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ORIGINAL ARTICLE

Comparison of two different transection techniques in liver surgery—an experimental study in a porcine model

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Abstract
Aims Postoperative morbidity and mortality after liver resection is closely related to the degree of intraoperative blood loss; the majority of which occurs during transection of the liver parenchyma. Many approaches and devices have therefore been developed to limit bleeding, but none has yet achieved perfect results up to now. The aim of this standardized chronic animal study was to compare the safety and efficacy of the LigaSure™ Vessel Sealing System (LVSS) with the stapler technique, which is one of the modern techniques for transecting the parenchyma in liver surgery.
Methods Sixteen pigs underwent a left liver resection (LLR). Eight pigs received a LLR by means of an Endo GIA, whereas the other eight pigs underwent liver parenchymal transection followed by simultaneous sealing by the LVSS. The operating time, transection time, blood loss during transection, and time of hemostasis were measured on the day of LLR (postoperative day 0/POD 0). Animals were re-explored on postoperative day 7 (POD 7) and the transection surface of remnant liver was observed for fluid collection (hematoma, biloma, and abscess), necrosis, and other pathologies. A biopsy was taken from the area of transection for histopathological examination.
Results All animals survived until POD 7. Operating time and transection time of the liver parenchyma on POD 0 was significantly shorter in the stapler group. There was no significant difference between the two groups in terms of blood loss during transection, time of hemostasis and number of sutures for hemostasis on POD 0, morbidity rate, as well as the histopathological examination on POD 7. Furthermore, the material costs were significantly higher in the stapler group than in the LVSS group.
Conclusion In this standardized chronic animal study concerning transection of the parenchyma in liver surgery, LVSS seems not only to be safe, but also comparable with the stapler technique in terms of morbidity and mortality. Additionally, LVSS significantly reduces material costs. However, the transection time is significantly longer for LVSS than for the stapler resection technique.

Keywords Left liver resection · LigaSure · Abscess · Fluid collection

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Introduction

Surgery remains the best method of treating liver tumors and is still the only curative procedure performed for malign liver pathologies. Despite standardized techniques for liver resections (LRx), LRx has been reported to yield morbidity rates of 10–35 % at high-volume centers, and surgical death rates after elective LRx range from 0.7 to 3.9 % [1–3]. The morbidity rate is influenced by the American Society of Anesthesiology score, the extent of resection, presence of a steatosis, and an associated extrahepatic procedure [3]. Perioperative bleeding, bile leaks, biliary fistulas, hepatic failure, intra-abdominal infection, peritonitis, and abscess represent the major surgical complications [4–7]. Various studies have demonstrated that the postoperative morbidity and mortality rates for patients undergoing LRx is closely

related to the degree of intraoperative blood loss, the majority of which occurs during transection of the liver parenchyma [4, 6, 8]. Various approaches and devices have therefore been developed for the safe and careful dissection of parenchyma. The standard techniques used in liver surgery are the CUSA™, the water jet dissector, the electrocautery, the stapler cutter, and the old, but still used, clamp crushing technique [7, 9]. On the one hand, there are instruments that transect the parenchyma but are not able to achieve hemostasis, such as the Cavitational Ultrasonic Surgical Aspirator (CUSA) and the water jet scalpel. On the other hand, there are various other devices that can directly reduce blood loss, such as the unipolar or bipolar cautery, harmonic scalpel, stapler, laser system, microwave tissue coagulator, and the floating ball system, developed by TissueLink [10]. Liver surgery still remain challenging, and as clear data for comparing various liver transection techniques are scarce, the current choice of technique is often based on the individual surgeon's preference [9].

In recent years, alternative techniques with new time-saving instruments to reduce blood loss during transection of the liver parenchyma have been developed. The LigaSure™ Vessel Sealing System (LVSS) was developed for transection and hemostasis rather than sutures, ligatures, clips, and other standard hemostasis techniques. The system allows the secure transection of tissue and, with the same device, sealing of vessels with a diameter up to 7 mm by denaturing collagen and elastin within the vessel wall and in the surrounding connective tissue [11, 12]. The LVSS delivers an appropriate amount of high-current, low-voltage energy to seal the tissue bundle [13]. This technique is suitable for both open and laparoscopic surgery [14]. Experimental and clinical studies have confirmed its efficacy and safety in many general surgical, urological, and gynecological procedures [14–19]. LVSS technology is often used in combination with other techniques, for example, clamp crushing, where vessels over 5–6 mm in diameter are sutured [10]. In our study, we used the LVSS as the sole technology for transecting the liver parenchyma in the LVSS group. In the literature, we only found one chronic animal study, in which the use of LVSS is laparoscopically compared with the stapler cutter, one of the standard techniques for transection and hemostasis of a small part of the liver without focussing on the histopathological changes at the transection surface of the remnant liver parenchyma [20].

