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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Laparoscopic cholecystectomy by ultrasonic dissection without cystic duct and artery ligature

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Abstract
Background: Laparoscopic cholecystectomy (LC) is the gold standard treatment of gallstones. Nevertheless, there are some pitfalls due to the limits of current technology and the use of inappropriate ligature material, with a relevant risk of injuries and postoperative, mainly biliary, complications. Ultrasonically activated scissors may divide both vessels and cystic duct, with no need of further ligature, and possibly reduce the risk of thermal injuries.
Methods: A prospective nonrandomized clinical trial was started in 1999 to test harmonic shears (Ultracision, Ethicon Endo-Surgery, Cincinnati, OH, USA) in 461 consecutive patients undergoing LC in order to evaluate the theoretical benefits of ultrasonic dissection and the possible reduction in intraoperative bile duct injuries (BDIs) and postoperative complications. Patients were divided in two groups: in group 1 (HS; 331 patients) the operation was performed by *Ultracision* (including coagulation–division of cystic duct and artery); in group 2 (LOOP; 130 patients) the cystic duct, after coagulation–division by harmonic scissors, was further secured with an endo-loop. Both groups were further divided into two subgroups: *expert* and *surgeon-in-training*. The following categories of data were collected and analyzed: *individual patient data, indication for laparoscopic cholecystectomy, surgical procedure data* (associated procedures, intraoperative cholangiography, intraoperative complications, length of surgery, and conversion to open), and *postoperative course data* (postoperative morbidity, postoperative mortality, reinterventions, and postoperative hospital stay). Furthermore, biliary complications were analyzed as a single parameter comparing the incidence within groups and subgroups. Cumulative complications (intraoperative and postoperative) were also analyzed as a single parameter comparing their incidence in the series of each surgeon within the *surgeon-in-training* subgroup to the average results of the *expert* subgroup. Finally, length of surgery, postoperative complication rate, and length of postoperative hospital stay within subgroups were analyzed to evaluate the learning curve.
Results: Overall conversion rate was 0.87%. The mean operating time was 76.8 min (median, 70 min) in group 1 and 97.5 min (median 90 min) in group 2. BDI occurred in 1 case (0.32%) in the *surgeon-in-training* subgroup. Overall BDI rate was 0.22% (1/461). The overall incidence of postoperative bile leak was 2.7% (9 patients of subgroup 1 and 1 patient of subgroup 2). Clinical observation with spontaneous resolution occurred in 4 patients, and in 1 case the management consisted in an endoscopic biliary drainage; surgery was requested in the remaining cases. A laparoscopic approach was successfully attempted in all cases. Overall morbidity rate was 8.76% in group 1 and 13.84% in group 2. Rates of major complications, overall biliary complication, and postoperative bile leaks within the *expert* and *surgeon-in-training* subgroup differ significantly ($p = 0.026$, $p = 0.03$, and $p = 0.049$, respectively). There was 1 death (0.22%) due to sepsis that resulted from a small bowel injury by trocar insertion. Mean postoperative stay was 4.28 days for group 1 and 5.05 days for group 2.
*Conclusion:*No significant difference was found in both patient groups regarding postoperative mortality and complications, biliary complications, and especially cystic duct leaks. A retrospective comparison of literature data showed that use of ultrasonic dissection during LC seems to reduce the risk of BDI. Nevertheless, a learning curve in the use of ultrasonic-activated devices is required: a significant differences in postoperative major complications and biliary complications between the expert and the surgeon-in-training subgroups was shown. Furthermore, ultrasonic scissors misuse may cause bowel injuries in patients with severe adhesions, and this could represent a possible limitation for surgical safety.

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Table 1. Overall postoperative complication rate, intraoperative BDIs and BDI-related mortality rates in cumulative series of LCs[a]

Author	Year	No. of patients	Type of study	Overall postop complication rate (%)	Bile duct injury rate (%)	BDI-related mortality rate (%)
Buanes [31]	1996	3,083	MC	NA	0.5	NA
Deziel [31]	1993	77,604	MC	NA	0.84	NA
Gigot et al. [14]	1997	9,959	MC	NA	0.5	0.06 (9)[b]
Gouma [31]	1994	2,932	MC	NA	1.1	NA
Hjelmquist [20]	2000	11,164	MC	10.5	0.51	NA
MacFadyen et al. [27]	1998	112,532	MC	5.4	0.5	0.03 (3.56)
McMahon et al. [28]	1995	136,816	MC	NA	0.5	NA
Regoly-Merei et al. [33]	1998	26,440	MC	NA	0.56	0.02 (4.7)
Richardson [31]	1996	5,913	MC	NA	0.6	NA
Strasberg et al. [38]	1995	124,433	MC	NA	0.52	NA
Targarona et al. [39]	1998	1,670	MC	NA	0.95	0.12 (12)***
Z'graggen et al. [47]	1998	10,174	MC	10.38	0.31	0.03 (9.4)
Total		522,720			0.62	

[a] In Refs. [20] and [47], overall biliary complications (intraoperative and postoperative) respectively are 1.21 and 0.69%
[b] Mortality rate after BDI is shown in parentheses
NA, not available, MC, multicenter study

Key words: Laparoscopic cholecystectomy — Ultrasonically activated devices — Harmonic dissection

Laparoscopic cholecystectomy (LC) is the gold standard treatment of gallstones. The advantages of this surgical approach have been reported by a number of authors, showing both the positive impact of this method on the postoperative quality of the patient's life and its optimal short- and long-term results [25].

