTUS · Harmonic scalpel · Hemostatic dissection · Laparoscopic cholecystectomy

Ultrasonically activated devices have been used in laparoscopic and open surgery for hemostatic cutting since the introduction of the Harmonic Scalpel® by the Ultracision Company (Smithfield, RI, USA) in 1992. Such devices use the linear (longitudinal) vibration mode where the blade vibrates back and forth along its long axis. A new device based on a torsional mode of vibration has been developed and was introduced in 2003. The blade vibrates in a short arc around the waveguide axis. The registered name of this device is LOTUS™ (SRA Developments Ltd., Ashburton, Devon, England, UK). The fundamental differences between linear and torsional mode ultrasonically activated devices have been previously described [1]. In the case of the linear mode ultrasonically activated device (LM), the vibration of the blade generates frictional heat at the interface between blade and tissue. The torsional mode ultrasonically activated device (TM) has a different blade design that features grooves cut into the side facing the passive hinged jaw. It generates compression forces from the faceted edges of the blade directly into the target tissue grasped between the blade and the passive hinged jaw (Fig. 1). Studies that compared the LM with TM have shown good hemostatic capabilities with both devices, with the TM being superior for sealing large arteries >5.2 mm and veins up to 4.5 mm in diameter [1, 2]. The lateral

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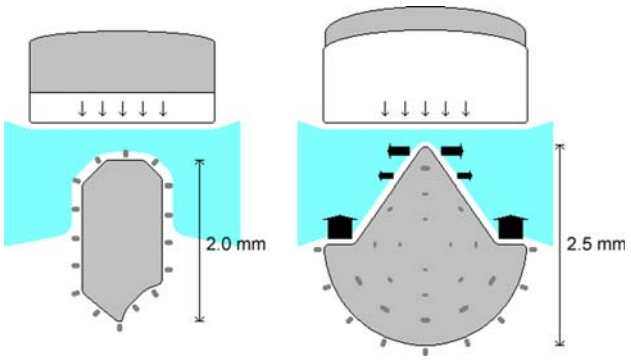

Fig. 1 Force generation profiles of the Harmonic Scalpel® (linear mode vibration, left) and the LOTUS™ (torsional mode vibration, right) blades in the cross-sectional planes [1]. The arrows on both inactive jaws pointing down toward the tissue and blade represent the forces that compress target tissue for coaptive coagulation. The grey dots represent shear forces that produce frictional heat where the blades come into contact with tissue, the mechanism of action of linear mode shears. The horizontal bold arrows represent cutting forces at the apex of the LOTUS™ blade compressing into the tissue and separating it sideways. The vertical bold arrows arising from both sides of the LOTUS™ blade represent compression forces that coagulate tissue

thermal spread determined histologically on cut vessels were limited to 1.12 ± 0.25 mm for the LM and 1.48 ± 0.34 mm for the TM from the cut margins [2].

The cost of each single-use TM was £200, compared with £303 for each single-use LM, representing a 34% reduction in the cost of disposable equipment per operation. LM and TM have not been previously compared in a clinical trial. It was hypothesized that use of TM for dissection of the gallbladder reduces the operative blood loss compared with LM.

Materials and methods

A prospective, randomized study was conducted in three hospitals: The General Infirmary at Leeds, Wharfedale General Hospital, and Nuffield Hospital Leeds between October 2003 and November 2007. The study was approved by the Leeds (West) Research Ethics Committee (References 03/009 and 04/Q1205/143). The trial registration number is ISRCTN87527062 (http://www.controlled-trials.com).