The aim of this standardized chronic experimental study was to compare the safety and efficiency of the LVSS with the stapler cutter, one of the standard techniques for transection and hemostasis of liver parenchyma, in a porcine model. Furthermore, we aimed to evaluate and compare the histopathological examination at the transaction surface of the remnant liver after 1 week of survival for the first time.

Materials and methods

Study design

Sixteen young Landrace pigs (range: 25–30 kg) were randomly assigned to two groups. Eight animals in group 1 (stapler group) underwent a left liver resection (LLR), a resection of the segments 2–4 with an Endo GIA-45 white cartridge 2.5 mm (Tyco Healthcare, Autosuture, Florida, USA) in the parenchymal phase. In group 2 (LVSS group), the liver of eight pigs was transected and simultaneously sealed using the LigaSure Atlas™ device (Valleylab™, Boulder, Colorado, USA). On the day of the operation (postoperative day 0/POD 0) animal and specimen weight were registered. The operating time (time from incision to closure of the abdomen wall), transection time (time to complete the dissection of the liver parenchyma), blood loss during transection, and time of hemostasis (time needed to achieve a complete hemostasis of the cut surface) were measured. Furthermore, the costs of material were analyzed. Afterwards, the abdomen was closed and the pigs were visited every day for 7 days. After 7 days, a re-exploration was performed and the transection surface of the remnant liver was observed for fluid collection (hematoma, biloma, abscess), necrosis, and other pathologies of the transection surface. Finally, a biopsy was taken from the area of transection for a histopathological examination (hemorrhage, inflammation, necrosis, and ductular reaction/metaplasia). At the end of the experiment, all pigs were killed.

Animal preparation and anesthesia

All pigs were fasted 12 h before surgery with free access to water. The animals were premedicated with 10–20 mg/kg Ketanest (ketamine) plus 4 mg/kg Stresnil (azaperone) and 0.5 mg/kg Dormicum (midazolam) administered intramuscularly. This process was followed by an intravenous injection of Ketanest and Dormicum (same dose) plus 0.04 mg/kg atropine. General anesthesia was induced by isoflurane 2 % in an oxygen (1/1) mixture through an endotracheal tube, and maintained on a close circuit with mechanical ventilation. A prophylactic dose of Baytril (enrofloxacin) was administered as an antibiotic medication and Novalgin (metamizole sodium) as a pain medication. All animals were given 500 ml NaCl 0.9 % solution as a volume substitution, and depending of the intraoperative blood loss, further volume therapy was administrated.

Surgical procedure

All surgeries were performed by the same team of surgeons. The pigs were laid supine and the abdomen was prepared and draped in a sterile fashion. The peritoneal cavity was entered through a midline incision. After the gallbladder was removed,

the left liver was mobilized and the left portal vein, left hepatic artery, and left bile duct were prepared. Next, the left hepatic artery and portal vein were transected. The demarcation of the left liver was marked with the electrocautery (Fig. 1). These steps were performed on all sixteen pigs as part of a standardized procedure. Afterwards, the pigs were randomized into either the stapler (n=8) or the LVSS (n=8) group. The liver parenchyma was transected using two different surgical techniques along the mark. In group 1, the liver was transected using an Endo GIA (Fig. 2), whereas in group 2, the LigaSure Atlas™ device, connected to a ForceTriad™ energy platform, was used (Fig. 3). After transection of the liver veins (outflow) with an Endo GIA, the transection area of the remnant liver was coagulated by an electrocautery or sutures (Prolene 3-0) if necessary. Finally, the abdominal fascia was closed with a running suture (MonoPlus® Loop, Braun, Germany) and the skin was approximated with staples. No intra-abdominal drains were used in our study. The animals were allowed to awaken from anesthesia, and extubation was performed when clinically indicated.