Standard laparoscopic cholecystectomy is commonly accomplished by means of specialized instruments (electrosurgical hook or spatula, scissors, and clip-applier) and high-frequency monopolar dissection technology. Laparoscopic cholecystectomy is a safe technique. Nevertheless, there are some pitfalls due to the limits of current technology, technique, and the use of inappropriate ligature material with a relevant risk of injuries and postoperative complications (Table 1) [11–13, 20, 27, 40, 47]. These risks include bile leakage due to the slippage of clips [17, 30], common bile duct (CBD) stone formation due to the migration of ligature material, which may be a potential nidus for mineral and bacterial deposits [9]; deep tissue damage with possible distant tissue damage by high-frequency electrosurgery [34]—this may be unnoticed, involving vascular and biliary structures in the vicinity of the cystic duct and artery [14, 26, 42]; and visceral and solid organ injuries due to frequent instrument exchange, sometimes performed without optic guidance.

Ultrasound dissection technology involves the application of ultrasound within the harmonic frequency range to tissues, thus causing three effects that act synergistically: cavitation, coaptation/coagulation, and cutting. The lateral energy spread is minimal, and the risk of distant tissue damage is lower than that of high-frequency electrosurgery [3, 16, 34]. Recently, researchers have argued that tissue temperature at the point of application is not as low as previously reported, and that the use of ultrasonic dissection in the vicinity of low-flow structures, such as the bile duct, may be dangerous.

We started performing laparoscopic cholecystectomy using the Harmonic Shears (Ultracision, Ethicon Endo-Surgery, Cincinnati, OH, USA) for both dissection and closure/division of the cystic duct and artery, after extensive *in vivo* tests, in order to evaluate the theoretical advantages of ultrasonic dissection. Therefore, in addition to the optic and traction instruments, only one other instrument was used during the entire procedure. The prospective clinical trial was carried out in the Department of Surgery of San Giovanni Hospital in Rome, and the relevant results are herein reported.

Materials and methods

Physical principles and technical features of the ultrasonically activated device

Ultrasonic devices use longitudinal mechanical waves with a frequency higher than 20,000 cycles per second. Piezoelectrical elements expand and contract when electrically activated, converting electrical energy to longitudinal mechanical motion. *Ultracision* (Ethicon Endo-Surgery) has a frequency of 55.5 KHz and an amplitude ranging from 60 to 80 μm.

Two types of harmonic shears available off the shelf were used during the trial: the LCS15 (Ultracision, Ethicon Endo-Surgery), featuring a 10-mm diameter shaft and straight blades with three working positions, and the LCSC5 (Ultracision, Ethicon Endo-Surgery), featuring a 5-mm diameter rotating shaft and curved blades with a fixed working position. Ultrasonically activated shears feature multiple functions: grasping, coagulation, cavitation, cutting, and dissection.

Applied with sufficient power, US waves fragment tissue. Fragmentation is strictly related to the water content of tissue: the higher the water content, the easier the fragmentation. Ultrasonic vibration causes cavitation and separation of tissue in front of the tip. The cavitational effect is due to the backstroke of the blade, which creates low pressure in cells and tissues: hence, fluids in cells and tissues vaporize, cells explode, and tissues expand. Coagulation is accomplished by conversion of ultrasonic energy into localized heat, which has been reported to range from 60 to 100°C [3], is a function of: time–power–pressure–tension, and is improved by decreasing the power output. Because the scissors are not heated, they do not become hot. Higher temperature detected at the tip of the instrument after use is due to heat transfer from tissue to effector (blades): therefore, the coagulum does not stick to the blade. During activation of ultrasonic devices,

