Effectiveness of the LigaSure Small Jaw Vessel-Sealing System in Hepatic Resection

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ABSTRACT

Background In hepatic resection for liver tumors, reducing operation time and blood loss are important for postsurgical complication prevention. This study aimed to compare the safety and efficacy of the LigaSure Small Jaw (Covidien, Boulder, CO) with those of the Cavitation Ultrasonic Surgical Aspirator (CUSA) system (Integra Life Sciences, Plainsboro, NJ) in hepatic surgery.

Methods We enrolled 102 patients with liver tumors, of whom 51 underwent liver resection with the CUSA (CUSA group) between March 2004 and April 2011. Another 51 underwent resection with the LigaSure Small Jaw (LS group) between June 2011 and July 2012. We stratified patients by time period depending on the instrument used, and compared operative duration; intraoperative bleeding; and postoperative liver function and complication rate.

Results Total operation time (mean \pm SD) was significantly shorter in the LS group than in the CUSA group (358.8 \pm 91.7 versus 460.6 \pm 146.1 min, P < 0.001). Blood loss was not significantly different between the 2 groups. Frequency of postoperative complications was lower, but not significantly, in the LS group.

Conclusion The LigaSure Small Jaw may allow a shorter total operative duration than the CUSA device.

Key words blood loss; LigaSure Small Jaw; liver resection; operative time

In recent years, vessel-sealing systems have been developed and used widely in the fields of urologic, gynecologic, and gastrointestinal surgery. Our department previously used the Cavitation Ultrasonic Surgical Aspirator (CUSA) (Integra Life Sciences, Plainsboro, NJ) for liver resection. Under this system, liver resection generally comprises two separate procedures: First, crushing of the liver parenchyma and subsequent aspiration of the crushed tissue and blood to expose the intrahepatic vessels; and second, ligation or sealing of the exposed vessels, which is typically achieved by manual ligation, clips, or electrocautery.

The use of LigaSure instruments confers several advantages, including sealing of the intrahepatic vessel

without foreign bodies such as clips, a smaller number of ties required to complete the procedure, and the ability to close vessels that are of larger diameter, up to 7 mm, than those that can be closed by electrocautery. These procedures are all performed using a single instrument.

In February of 2011, the LigaSure Small Jaw (Covidien, Boulder, CO) (Fig. 1) was introduced as the newest instrument in the LigaSure family of advanced surgical vessel-sealing devices with a cutting blade. The instrument is a manual device 18.8 cm in length that is designed to be used in confined surgical spaces where access and visibility are limited. This instrument is designed for open surgery, offers the ability selectively to cut or grasp tissue and permanently seal vessels up to and including those 7 mm in diameter, lymphatic vessels and tissue bundles without sutures, staples or clips.

We considered the features of this instrument to resemble those of a Pean clamp, which is used to perform crimping and crushing. Although the LigaSure Small Jaw is somewhat wider than a Pean clamp, the device can be effectively used to crush liver parenchyma. More importantly, liver resection is known to have a relatively high risk of intraoperative hemorrhage; therefore, bleeding must be strictly controlled.

Studies evaluating the advantages of LigaSure instruments compared with the conventional clump crushing method have demonstrated reduced blood loss during liver resection; 6-8 however, LigaSure Small Jaw has not yet been evaluated with respect to a reduction in blood loss in liver resection. LigaSure Small Jaw is a smaller size than conventional LigaSure instruments, and it is easy to handle and manage, similar to the conventional clump crashing method. We expected that the device would reduce the amount of bleeding in laparotomy for liver resection.

We have found the LigaSure instrument to confer distinct advantages, including control of bleeding, crush-

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Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; CUSA, Cavitation Ultrasonic Surgical Aspirator; LS, LigaSure



Fig. 1. LigaSure Small Jaw (Covidien; Boulder, CO). Left: whole image of the vessel (18.8 cm in length). Right: enlarged image of the vessel head when the vessel is in an opened state, viewed from the bottom of the vessel head.

ing ability similar to that of a Pean clamp, and the ability to seal and cut almost simultaneously during liver transection. We therefore switched from the CUSA to the LigaSure Small Jaw in June of 2011. The goal of this study was to compare the safety and efficacy of the LigaSure Small Jaw vessel-sealing system with those of the CUSA in liver resection.

MATERIALS AND METHODS

This was a retrospective study of 225 patients who underwent hepatic resection at our institution between March 2004 and July 2012. Patients were assigned to groups treated with liver resection with the CUSA device (CUSA group, n = 51) from March 2004 to April 2011, or the new LigaSure Small Jaw vessel-sealing system (LS group, n = 51) from June 2011 to July 2012. Between March 2004 and April 2011, we performed all operations using the CUSA. Patients were consecutively selected during the trial period, but excluded if they had undergone laparoscopic liver resection, or were missing data related to pre- or post-operative liver function. This resulted in 102 patients being chosen to be analyzed in this study. The difference in the recruitment period for the CUSA and LS groups is a result of the increase in operations for liver cancer in recent years; our institution had more patients in the latter period compared with those in the former period.