Measurement protocol

All pigs began a regular diet after 6 h on POD 0 and were visited twice a day. General appearance, food intake, stool output, as well as occurrence of bleeding at the surgical wound were checked during each visit. Body weight was measured before LLR and before re-exploration. Operating time of each transection technique for POD 0 was measured from the point of incision to skin closure. The time of liver parenchyma transection on POD 0 and the blood loss during this step was measured with the stapler or the LigaSure Atlas™ device from the beginning to the end of the transection of the liver parenchyma. The blood loss during this step was measured by a separate suction device. After transection of the liver, the time of hemostasis with electrocautery and sutures was measured on POD 0 until the transection surface of remnant liver was no longer oozing. The number of sutures for hemostasis was also listed. When the stapler was used for transection, the number of cartridges used was listed to analyze the material costs. The material costs in the stapler group consisted of the number of cartridges used (38.90 Euro per cartridge) as well as the Endo GIA (315 Euro), and in the LVSS group, the costs consisted of the LigaSure Atlas™ device (275 Euro).

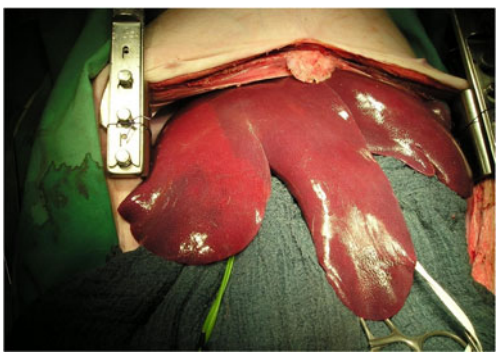

Fig. 1 Demarcation of the left liver shortly after transection of the left hepatic artery and portal vein

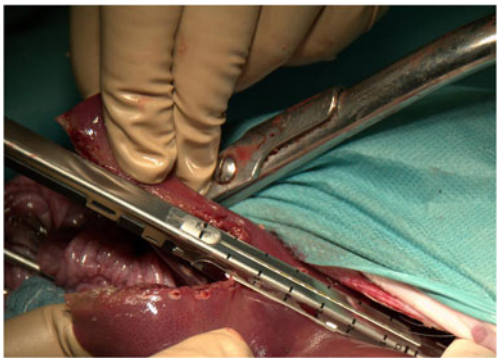

Fig. 2 Transection of the liver parenchyma with an Endo GIA-45 white cartridge 2.5 mm (Tyco Healthcare, Autosuture) (Group 1)

Re-exploration surgery

After performing anesthesia using the methods mentioned above, the abdomen was re-explored on POD 7 through a midline incision and examined for the presence of fluid collection (hematoma, biloma, abscess), necrosis, and other pathologies at the transection surface of the remnant liver. In case fluid collection was present, a swab was taken to identify a potential abscess. A biopsy was taken from the area of transection and fixed in 4 % formalin for a histopathological examination. At the end of the experiment, all animals were put to sleep with a central venous injection of potassium chloride (2 mmol/kg) in deep anesthesia.

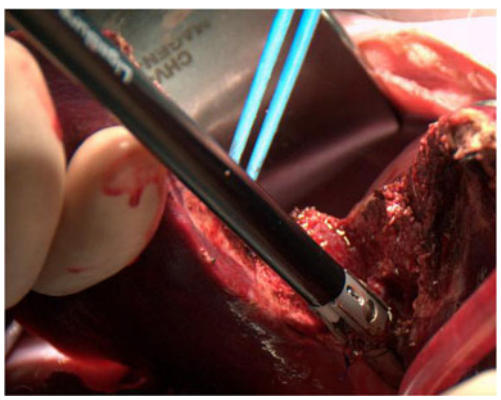

Fig. 3 Transection of the liver parenchyma with the LigaSure Atlas™ device (Valleylab™) (Group 2)

Histopathological examination

After the fixation in 4 % formalin solution, the specimen was dehydrated and embedded in paraffin, cut with the microtome, treated with xylol and diluted in solution with progressively increasing concentrations of alcohol. The specimen was than stained with hematoxylin eosin. The liver specimen was examined for hemorrhage, inflammation, necrosis, and ductular reaction/metaplasia by subjectively awarding a grading score between 1 and 3 as an expression of the intensity of the pathological alterations. The intensity of the pathological alterations was obtained by the combination of width, depth, and density. All histopathological samples were analyzed by a blinded pathologist.

Ethics guidelines

This study was approved by the German Committee on Animal Care, the Regierungspräsidium Karlsruhe, and the Ethics Committee of the Medical Faculty at Heidelberg University. All animals received humane care in compliance with the National Research Council's criteria for humane care, as outlined in the Guide for the Care and Use of Laboratory Animals, prepared by the National Institute of Health (NIH publication 86–23, revised 1985).