The devices compared were the Harmonic Scalpel® (Ethicon Endo-Surgery, Cincinnati, Ohio, USA) using the single-use LCSC5 (36-cm long, 5.5-mm diameter) shears with a 15-mm active curved blade (LM) and the LOTUS™ with the reusable SV2-370 handpiece and the single-use SV2-370D jaw actuator exposing a 12-mm active straight blade (TM). Both systems comprised a generator, foot activated pedals, handpiece, waveguide, and blade. In each, the transducer was housed within the handpiece. A moveable jaw holding a polytetrafluoroethylene (PTFE) insert compressed the target tissue against the blade. The components of the acoustic systems vibrate harmonically at 55.5 kHz in the case of the Harmonic Scalpel® and at 36.0 kHz in the case of the LOTUS™.

The inclusion criteria were patients who underwent elective laparoscopic cholecystectomy with or without intraoperative cholangiography. The exclusion criteria were patients with any of the following conditions: oral anticoagulant treatment; a known coagulation disorder; American Society of Anesthesiologists (ASA) score 3 or more; younger than aged 16 years; pregnancy; mental illness; or the need to explore the common bile duct at the time of surgery.

Patients undergoing laparoscopic cholecystectomy were given a patient information sheet after admission to the hospital. They were invited by the researchers to take part in the study, and a written informed consent was obtained from each patient entering into the study, in addition to the routine consent for the operation.

Randomization by envelope was done in each hospital just before the operation. All the operations were performed under general anesthesia. A standardized anaesthetic regimen was used. In particular, the use of intravenous ketorolac (a nonsteroidal anti-inflammatory drug used for postoperative pain control) was avoided because it might influence the hemostatic profile. After creation of the pneumoperitoneum with carbon dioxide insufflation, all the required cannulae were inserted and a liver retractor was placed to provide exposure of the gallbladder. Gallbladder dissection was performed by using a standardized technique starting with a combination of energized and blunt dissection of the Calot's triangle first, whenever possible, before dissecting the gallbladder from its attachment to the liver. A video recording of the procedure was performed as a routine. The time taken from the commencement of gallbladder dissection to the completion of cholecystectomy, i.e., when the gallbladder was freed from any attachment, was recorded. Time spent preparing and performing a routine intraoperative cholangiography was excluded from gallbladder dissection time. This was the time interval between making an opening to the cystic duct for insertion of the cholangiography catheter until the time when the cystic duct is divided after completion of cholangiography. The cystic artery was sealed and divided with the ultrasonic device and the cystic duct was ligated with Absolok® (PDS locking clip, Ethicon, Inc.). The numbers of applications for hemostatic cutting and reapplications to achieve hemostasis were noted. A suction-irrigation device was used during each procedure. Warmed 0.9% w/v sodium chloride solution was used for irrigation, and all visible blood and fluid were suctioned out and collected in a container. A 4- or 5-mm drain was placed

with its tip in the gallbladder fossa in most cases to observe for bile leakage or bleeding during the postoperative period.

At the completion of the operation, the volume of suction fluid was measured and a specimen was collected and sent to the hematology laboratory for estimation of hemoglobin concentration [Hb]. Blood loss was estimated using the following equation:

$$\text{Volume of blood loss} = \text{Volume of suction fluid} \times [\text{Hb}] \text{ of fluid}/[\text{Hb}] \text{ of patient's blood.}$$

The postoperative management of patients followed our normal clinical routine, with removal of drain after approximately 4 hours and discharge from hospital within 24 hours of surgery. The output from the drain was not routinely measured or analyzed for blood loss. Technical difficulties or complications encountered during or after the operations were noted. When necessary, video recordings of the procedures were reviewed.

The primary outcome measure was intraoperative blood loss. Secondary outcome measures included gallbladder dissection time, gallbladder perforation rate, the need for monopolar electrocoagulation, and the incidence of intraoperative and postoperative complications thought to be related to the use of the ultrasonically activated shears.

Statistical analysis

The calculation of sample size was based on an estimated difference in operative blood loss of 25% (20 ml vs. 15 ml) between LM and TM. A common standard deviation of 12.5 ml for operative blood loss was assumed. With a power of $\beta = 80\%$ and $p < 0.05$ (two-tailed), this difference could be detected with 77 patients in each group [3].