Surgical technique

Two surgeons (K. E. and Y. H.) alternately performed all operations in this study. No patient was specifically assigned to either doctor. Liver transection was achieved using primarily either the CUSA or LigaSure Small Jaw. In both groups, water-cooled bipolar forceps and the VIO BiClamp (ERBE GmbH, Tübingen, Germany) were used in combination. The Pringle maneuver was performed

intermittently with 15 min of clamping and 5 min of unclamping, patients were excluded if the intestinal adhesion proximal to the hepatoduodenal ligament was severe.

In the CUSA group, liver parenchyma was crushed using the CUSA device and exposed vessels were successively manually ligated or clipped, then sealed and cut. In contrast, the LigaSure Small Jaw was used to crush liver parenchyma similarly to using a Pean clamp, seal residual vessels up to about 7 mm in diameter and complete dissection throughout the procedure. All procedures, such as abdominal section, detaching and unfolding liver, washing surgical field, indwelling drain tube and abdominal closure, were similarly performed throughout the operations between the 2 groups.

Surgical outcomes

Surgical outcomes included operative duration, intraoperative blood loss and postoperative variables. Postoperative variables were liver function and complications. Postoperative liver function was assessed by measuring laboratory data on postoperative days 1, 3, 5 and 7. Of these data, the maximum transaminase value, maximum bilirubin value and minimum albumin value were used for analysis.

Statistical analysis

Quantitative variables were compared using analysis of variance. Comparisons between groups were performed using the chi-square test and Student's t-test. All data are expressed as the mean \pm SD. P < 0.05 was considered to represent statistical significance.

RESULTS

Characteristics of the 102 patients are presented in Table 1. The LS group was older than the CUSA group (P < 0.05). No statistically significant differences were found between the 2 groups for clinical features, in-

Table 1. Background characteristics

| | CUSA group | LS group | P |
|---|-------------------------|--------------------------|----------|
| Number of patients | 51 | 51 | |
| Duration of use | Mar. 2004-Apr. 2011 | Jun. 2011-Jul. 2012 | |
| Sex (male/female ratio) | 38/13 | 43/8 | 0.3273† |
| Age, mean \pm SD [range], yr | $63.9 \pm 11.2 [40-81]$ | $68.9 \pm 9.9 [46 - 85]$ | < 0.05†† |
| Background liver | | | |
| Hepatitis B | 19 (37.2%) | 23 (45.1%) | 0.2911† |
| Hepatitis C | 17 (33.3%) | 10 (19.6%) | |
| Others | 15 (29.4%) | 18 (35.3%) | |
| Cause of disease | | | |
| Hepatocellular carcinoma | 33 (64.7%) | 33 (64.7%) | 0.9286† |
| Metastatic liver tumor | 13 (25.5%) | 14 (27.5%) | |
| Cholangiocarcinoma | 5 (9.8%) | 4 (7.8%) | |
| Pathological findings of non-cancerous region | | | |
| Normal liver (nl) | 13 (25.5%) | 11 (21.6%) | 0.3301† |
| Chronic hepatitis (ch) | 26 (51.0%) | 32 (62.9%) | |
| Liver cirrhosis (lc) | 12 (23.5%) | 8 (15.7%) | |
| Preoperative liver function, mean \pm SD | | | |
| Total bilirubin, mg/dL | 0.73 ± 0.27 | 0.74 ± 0.26 | 0.9412†† |
| Aspartate aminotransferase, U/L | 40.1 ± 49.9 | 36.8 ± 21.6 | 0.6607†† |
| Alanine aminotransferase, U/L | 36.3 ± 28.8 | 32.7 ± 23.2 | 0.4177†† |
| Albumin, g/dL | 3.97 ± 0.44 | 4.01 ± 0.40 | 0.2165†† |
| Indocyanine green retention, % | 12.6 ± 5.9 | 13.8 ± 6.1 | 0.3754†† |
| Type of hepatectomy | | | |
| Partial hepatectomy | 14 (27.5%) | 9 (17.6%) | 0.2391† |
| Subsegmentectomy | 8 (15.7%) | 4 (7.8%) | |
| One hepatic segmentectomy | 11 (21.6%) | 18 (35.3%) | |
| Two hepatic segmentectomy or over | 18 (35.3%) | 20 (39.2%) | |

CUSA group, group treated with the Cavitation Ultrasonic Surgical Aspirator system; LS group, group treated with the LigaSure Small Jaw system.

Statistics: †chi-square test; ††Student's t-test.