Statistical analysis

All calculations were conducted using SPSS (SPSS® Version 16.0, Chicago, Illinois, USA). The continuous variables (animal and specimen weight, operative time, resection time, blood loss, number of sutures, and time of hemostasis) were distributed normally in both groups (Shapiro–Wilk test). Values are presented as mean±standard deviation, and range of the mean for continuous variables. Continuous variables were compared using Student's *t* test. Categorical data (complications) were compared using Fisher's exact test. A two-sided p value<0.05 was considered statistically significant.

Results

All animals survived until they were put to sleep on POD 7. On POD 0, there was no significant difference between the two groups regarding the weight of the operated animals (stapler: 27.8 kg±1.6 kg, range 25–29 kg; LVSS: 27.2-kg±2.0 kg, range 25–30 kg). Furthermore, on POD 0, liver resection specimens from the two groups were also comparable in weight (stapler: 219.3 g±22.9 g, range 190–250 g; LVSS: 223.5 g±40.4 g, range 178–245 g). On POD 7, there was also no significant difference between the two groups regarding the weight of the operated animals (stapler: 27.1 kg±2.5 kg, range 23–30 kg; LVSS: 26.1 kg±1.6 kg, range 23–28 kg).

Operating time, transection time of the liver parenchyma, blood loss during transection, time of hemostasis, number of sutures for hemostasis, and material costs in both groups are summarized in Table 1 for POD 0. Operating time on POD 0 was significantly shorter (7.7 min/13 %) in the stapler group than in the LVSS group. The transection time of the liver parenchyma was also significantly shorter (9.5 min/75 %) in the stapler group than in the LVSS group. Blood loss during transection was not significantly different in the two groups, but there was a clear trend towards reduced blood loss in the stapler group compared to the LVSS group. The time of hemostasis and the number of sutures for hemostasis after LLR on the surface of the remnant liver were similar in both groups. The number of cartridges used was 6.8±1.0 (range 5–8) in the stapler group. The material costs were significantly higher (around 300 Euro/52 %) in the stapler group compared to the LVSS group.

Complications at the transection surface of the remnant liver and the overall morbidity of the two different liver parenchyma transection techniques for POD 7 are listed in Table 2. On POD 7, there was no difference between the two groups regarding fluid collection at the transection surface of the remnant liver. There was no hematoma in either group. One biloma was seen in the stapler group and one abscess in the LVSS group. Two animals in the stapler group developed macroscopic necrosis, whereas no macroscopic necrosis was observed in the LVSS group. In conclusion, overall complications at the transection surface of the remnant liver were not significant in either the stapler group or the LVSS group. One animal in the stapler group developed an abscess along the stomach, whereas no abdominal cavity complication was observed in the LVSS group. The overall morbidity was therefore insignificant in both groups.

On POD 0, the histopathological examination revealed a liver parenchyma without pathological alterations in all 16 of the animals (100 %). Additionally, on POD 7, a new tissue specimen from the transection surface of the remnant liver was taken and examined for hemorrhage (a), inflammation (b), necrosis (c) and ductular reaction/metaplasia (d) (Fig. 4) by subjectively awarding a grading score between 1 and 3 as an expression of the intensity of the pathological alterations (Table 3). A statistical difference in the grading score for all four parameters was not observed between the two groups.

Discussion

To limit blood loss, which mainly occurs during transection of the liver parenchyma, a variety of surgical techniques and instruments are used by liver surgeons, based on their judgment, experience, and the individual nature of the operative

Table 1 Comparison of measured data on POD 0 of the two different transection techniques

	Stapler group (n=8)	LVSS group (n=8)	p value
Operating time (min)[a]	53.4±4.0 (50–60)	61.1±6.3 (52–70)	**0.011**
Transection time of the liver parenchyma (min)[a]	3.1±0.6 (2–4)	12.6±3.5 (8–18)	**<0.0001**
Blood loss during transection (ml)[a]	281.3±79.9 (200–450)	412.5±155.3 (150–600)	0.052
Time of hemostasis (min)[a]	13.4±2.7 (9–17)	13.0±3.5 (11–20)	0.811
Number of taken sutures for hemostasis[a]	6.5±1.9 (4–10)	6.3±0.9 (5–8)	0.744
Material costs (Euro)[a]	579.5	275	**<0.0001**

p-values <0.05 are considered significant and emphasized in bold

LVSS LigaSure™ Vessel Sealing System, *POD 0* day of left liver resection

[a] Values are mean plus/minus standard deviation and range in parenthesis

procedure, in an attempt to reduce surgical morbidity. However, the optimal surgical technique (scalpel vs. CUSA vs. stapler vs. LVSS, etc.) has not yet been defined. For example, Schemmer et al. noticed in a review, that the use of the stapler cutter technique for the parenchymal phase of liver resection is a fast, safe, and cost-effective surgical procedure, while overall morbidity and mortality rates are comparable to those of other high-volume centers using conventional standard resection techniques, such as ultrasound dissection and microwave tissue coagulation transection using water jets [21]. The high rates of clinically significant complications after LRx have lead to development of various new techniques.