SPSS Version 12.0.1 (SPSS, Inc., Chicago, IL, USA) statistical software was used to analyze data. Univariate comparison of categorical factors was performed with χ^2 or Fisher's exact tests. Univariate comparison of quantitative factors was performed with the Mann-Whitney U test. A two-tailed p value of <0.05 was considered statistically significant.

Results

During the period of October 2003 to November 2007, 158 patients were randomized in this study: 78 to TM and 80 to LM. Three patients allocated to TM and four patients allocated to LM were excluded from analysis (Fig. 2). Comparison of patient demographics from the two groups did not show any significant differences in age, sex, body mass index (BMI), and ASA score. A small proportion of patients from each group had previously undergone diagnostic or therapeutic endoscopic retrograde cholangiopancreatography (ERCP) for bile duct stones (Table 1). There was no significant difference in the presence of adhesions around the gallbladder, acute/chronic inflammation of the gallbladder, wall thickening, or significant distension of the gallbladder, which are factors that might have contributed to increased dissection time and blood loss. There was no significant difference in the incidence of technically difficult gallbladder dissection in both groups (Table 2). There was no significant difference in the proportion of patients who had intraoperative cholangiography in both groups. The incidence of gallbladder perforation during dissection also was not significantly different (Table 3). There was no difference in the gallbladder dissection time and overall operating time (minus time spent on performing cholangiography) between the groups. The distribution of gallbladder dissection time for both groups is shown in Fig. 3.

In approximately one-half of the patients in each group, reapplications of the ultrasonic shears were required for ineffective hemostasis during tissue dissection (Table 3). There was no difference in the frequency with which other hemostatic agents, such as Surgicel® absorbable hemostat (oxidized regenerated cellulose, Ethicon Endo-Surgery Inc., Johnson & Johnson) or monopolar electrosurgery was used to treat bleeding areas that could not be satisfactorily controlled with the ultrasonic devices (Table 3).

The median operative blood loss was 5 ml for the TM group compared with 10.5 ml for the LM group; this difference in median of 5.5 ml did not reach statistical significance ($p = 0.105$; Table 3). The distribution of operative blood loss for both groups is shown in Fig. 4. The 95% confidence interval for the difference in median operative blood loss was -1.3 to $+9.5$ ml.

One patient in the LM group had massive hemorrhage (925 ml blood loss) caused by a bleeding artery was controlled with laparoscopic suturing. Another patient in the LM group developed hemoperitoneum and required urgent laparoscopic exploration. No focal bleeding point was found and a washout of the hemoperitoneum was performed. Both patients did not have any further bleeding complications and did not require a blood transfusion. No other complications were encountered. All operations were completed without needing to convert to open.

Discussion

Conventional ultrasonic dissection has some advantages over monopolar electrosurgery in laparoscopic surgery. For example, a randomized study of ultrasonically activated