Table 2. Operative duration

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|---------------------------------|-------------------------------|----------------------------|----------|--|
| | CUSA group | LS group | P | |
| Operative duration [range], min | $460.6 \pm 146.1 [160 - 803]$ | $358.8 \pm 91.7 [177-630]$ | < 0.0001 | |
| Non-cancerous region | | | | |
| Non-cirrhosis (nl/ch) | 442.7 ± 1498.8 | 350.9 ± 95.3 | < 0.005 | |
| Cirrhosis (lc) | 518.8 ± 121.2 | 401.0 ± 56.3 | < 0.05 | |

Data, mean ± SD.

ch, chronic hepatitis; CUSA group, group treated with the Cavitation Ultrasonic Surgical Aspirator system; lc, liver cirrhosis; LS group, group treated with the LigaSure Small Jaw system; nl, normal liver. Statistics: Student's *t*-test.

cluding condition of the livers (cirrhotic versus noncirrhotic), cause of disease, pathological findings of noncancerous regions and preoperative liver function; or for type of hepatectomy.

Operative duration is shown in Table 2 and total blood loss is shown in Table 3. The entire operative duration was 460.6 ± 146.1 min (range, 160-803 min) for the CUSA group and 358.8 ± 91.7 min (range, 177-630 min) for the LS group. Total operative duration was significantly shorter in the LS group for both non-cirrhotic (P < 0.005) and cirrhotic (P < 0.05) livers.

There was less intraoperative blood loss in the LS group (681.7 \pm 543.7 mL; range, 34–2,500 mL) than in the CUSA group (894.0 \pm 856.2 mL; range, 20–3,710 mL) but the difference was not statistically significant.

Postoperative liver function parameters for each group are listed in Table 4. Among these outcomes, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) were much higher after procedures using the LigaSure Small Jaw than in those using the CUSA. Postoperative total bilirubin and albumin were not statistically different between the 2 groups.

Table 3. Intraoperative blood loss

| | CUSA group | LS group | P | |
|---------------------------------------|-------------------------|-----------------------------|--------|--|
| Intraoperative blood loss [range], mL | 894.0 ± 856.2 [20–3710] | $681.7 \pm 543.7 [34-2500]$ | 0.1641 | |
| Non-cancerous region | | | | |
| Non-cirrhosis (nl/ch) | 817.3 ± 822.7 | 672.2 ± 552.2 | 0.3733 | |
| Cirrhosis (lc) | 1143.3 ± 951.5 | 733.1 ± 527.7 | 0.3459 | |

Data, mean ± SD.

ch, chronic hepatitis; CUSA group, group treated with the Cavitation Ultrasonic Surgical Aspirator system; lc, liver cirrhosis; LS group, group treated with the LigaSure Small Jaw system; nl, normal liver.

Statistics: Student's *t*-test.

Table 4. Postoperative liver function

| | CUSA group | LS group | P |
|---------------------------------|-------------------|-------------------|---------|
| Total bilirubin, mg/dL | 1.82 ± 1.14 | 1.91 ± 1.17 | 0.4329 |
| Aspartate aminotransferase, U/L | 442.5 ± 259.6 | 683.7 ± 500.6 | < 0.005 |
| Alanine aminotransferase, U/L | 356.6 ± 253.1 | 599.9 ± 439.0 | < 0.001 |
| Albumin, g/dL | 2.75 ± 0.34 | 2.66 ± 0.35 | 0.1726 |

Data, mean \pm SD.

CUSA group, group treated with the Cavitation Ultrasonic Surgical Aspirator system; LS group, group treated with the LigaSure Small Jaw system.

Statistics: Student's t-test.

Table 5. Postoperative complications

| • | • | | | |
|-------------------------|------------|----------|-----------|----------|
| | CUSA group | LS group | Total | P |
| Bile leakage | 8 (15.7%) | 2 (3.9%) | 10 (9.8%) | 0.0539 |
| Bile duct stenosis | 0 (0.0%) | 1 (2.0%) | 1 (1.0%) | > 0.9999 |
| Pleural fluid | 3 (5.9%) | 4 (7.8%) | 7 (6.9%) | > 0.9999 |
| Wound infection | 4 (7.8%) | 2 (3.9%) | 6 (5.9%) | 0.6779 |
| Intraperitoneal abscess | 3 (5.9%) | 1 (2.0%) | 4 (3.9%) | 0.6175 |
| Pneumonia | 0 (0.0%) | 1 (2.0%) | 1 (1.0%) | > 0.9999 |

CUSA group, group treated with the Cavitation Ultrasonic Surgical Aspirator system; LS group, group treated with the LigaSure Small Jaw system.

Statistics: Student's t-test.