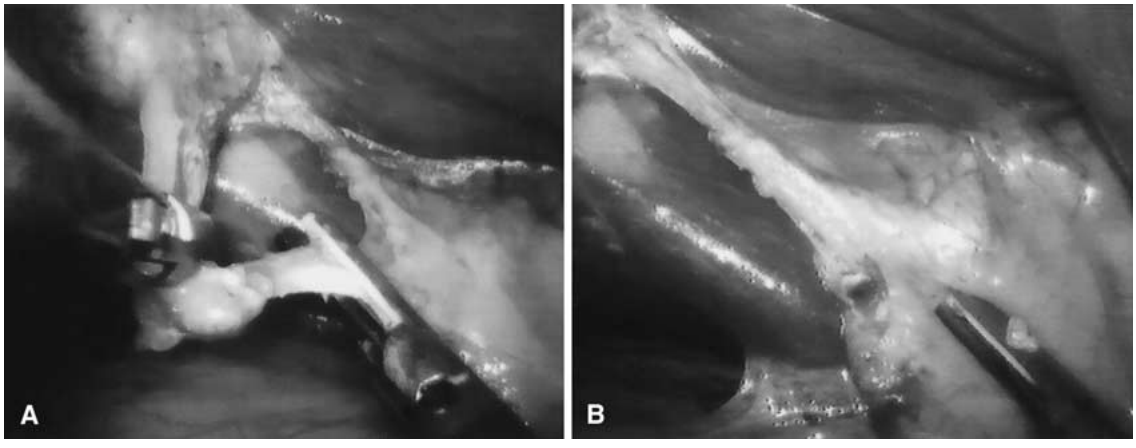

Fig. 1. Coagulation–division of the cystic duct. **A** The duct is held to avoid excessive tension between the jaws of US shears. **B** Final view of the transected duct with its yellowish sealed lumen.

there is no smoke production, no charring, and no debris accumulation, but mist may be generated by vibration.

Patients

A prospective nonrandomized trial was performed from January 1999 to June 2001 and included 461 consecutive patients (295 females and 166 males) aged 14–91 years who underwent laparoscopic cholecystectomy by harmonic dissection. Patients were divided in two groups: group 1 (HS—Harmonic Shears only) consisted of 331 patients who underwent a LC performed by means of *Ultracision* (including coagulation–division of cystic duct and artery); group 2 (LOOP—cystic duct stump reinforced by endo-LOOP application) consisted of 130 patients in whom the cystic duct, after coagulation–division by harmonic scissors, was further secured with an endo-loop of absorbable suture material. Inclusion in the study was determined by the surgeon at the time of surgery based on subjective, technical, or anatomical reasons (e.g., division of the structure occurring too quickly, acute cholecystitis, and dilated cystic duct). In order to evaluate late complications of the biliary tract, a minimum 6-month follow-up was required, and analysis of data began in December 2001. The total number of surgeons who participated in this study was 27 (6 experts and 21 surgeons-in-training). Surgeons with experience in both laparoscopic surgery and the use of *Ultracision* were considered experts, whereas residents, surgeons who performed less than 50 laparoscopic cholecystectomy, and surgeons who had never used ultrasonically activated devices were considered *surgeons-in-training*. Only residents and surgeons who performed less than 50 LCs were supervised by experts. The clinical trial started after formal approval by the hospital ethical committee; all patients were informed about both procedure and technology, and all signed an informed consent form.

Surgical technique

Two 5-mm and two 10-mm ports are placed in the standard position on the upper abdomen, with the patient lying in the supine position with legs apart. The first trocar is inserted with a modified open laparoscopy approach. The surgeon stands between the legs, with the camera assistant on his or her right. The following instruments are employed: a 10-mm, 30° angle view scope, harmonic scissors, grasping forceps (reusable), and a 5-mm suction probe (reusable). The grasping forceps and the 5-mm suction probe are inserted through the right flank 5-mm cannula and the subxiphoid 5-mm cannula, respectively. The forceps is used to grasp the infundibulus, making a rightward traction, and the probe is used to make gentle upward traction at the level of segment IV, thus improving the exposure of Calot's triangle. At this point, all dissection maneuvers are carried out bluntly by means of harmonic scissors, which are used as a dissector, without activation. The cystic artery is prepared and controlled first, then the cystic duct is approached. Coagulation–division of the artery are achieved quickly with both LCS devices (see physical principles and technical features of the ultrasonically activated device). Division of the cystic duct requires a double application of the ultrasonically activated shears. The blades are first applied more proximally for a few seconds to achieve a simple sealing of the lumen, then they are applied a few millimeters distal to the previous application site, holding the grasp until division of the duct is accomplished (Fig. 1). The blades must not be closed with excessive force and tending of the structure by inadvertent traction should be avoided. When the LCS15 device is used, the effective blade is rotated to the flat position to provide a better and wider sealing process. Intraoperative cholangiography was only selectively performed. When requested, it is performed before division–coagulation of the cystic duct, which is dissected free in its whole length: hence, a small opening is created in the wall by holding no more than one-third of the structure between yaws, while the ultrasonic shears are activated. If the LCS15 device is used, the active blade is rotated to the cutting position to better accomplish this task. Closure–division of the cystic duct is then carried out proximal to the opening according to the previously described technique. Gallbladder dissection from the liver bed is carried out as usual. Control of oozing from the liver bed is easily achieved by applying the blades of the ultrasonically activated devices tangentially to tissue. Peritoneal drainage was selectively used for patients with acute cholecystitis, intraoperative bleeding, and opening of gallbladder during dissection. Drainage is usually removed after 24 h.

Endo-loop variant

In cases of severe acute cholecystitis (in which the cystic duct is often very fragile), when the cystic duct is larger than 3 mm (external diameter), or when its division occurs too quickly to guarantee safe sealing of the lumen, after its coagulation–division the duct is further secured by means of an endo-loop of absorbable suture material (polyglactin).