One such new technology is the LVSS, which is safe and effective in several laparoscopic and open operative procedures [14]. By applying bipolar electrothermal energy in a feedback-controlled fashion, vessel walls and surrounding connective tissue can be coagulated by denaturing both collagen and elastin. In a standardized chronic experimental study for open surgery, we therefore compared the use of LVSS and the stapler cutter technique, which is routinely used in our center for left hemihepatectomies [22]. The entire experiment proved highly relevant for the clinic, and the two techniques applied were carried out according to standard procedures. The aim of this standardized chronic experimental study in pigs was to compare the LVSS with the stapler cutter transection and closure technique for operating time, transection time of the liver parenchyma, material costs, decreased blood loss during transection of the liver parenchyma, and postoperative complication rate, including hematoma, biloma, or abscess formation in LRx. To this effect, operating time, transection time, blood loss during transection, time of hemostasis, and number of sutures for hemostasis on POD 0 and all macroscopic and histopathological changes on the transection surface of the remnant liver as well as macroscopic changes in the abdominal cavity on POD 7 were included. This study design enabled—for the first time—a macroscopic and histopathological analysis and comparison of the transection surface of the remnant liver using two different transection techniques in LRx. Furthermore, the data of our standardized chronic experimental study were used as background of a randomized controlled trial in humans, which already is running in our hospital.

Intraoperative blood loss in LRx is one of the critical factors influencing the development of postoperative complications (e.g., hematoma, biloma, and abscess) [4, 6, 8]. Our data indicate that the liver can be safely and efficiency transected and sealed by the LVSS. Blood loss during the

Table 2 Comparison of complications at the transection surface of the remnant liver and overall morbidity of the two different transection techniques on POD 7

	Stapler group (n=8)	LVSS group (n=8)	p value
Hematoma at the transection surface of the remnant liver [n (%)]	0 (0.0)	0 (0.0)	1.000
Biloma at the transection surface of the remnant liver [n (%)]	1 (12.5)	0 (0.0)	1.000
Abscess at the transection surface of the remnant liver [n (%)]	0 (0.00)	1 (12.5)	1.000
General fluid collection at the transection surface of the remnant liver [n (%)]	1 (12.5)	1 (12.5)	1.000
Macroscopic necrosis at the transection surface of the remnant liver [n (%)]	2 (25.0)	0 (0.0)	0.466
Overall complications at the transection surface of the remnant liver [n (%)]	3 (37.5)	1 (12.5)	0.569
Abdominal cavity complications (abscess along the stomach) [n (%)]	1 (12.5)	0 (0.0)	1.000
Overall morbidity [n (%)]	4 (50.0)	1 (12.5)	0.282