Postoperative complications occurred in 18 patients in the CUSA group and in 11 patients in the LS group (Table 5). Eight patients (13.9%) in CUSA group and 2 patients (5.6%) in LS group experienced bile leakage, with a difference that was not significant. Other complications, including bile duct stenosis, pleural fluid, wound infection, intraperitoneal abscess and pneumonia, were not significantly different between the 2 groups.

DISCUSSION

A randomized clinical trial comparing ultrasonic with manual clamp transection of the liver showed no difference in blood loss or operation time. In our practice, exposure of vessels and bile ducts using the CUSA required a great deal of time, whereas the LigaSure Small Jaw made it possible to expose residual vessels by

crushing, then sealing and cutting a vessel using a single device, which greatly reduced performance time. For safety, the most challenging exposures of major hepatic veins and Glisson's capsule were performed using a Pean clamp.

This study shows that the LigaSure Small Jaw can be safely used during liver parenchymal resection and significantly reduces the operation time for liver resection compared with the CUSA device. This result represents an operative duration approximately 100 min shorter for the LS group than for the CUSA group (P < 0.0001). Shortening the operation time in liver resection has been demonstrated in previous studies using conventional LigaSure, but not yet with the newest device, LigaSure Small Jaw. Time reduction was also observed for resection of cirrhotic livers, which are difficult to sever by the crush-clamp technique using a Pean clamp

and often difficult to achieve hemostasis. An advantage of using the LigaSure is that sealing of blood vessels does not require direct exposure, which can increase operative time and cause unnecessary bleeding.

Previous studies have demonstrated that using LigaSure instruments reduced the amount of blood loss in liver resection compared with conventional clump crash methods.^{6–8, 10} However, Dokelstic et al. compared 3 instruments, the clamp crushing method, CUSA and LigaSure in liver resection, and found no difference in the intraoperative blood loss between the groups.¹¹

A study comparing the LigaSure Small Jaw with conventional suture ligation in thyroidectomy showed intraoperative blood loss to be statistically significantly less for the LigaSure Small Jaw.¹² Although this single study showed a reduction in blood loss by the LigaSure Small Jaw in thyroidectomy, this device had not yet been evaluated in liver resection.

Our results showed that total blood loss in patients with non-cirrhotic liver in the LS group was approximately 20% less than in the CUSA group, and in patients with cirrhotic liver, blood loss in the LS group was also 20% less than in the CUSA group. However, these data were not significantly different. LigaSure's advantage over CUSA with respect to mitigating bleeding has not yet been demonstrated.

Postoperative transaminase was considerably higher in the LS group than in the CUSA group. In one study, LigaSure diathermy was shown to be associated with significantly higher transaminase levels than conventional techniques.7 According to those authors, the scalded liver parenchyma on the cut surface may have explained this increase, as the maximum AST value was significantly correlated with the resection time and area. Follow-up computed tomography revealed the burned area on the cut surface on the liver. In that study, the levels of AST and ALT were not significantly different on postoperative day 5 between the 2 groups, and were nearly the same level on postoperative day 7. In this study, we also demonstrated that the level of these enzymes were similar on postoperative day 5 between the 2 groups (date not shown). An explanation for this may be that the damage to scalded liver parenchyma resolved over time and transaminases reverted to normal levels.

In a study examining and comparing 4 sealing devices, including LigaSure instruments, the degree of lateral thermal spread of the LigaSure instruments was 55.5 °C, 2 mm away from the cut surface. ¹³ This supports the hypothesis that tissue was burned by thermal spread with the devices, which caused increased postoperative transaminase levels.

Among postoperative complications, an increased risk of bile leakage had been identified as a possible

defect of the vessel-sealing system, 14, 15 whereas several studies have shown a decreased rate of this complication in the LigaSure instrument groups. 6, 16, 17 Comparison of postoperative bile leakage between LigaSure and conventional-method groups was reported in 3 randomized controlled trials^{6, 11, 18} and 3 non-randomized studies.^{8, 16, 19} The overall risk of bile leakage was 63% lower in the LigaSure groups than in the conventionalmethod groups (odds ratio 0.37; 95% confidence interval 0.17-0.78; n = 559). This outcome supports the theory that an advantage of the LigaSure is its ability to seal both biliary and vascular structures. Our results confirm this, showing a low incidence of bile leakage associated with the use of the vessel-sealing system. Our results did not statistically demonstrate the efficacy in reducing bile leakage in the LS group, which was presumably because the number of occurrences was too small for comparison; however, our results do suggest the LigaSure Small Jaw can potentially reduce the incidence of bile leakage.

The LigaSure Small Jaw Instrument was superior to the CUSA in terms of shortening operative time. It was also better at reducing intraoperative hemorrhage and postoperative complications, but these effects did not reach clinically significant levels. Overall, using LigaSure Small Jaw Instrument can be advantageous in liver resection.

The authors declare no conflict of interest.

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