Follow-up

Patients were followed-up at postoperative months 1 and 6. All patients underwent clinical examination, and blood was sampled for bilirubin, aminotransferase, alkaline phosphatase, and γ-glutamiltransferase levels at postoperative month 1. Patients with symptoms or alteration of blood analyses were further investigated with ultrasound scanning.

Analysis of data

Both groups were divided into two subgroups, depending on whether an expert or a surgeon-in-training was performing surgery. Data were collected prospectively by four surgeons in charge using a customized

Table 2. Details of LCs within the study group[a]

	HS		LOOP	
	Expert (155)	In training (176)	Expert (59)	In training (71)
Patient age (years)				
Mean	53.2	54.1	56.6	54.5
Median	54	55	60	54
Emergent procedures	15 (9.68%)	14 (7.95%)	11 (18.64%)	4 (5.63%)
Length of surgery (min)				
Mean	76.44	77.8	100.25	93.54
Median	70	70	90	90
Range	10–242	10–224	30–180	25–300
Indications for cholecystectomy				
Symptomatic gallstones and chronic	98 (63.2%)	124 (70.4%)	25 (42.4%)	37 (52.1%)
Acute cholecystitis	49 (31.6%)	46 (26.1%)	25 (42.4%)	27 (38%)
Gallstones and pancreatitis	4 (2.6%)	3 (1.7%)	3 (5.1%)	2 (2.8%)
Gallstones and CBD stones	4 (2.6%)	3 (1.7%)	6 (10.2%)	5 (7%)
Associated procedures				
Nissen–Rossetti procedure	10			
CBD exploration	3		2	1
Umbilical hernia repair	2			
Adrenalectomy	1	1		
Rendez-vous	2			
Inguinal hernia repair	1			
Appendectomy	1			
Splenectomy	1			
Left colectomy	1			
Ovarian cyst resection	1	1	2	
Omentectomy			1	
Transduodenal papillotomy			1	

[a] HS, LC totally performed by US-activated shears; LOOP, LC with the cystic duct further secured by an endo-loop

database sheet. The following categories of data were collected and analyzed: *individual patient data* (gender and age), *indication for laparoscopic cholecystectomy* (disease or emergent or elective operation); *surgical procedure data* (associated procedures, intraoperative cholangiography, intraoperative complications, length of surgery, and conversion to open), and *postoperative course data* (postoperative morbidity, postoperative mortality, reinterventions, and postoperative hospital stay). Furthermore, biliary complications were analyzed as a single parameter comparing the incidence within the HS and LOOP groups and the expert and *surgeon-in-training* subgroups. Postoperative complications were defined as minor or major according to the Clavien classification [10]. All non-life-threatening complications that required only bedside procedures and did not significantly extend hospital stay were classified as *grade I* and all other complications were classified as *grades II–IV*. Also cumulative major complications (intraoperative and postoperative) were analyzed as a single parameter comparing their incidence within the *surgeon-in-training* subgroup to that of the *expert* subgroup. Furthermore, length of surgery, postoperative complication rate, and length of postoperative hospital stay within the *expert* and *surgeon-in-training* subgroups were analyzed on a year-by-year basis to evaluate the learning curve. Data were analyzed using Statistica for Windows 5.0 software (Statsoft). Student's *t*-test, chi-square, and Yates corrected chi-square tests were used to compare and evaluate statistical differences between groups and subgroups. Fisher's exact test was also used for data analysis of each of the surgeons within the *surgeon-in-training* subgroup. A p value < 0.05 was considered significant. Finally, costs of disposable items used during LC in our department before and during the trial were calculated to evaluate the "financial factor."

Results

There were 216 females and 115 males in group 1 and 80 females and 50 males in group 2. The age range for group 1 was 17–91 years, and that for group 2 was 14–89 years (Table 2).

Forty-four patients were operated on an emergency basis, and 417 patients underwent elective surgery. Table 2 shows the distribution of emergency LC within the *study groups* and the relevant indication for surgery.

In 32 patients, an associated procedure was performed [25 patients in group 1 (7.55%) and 7 patients in group 2 (5.38%)]. 29 (13.55%) patients in the *expert* series and 3 (1.21%) patients of the *surgeon-in-training* series. Also in these cases, the procedure was performed using only the harmonic shears. The reported operating time was calculated to include the time required for associated procedures. The operating time ranged from 10 to 255 min in group 1 (mean, 76.8 min; median, 70 min) and from 25 to 300 min (mean, 97.5 min; median, 90 min), in group 2. Conversion rate was 1.33% among experts and 0.64% among surgeons-in-training. Conversion in the expert series was due to technical problems related to severe distortion of anatomy in both cases, whereas in the *surgeon-in-training* series it was due to CBD injury in one case and uncontrollable bleeding in another case.