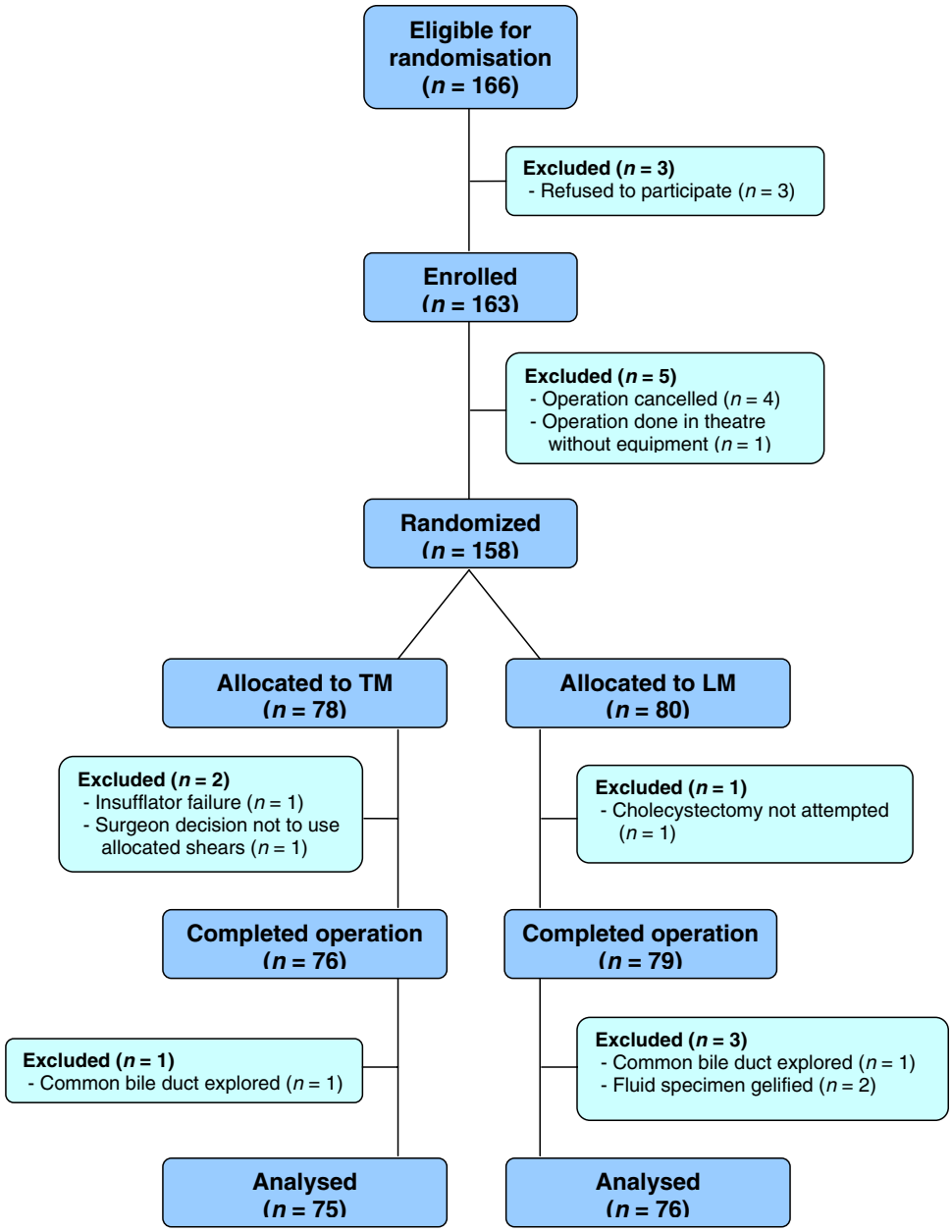

Fig. 2 Flow diagram of participants in the trial

Table 1 Demographic details of patients randomized to TM and LM

Variable	TM group ($n = 75$)	LM group ($n = 76$)	p value
Age (yr)	51 (23–81)	47 (16–81)	0.468
Male gender	15 (20)	17 (22)	0.722
BMI (kg/m^2)	29.4 (19.4–46.3)	27.9 (17.3–52.1)	0.367
ASA score 1	36 (48)	41 (54)	0.465
Previous ERCP	6 (8)	9 (12)	0.449

ERCP endoscopic retrograde cholangio-pancreatography

Data are median (range) or numbers (%) unless otherwise indicated

device compared with monopolar electrosurgery for laparoscopic cholecystectomy reported significant reduction in the mean operative time, blood loss, and postoperative hospital stay [4]. Other studies have shown significantly lower incidence of inadvertent gallbladder perforation during laparoscopic cholecystectomy using ultrasonic dissection compared with electrocautery [5, 6]. Ultrasonic dissection also was associated with less nausea and pain after laparoscopic cholecystectomy [7]. Such data do not necessarily advocate the routine use of ultrasonic dissection for laparoscopic cholecystectomy but are valuable to demonstrate the benefits of ultrasonic dissection using a common operation. Similarly, in this study, laparoscopic cholecystectomy was used to compare the performance of TM vs. LM.