Intraoperative cholangiography was attempted in 11 (3.32%) of 331 LCs performed by means of ultrasonically activated scissors and in 15 (11.54%) of 130 LCs with the cystic duct further secured by an endo-loop. In 6 cases, a CBD exploration followed cholangiography, and in no case was intraoperative cholangiography unsuccessful.

The overall morbidity rate was 8.76% (29/331) in group 1 versus 13.84% (18/130) in group 2. According to the Clavien classification, postoperative complications were further categorized as major and minor depending

Table 3. Rates of postoperative complications and biliary complications and length of hospital stay in LCs totally performed by ultrasonically activated shears (HS) and LCs with the cystic duct further secured by an endo-loop (LOOP)[a]

	HS		LOOP	
	Expert (155)	In training (176)	Expert (59)	In training (71)
Complication				
Major complications (grades II–IV)				
Ieal perforation		3 (1.70%)		
Bile leaks (surgical treatment)	1 (0.64%)	3 (1.70%)		1 (1.41%)
Abscess				1 (1.41%)
Pancreatitis (mild)	1 (0.64%)			1 (1.41%)
Chest infection				1 (1.41%)
CBD injury		1 (0.57%)		
Overall	2 (1.3%)	7 (4%)		4 (5.6%)
Minor complications (grade I)				
Bile leaks (conservative management)		1 (0.57%)		
Bile leaks (observation)		2 (1.14%)		2 (2.82%)
Abdominal fluid collection	1 (0.64%)	2 (1.14%)	4 (6.78%)	1 (1.41%)
Subclinical increase in pancreatic enzymes	1 (0.64%)			1 (1.41%)
Pleural effusion		1 (0.57%)		
Respiratory impairment			2 (3.39%)	
Jaundice			1 (1.69%)	1 (1.41%)
Urinary retention	1 (0.64%)	1 (0.57%)		
Fever	5 (3.22%)	6 (3.41%)	2 (3.39%)	
Overall	8 (5.2%)	13 (7.4%)	9 (15.2%)	5 (7%)
Postoperative hospital stay (days)				
Mean	4.4	4.1	5.2	4.9
Median	3	3	3	3
Range	1–35	2–35	2–20	1–64

[a] Complications were graded according to the Clavien classification
[b] One postoperative death

on whether they were potentially life threatening, whether a reoperation was needed to treat them with or without residual disability, and whether hospital stay was prolonged, as a result of them [10]. Differences between groups were not significant (Table 3). No significant difference for bile leak rate was found between groups 1 and 2.

Overall mortality rate was 0.22% (1/461): one LC in the *surgeon-in-training* subgroup in group 1 was complicated by an unrecognized small bowel injury due to trocar insertion (Table 3). Postoperative death occurred after three reinterventions because of sepsis. Mean postoperative hospital stay was 4.28 days in group 1 and 5.05 days in group 2. Differences were not statistically significant. Table 3 shows range, mean, and median postoperative stay of the study groups.

Data concerning the *expert* and *surgeon-in-training* subgroups are presented in Tables 4 and 5. Major complications occurred in 0.93% of patients (2/214) in the *expert* subgroup and in 4.05% (10/247) in the *surgeon-in-training* subgroup, whereas minor complications in the two subgroups occurred in 7.94% (17/214) and 7.29% (18/247), of patients, respectively. The rate of major complications within the *expert* and *surgeon-in-training* subgroups (including 1 case of BDI for which additional surgery was needed during the postoperative course) differs significantly (chi-square test, $p = 0.026$).

One or more reinterventions were required in seven patients: three for cystic duct leaks, one for biliary leakage from the liver bed, two for small bowel perforations, and one for small bowel perforation combined with cystic duct leakage. Thus, a small bowel perforation occurred in three patients: in two cases, it occurred after extensive adhesiolysis for severe adhesions, whereas in one case it was caused by first trocar insertion. Surgery for simple cystic duct leak consisted of relaparoscopy and closure of the cystic duct stump by endo-loop application. Biliary leakage from the liver bed was treated by single stitch through a laparoscopic approach. Direct suture was successfully attempted in one of three bowel injuries. A segmental resection with anastomosis was performed in the remaining cases. The surgical treatment was successful in one case only, whereas additional surgery consisting of a diversion ileostomy was performed in the patient with trocar injury. Reoperations were needed in six patients in the *surgeon-in-training* subgroup and one patient in the *expert* subgroup; however, the difference was not statistically significant.

Biliary complications within subgroups are shown in Table 5. Ten complications occurred in the *surgeon-in-training* subgroup and 1 in the *expert* subgroup: rates of overall biliary complication and bile leaks within the *expert* and *surgeon-in-training* subgroups differed significantly (respectively, chi-square test, $p = 0.01$ and $p = 0.022$; Yates corrected chi-square, $p = 0.03$ and $p = 0.049$). Intraoperative biliary complication occurred in 1 BDI in the *surgeon-in-training* subgroup (0.40%, 1/247). Mortality was nil in the *expert* subgroup and 0.40% (1/247) in the *surgeon-in-training* subgroup.

Only the cost of disposable instruments used during the procedure was considered to evaluate the financial impact of LC by ultrasound dissection. In addition to trocars, standard LC disposable items were one scissors, one clip applier and, in LCs by ultrasound dissection,

Table 4. Details of LCs within the e*xpert* and *surgeon-in-training* subgroups

	Expert (214)	In training (247)
Patient age (years)		
Mean	54.9	54.3
Median	55	55
Emergent procedures	26 (12.15%)	18 (7.29%)
Length of surgery (min)		
Mean	82.7	82
Median	75	75
Range	10–240	10–300
Indications for cholecystectomy		
Symptomatic gallstones	123 (57.48%)	161 (65.18%)
Acute cholecystitis	74 (34.58%)	73 (29.5%)
Gallstones and pancreatitis	7 (3.27%)	5 (2.02%)
Gallstones and CBD stones	10 (4.67%)	8 (3.24%)
Associated procedures		
Nissen–Rossetti procedure	10	
CBD exploration	5	1
Umbilical hernia repair	3	1
Adrenalectomy	2	
Inguinal hernia repair	2	
Rendez-vous	1	1
Appendectomy	1	
Splenectomy	1	
Left colectomy	1	
Ovarian cyst resection	1	
Omentectomy	1	
Transduodenal papillotomy	1	

Table 5. Rates of postoperative and biliary complications and length of hospital stay within the *expert* and the *surgeon-in-training* subgroup[a]

	Expert (214)	In training (247)
Postoperative complications		
Major complications (grades, II–IV)		
Ileal perforation		3 (1.21%)[b]
Bile leaks (surgical treatment)	1 (0.47%)	4 (1.62%)
Abscess		1 (0.4%)
Pancreatitis (mild)	1 (0.47%)	1 (0.4%)
Chest infection		1 (0.4%)
CBD injury		1 (0.4%)
Overall	2 (0.93%)	11 (4.4%)
Minor complications (grade I)		
Bite leaks (conservative management)		1 (0.4%)
Bile leaks (observation)		4 (1.62%)
Abdominal fluid collection	5 (2.33%)	3 (1.21%)
Subclinical increase in pancreatic enzymes	1 (0.47%)	1 (0.4%)
Pleural effusion		1 (0.4%)
Respiratory impairment	2 (0.93%)	
Jaundice	1 (0.47%)	1 (0.4%)
Urinary retention	1 (0.47%)	1 (0.4%)
Fever	7 (3.27%)	6 (2.43%)
Overall	17 (7.9%)	18 (7.3%)
Postoperative hospital stay		
Mean	4.6	4.2
Median	3	3
Range	1–35	1–64

[a] Complications were graded according to the Clavien classification
[b] One postoperative death

one harmonic shears. Compared with standard LC the costs for disposable instruments were similar: approximately 430 Euro for the harmonic shears vs approximately 427 Euro for the combination of scissors and clip applier. When an endo-loop was used to further secure the cystic duct, the cost increased by approximately 23 Euro.

Discussion

Nonabsorbable suturing material has been always avoided in biliary tract surgery. With the advent of LC, closure of the cystic duct by metal clips has become a routine procedure due to its ease. Nonetheless, there are reports of both clip slippage and migration into the

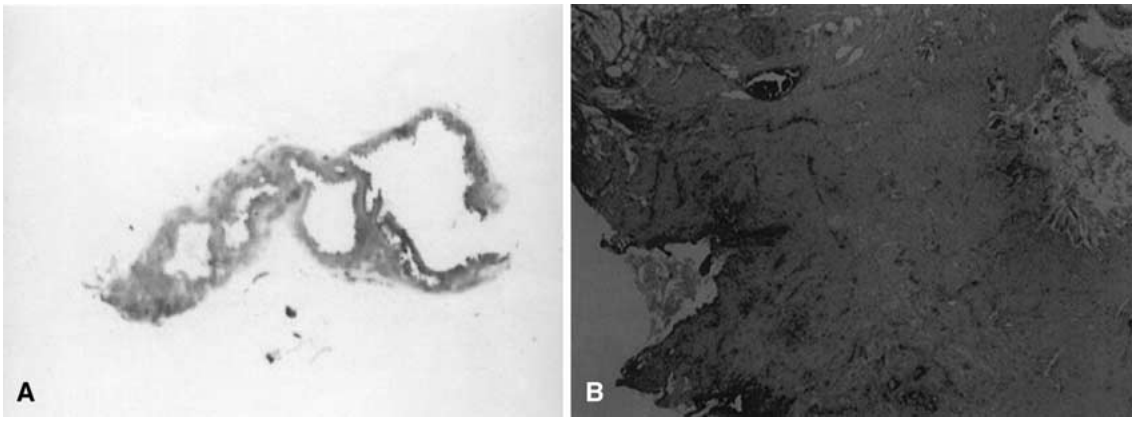

Fig. 2. Histologic pattern of the cystic duct stump after coagulation–division by ultrasonically activated shears (sagittal section). The lumen is sealed by a welding process due to collagen denaturation (hematoxilin and eosin stain).

biliary tract [2, 17, 23, 30, 35]. Furthermore, CBD stone formation due to migration of various mono- and polyfilament ligature materials has also been reported [9].