The handpieces of ultrasonic devices are electrically grounded. This removes the risk of electric injury to the

Table 2 Characteristics of the gallbladder at laparoscopy in patients randomized to TM and LM

Variable	TM group ($n = 75$)	LM group ($n = 76$)	p value
Normal GB	40 (53)	40 (53)	0.931
GB adhesions	24 (32)	24 (32)	0.956
Thickened GB wall	15 (20)	14 (18)	0.805
Distended GB	6 (8)	10 (13)	0.303
Inflamed GB	7 (9)	6 (8)	0.753
Difficult GB dissection	15 (20)	17 (22)	0.722

GB gallbladder

Data are numbers (%) unless otherwise indicated

Table 3 Comparison of perioperative events and blood loss for patients randomized to TM and LM

Variable	TM group ($n = 75$)	LM group ($n = 76$)	p value
Intraoperative cholangiography	54 (72)	60 (79)	0.321
Gallbladder perforation	22 (29)	24 (32)	0.764
Dissection time (min)[a]	17 (5–60)	21 (5–49)	0.248
Operative time (min)[a]	52 (22–105)	54 (20–176)	0.97
No. of applications of device	69 (32–197)	66 (15–168)	0.316
Reapplication of device	36 (48)	43 (57)	0.291
Use of Surgicel®	4 (5)	10 (13)[b]	0.159
Use of electrosurgery	10 (13)	13 (17)[b]	0.519
Operative blood loss (ml)	5 (0–178)	10.5 (0–925)	0.105
Postoperative bleeding	0	1	–

Data are median (range) or numbers (%) unless otherwise indicated

[a] Time taken for cholangiography has been deducted

[b] In two patients, both Surgicel® and electrosurgery were used

user or the patient. The absence of electrical energy beyond the piezo-electric transducer also removes the risk of inadvertent electrical burns if the shaft of the instrument makes contact with structures outside the field of vision. Ultrasonic devices cut and coagulate tissues at temperatures well below those generated by electrosurgery, without the generation of smoke that can dangerously impair visualization of the operating field [8–10]. However, the tip of the waveguide gets hot (with both modes of operation) during use and contains more metal than electrosurgical devices. Consequently, great care must be taken to avoid unintentional contact of a hot waveguide with viscera. Although there is an aerosol effect from both modes that creates a transient mist, this does not usually cause a significant problem because the droplets rapidly settle out.

In this study, there was no significant difference in the operative time, blood loss, and gallbladder perforation rate time between TM and LM groups. Blood loss during

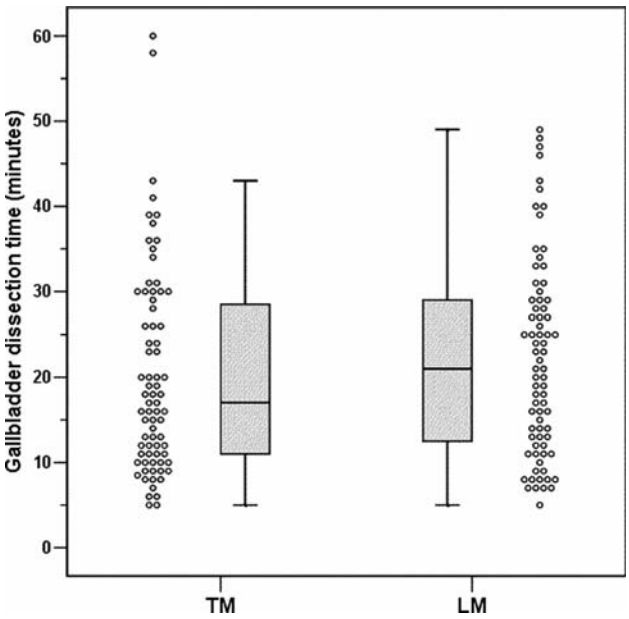

Fig. 3 Distribution and boxplot of gallbladder dissection time for TM and LM groups