The characteristics of the ultrasonically activated shears described previously make the use of this instrument in laparoscopic procedures promising in terms of ergonomics and safety. There have been other reports on the use of ultrasonically activated devices during LC [32, 37, 41], in which the harmonic scalpel or shears were employed for dissection only or for dividing the cystic artery. In 1999, the use of ultrasonically activated shears for both dissection and closure–division of the cystic duct and artery was first reported [21]. The current study was performed to determine the possible role of ultrasonically activated scissors in LC, mainly focusing on the reduction of BDIs and biliary complication. Ultrasonic shears have proven effective in a number of advanced laparoscopic procedures, providing better control of oozing from dissected tissues and making the procedures more expeditious. Long-lasting application of ultrasonic energy on vessels causes collagen in the wall to denature and seal the lumen. Application of ultrasonic energy to other hollow structures, such as the cystic duct, has been proven to have similar tissue effects [21].

Histology examination of the cystic duct clearly showed the sealing of the lumen caused by collagen homogenization with resulting distortion of glands profile, epithelial detachment, cell welding, nuclear lengthening, and nuclear chromatin homogenization. Fissures and cavitation effects may be visible on the cutting edge (Fig. 2) [21]. All morphological changes were found within 1.5 mm from the cutting edge. The airtight pressure of the sealed cystic duct was calculated to be higher than 320 mmHg in the first 50 cases [21].

A review of the English literature published from 1992 to 2001 regarding the incidence of intraoperative BDIs during LC showed rates ranging from 0 to 1.28% [7, 12, 14, 20, 24, 27, 28, 31, 33, 38, 39, 44, 47]. Considering the data from most of the largest cumulative series published in the past 10 years, we may assume that 0.60% rate of intraoperative BDI is a realistic value that mirrors the overall results of LCs worldwide (Table 1) [20, 27, 33, 47]. Furthermore, treatment of biliary tract injuries is often challenging for surgeons [31], may result in severe disability for patients, and has a mortality rate that has been reported to range from 3.56 to 12% [14, 27, 33, 39, 46, 47].

The incidence of BDI during LC is higher than that in open cholecystectomy [8, 14, 18, 36, 43], in which rates less than 0.25% have mostly been reported (range, 0.1–0.6%) [4, 15, 29, 40]. Therefore, improvement of safety standards in LC depends strictly on the decrease of biliary tract injuries. BDI incidence in our trial was 0.22%, comparable to the rate of open cholecystectomy.

In terms of safety, the main advantage of LC by means of ultrasonically activated shears is low-risk dissection in the proximity of biliary structures. Considering that thermal injuries account for no more than 30% of all major BDIs, other mechanisms should be advocated to explain the reduction of BDI in our series. The following important technical maneuvers may help prevent BDI: exposure of the Calot's triangle, identification and dissection of the gallbladder–cystic duct junction and CBD, and lateral traction of the gallbladder neck to avoid tenting of the bile duct. Also, inadequate application of metal clips may cause BDIs, and continuous instrument change may disturb the surgeon because he or she must look away from the operating field. Ultrasound dissection allows the surgeon to work in an almost bloodless field, which enhances discrimination of anatomical structures.

Bile duct lesions caused by coagulation–division with harmonic scissors may be wider than lesions after sharp division with standard scissors, but the bile duct wall is injured less than it is by monopolar electrocautery.

Conversion rate was lower than rates reported in the literature: 0.87% (4/461) compared to 1.2–8.2% in other series [5, 33, 39, 40]. The reason for conversion differs between the two subgroups: in the *surgeon-in-training* subset of LC, conversion was due to intraoperative complications, whereas inability to recognize anatomical structures or the presence of severe adhesions due to previous surgery caused conversion in the expert series.

No significant differences were found between the two groups. However, the majority of emergent procedures occurred in group 2.

Intraoperative cholangiography was not performed as a routine procedure in this trial; which is standard protocol of LC in our department. Increased values of bilirubin, γ-glutamiltransferase, and alcalyne phosphatase and a dilated cystic duct or bile duct on preoperative ultrasound scan are indications for selected intraoperative cholangiography; unclear anatomy at LC is an indication for intraoperative cholangiography as well.

Overall complication rate is similar to that reported by others [1, 12, 20, 27, 40, 47]. Complications occurred more often in group 2, in which the incidence of acute cholecystitis and emergent procedures was higher (13.84 vs 8.76% in group 1). The rate of minor complications was slightly higher than in other reports; this could be due to the type of trial and the prospective method of registration of every minor accident in the postoperative course [20].

The length of surgery in the *expert* and *surgeon-in-training* subgroups was similar. This was mainly due to the greater number of associated and emergent procedures in the *expert* subgroup and to the fact that the most difficult cases were treated by expert surgeons.