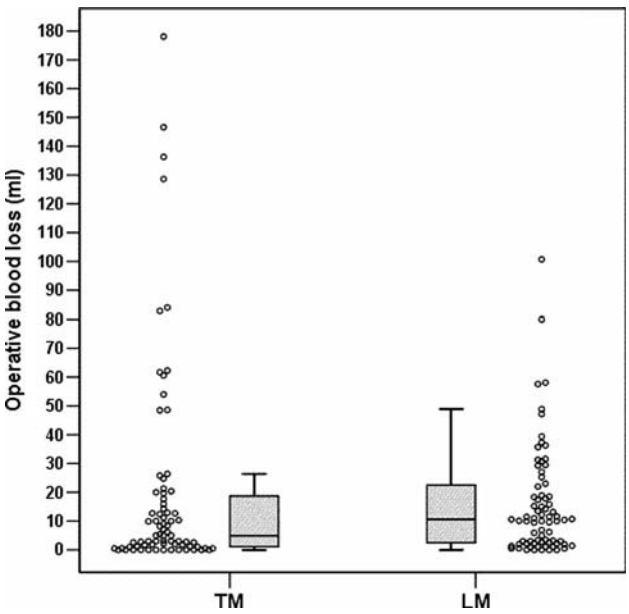

Fig. 4 Distribution and boxplot of operative blood loss for TM and LM groups (one extreme value of 925 ml from the LM group is not shown)

laparoscopic cholecystectomy was not all due to inadequate hemostasis during ultrasonic dissection. Some of the blood loss would have arisen from blunt or nonenergized tissue dissection. The exact proportion of blood loss from nonenergized tissue dissection was difficult to determine in each case. The 95% confidence interval for the difference in median operative blood loss was −1.3 ml to +9.5 ml in favor of TM. It is likely that this falls within a consensus range for noninferiority.

During this study, it has been observed that hemostasis on the gallbladder fossa could sometimes be difficult to achieve using the ultrasonically activated devices, despite repeated applications. This is mainly due to the inability of the devices to grasp liver tissue on a flat or concave surface. In such circumstances monopolar electrosurgery was used (13% in TM group, 17% in LM group) and found to be more effective. Our results for both TM and LM compared favorably to the previous report by Janssen et al. in which a much higher proportion of procedures performed with ultrasonic dissection "hook" (41%) used electrosurgery to stop small bleeds [5]. Alternatively or additionally, Surgicel® was applied to the oozing areas that could not be satisfactorily controlled with energy devices (5% in TM group, 13% in LM group). In one patient (LM group), there was massive hemorrhage (925 ml blood loss) caused by a bleeding artery that was controlled with laparoscopic suturing.

Full axial rotation of the blade is an advantage of LM to optimize visualization and protect important structures from risk of contact with the active blade. In addition, the back of the Harmonic Scalpel® blade has been designed to enable cutting, and the tip of the blade can be used to drill holes into tissue. The lack of axial rotation in the TM did not pose a significant problem for this operation because the range of comfortable wrist movement exceeds 180° and, in most situations, is adequate to provide the desired degree of rotation. The manufacturer has recently launched a newer version of torsional mode shears with a curved blade and 200° of axial rotation.

The surgeons who performed the operations in this study varied from experienced laparoscopic surgeons to trainee surgeons, reflecting the actual workforce in the surgical department performing this type of procedure. The experience of surgeons in the two groups was very similar, and case matching for this variable has not been necessary.

Conclusions

The present study concluded that torsional mode ultrasonically activated device LOTUS™ is similar in effectiveness and safety to the linear mode Harmonic Scalpel® as convincing evidence for superiority has not been demonstrated. There is, however, a cost benefit for using LOTUS™ compared with the Harmonic Scalpel®.

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