Postoperative bile leaks occurred in 2.17% of patients. Nine of 10 patients with postoperative bile leaks were operated on by surgeons-in-training: bile leak rate was significantly higher in this subgroup ($p = 0.022$; Yates corrected, $p = 0.049$). Five cases were treated conservatively—by clinical observation (4) or endoscopic sphincterotomy and biliary drainage (1). No minor leaks significantly affected postoperative hospital stay; in the 4 cases under clinical observation, the bile leak resolved spontaneously within 36–72 h. Exceeding accuracy in dissecting free the cystic duct has been advocated as the main reason for postoperative bile leaks [40]; the method of application of the ultrasonically activated shears for closure–division of cystic duct requires an extended cleaning of this structure and could explain the high incidence of such a complication in the *surgeon-in-training* series. Comparing overall results to those reported by others, use of ultrasonically activated shears does not seem to reduce the incidence of postoperative bile leaks [6, 19, 22, 44, 45].

Two crucial aspects regarding the use of ultrasonically activated devices during laparoscopic cholecystectomies are the modality of application of ultrasonic scissors and the presence of severe adhesions. The surgeon must become familiar with the instrument and avoid maneuvers such as pointing the tip toward delicate structures or touching them with the active blade immediately after use. Cavitation could cause injuries to organs, vessels, and ducts ahead of the instrument's tip and the active blade (which becomes hot after use) could endanger the bile duct, the gallbladder, or the bowel. Correct application of the ultrasonically activated shears onto the cystic duct is mandatory to avoid subsequent leakage.

Use of ultrasonic shears may be dangerous in the presence of severe visceral adhesions. In such cases, the hot active blade may cause thermal injuries to the bowel during dissection that are not easily recognized since there is neither change of color nor charring in damaged tissues. Two of the three bowel injuries that occurred in the *surgeon-in-training* series were due to instrument misuse: adhesiolysis performed with the active blade in contact with the bowel wall or bowel grasping immediately after instrument use with a still hot active blade. The 2.17% overall postoperative complication rate in our series comprised systemic complications not strictly related to the surgical technique: pancreatitis and respiratory complications were the most frequent, as similarly reported by other authors [47].

Postoperative death in our series was not related to the use of ultrasonically activated shears but occurred in a patient with previous gastric surgery with unnoticed bowel injury by first trocar insertion.

The long postoperative hospital stay in our trial was due to the number of associated procedures and a logistic factor. In fact, the majority of patients were referred to us from distant areas. In these cases, patient discharge was not considered advisable since a proper early postoperative survey would have not been guaranteed.

Both operating time and postoperative stay are affected by many variables (e.g., associated procedures, emergent procedures, difficult or high-risk cases selected for the *expert* subgroup); therefore, a comparative analysis of overall results in the two subgroups did not show any relevant differences. Comparative analysis on a year-by-year basis was carried out to evaluate the existence of a learning curve. Analysis of median operating time in the *surgeon-in-training* subgroup on a year-by-year basis showed a reduction from 80 to 62.5 min, whereas no significant reduction was found in the *expert* subgroup, as was expected.

Our data show a high level of safety for use of ultrasonically activated shears in the vicinity of the biliary structures. Nevertheless, as reported by Cuschieri, the temperature of the active blade after extensive use is probably higher than reported in initial studies [3, 16] and there may be risk of thermal injury by instrument misuse. Also, it may be argued that delayed biliary complications can occur after LC by means of ultrasonically activated shears. Nevertheless, at follow-up (6-month maximum) none of our patients suffered from postoperative biliary stricture as determined by ultrasound scan.

A learning curve in the use of ultrasonic shears does exist. Our data highlight two points. First, most likely, the learning curve within the *surgeons-in-training* subgroup was not completed during the trial because of the number of participating surgeons and the small number of LCs performed by some of them. Second, it is not possible to assess the real impact of the learning curve on our results since 16 of the surgeons-in-training started performing LC during this trial and performed fewer than 20 LCs as a whole; therefore, they were in the learning curve phase of LC as well. Major complications in the *surgeon-in-training* subgroup occurred during or after operations performed by four surgeons who had performed fewer than 20 LCs and by three surgeons who had performed many LCs but used the ultrasonic shears for the first time.

In addition to its safety, ultrasonically activated scissors enhance the overall ergonomics of surgery by

allowing the surgeon to work with both hands while focusing on the operating field throughout the operation without continuously changing instruments. Repeated instrument changes are typical of LC, in which dissector, scissors, and clip applier are all needed to accomplish the operation. This may lead to either unsafe maneuvers performed without optic guidance or frequent change of laparoscope direction to follow instrument insertion.

Finally, it has been said that ultrasonically activated devices are a too expensive to be employed for such a simple procedure as LC, which may have a poor cost: benefit ratio. Because of problems related to sterilization and their higher efficacy and ease of use, the standard policy in our operating theater is to employ disposable instrumentation for tissue dissection and division and for closure of structures. Cost analysis of disposable devices and consumables in standard LC and LC by ultrasound dissection did not show any significant difference.

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