LVSS LigaSure™ Vessel Sealing System, *POD 7* postoperative day 7

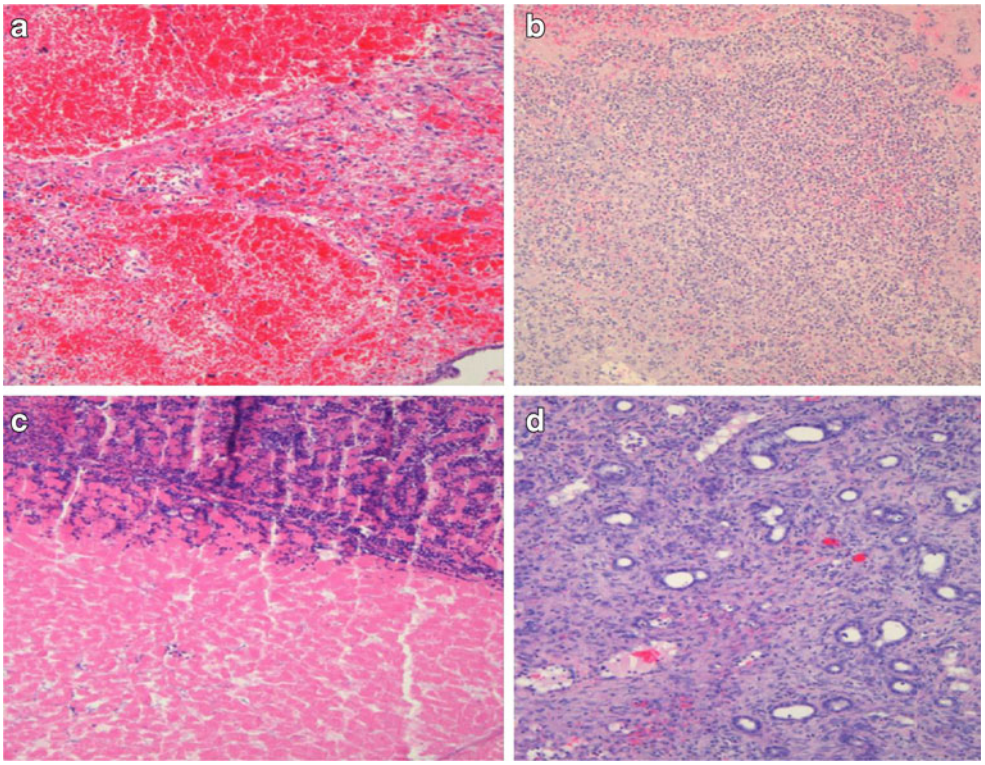

Fig. 4 Histopathological examination of the transection surface of the remnant liver on postoperative day 7 by subjectively giving of a grading score between 1 and 3 as an expression of the intensity of the pathological alterations. Examined for hemorrhage (**a**), inflammation (**b**), necrosis (**c**), and ductular reaction or metaplasia (**d**)

transection of the liver was not significantly different in either group. This is in accordance with Saidi et al., who also found no significant difference in blood loss during a laparoscopic resection of the liver segments 2 and 3 in a chronic experimental study comparing the LVSS with the stapler cutter [20]. Due to the standardized study with 16 healthy Landrace pigs, no other critical factors influencing the development of postoperative complications, like cirrhosis of the liver, could be investigated. Though, these risk factors should be addressed in further well-designed randomized controlled trials. However, transection time in our study is significantly longer in the LVSS group, which is related to the smaller piece of tissue that can be sealed and simultaneously transected with the branches of the LVSS instrument. Many more single steps for transecting the liver parenchyma are therefore necessary.

Because no significant differences between the two groups were found regarding morbidity, including hematoma, biloma, abscess, and necrosis at the transection surface of remnant liver on POD 7, transecting the liver by the LVSS can be considered to be as safe as the stapler cutter technique in our study. These findings are in accordance with other as yet scarce published data comparing the LVSS with the stapler cutter in LRx [20]. Furthermore, the statistically insignificant difference of the histopathological examination of a tissue specimen from the transection surface of the remnant liver, including hemorrhage, inflammation, necrosis, and ductular reaction/metaplasia is in accordance with this statement. Although there were no significant histopathological alterations between both transection techniques, this factor should be observed in further well-designed randomized controlled trials. Additionally, LVSS reduces significant material costs due to the number of cartridges used in the stapler group. This experience also relates accordingly to the published data of the above-mentioned study from Saidi et al., who described significantly higher material costs in the stapler group compared to the LVSS group [20].

Table 3 Grading score for the histopathological examination on POD 7 of the two different transection techniques

	Stapler group (n=8)	LVSS group (n=8)	p value
Hemorrhage[a]	1.3±1.0 (0.0–3.0)	1.3±0.5 (1.0–2.0)	1.000
Inflammation[a]	1.3±0.7 (0.0–2.0)	1.5±0.8 (1.0–3.0)	0.506
Necrosis[a]	2.4±0.7 (1.0–3.0)	2.1±0.6 (1.0–3.0)	0.483
Ductular reaction/metaplasia[a]	1.4±0.9 (0.0–2.0)	1.8±0.9 (1.0–3.0)	0.419

LVSS LigaSure™ Vessel Sealing System, *POD 7* postoperative day 7

[a] Values are mean plus/minus standard deviation and range in parenthesis

However, the significantly longer transection time in the LVSS group could have a negative consequence with regard to the overall costs in a clinical setting. Additionally, the comparison with the conventional crush and clamp technique would be very interesting at this point and should be observed in further well-designed randomized controlled trials.

In conclusion, the present standardized chronic animal study indicates that the use of the LVSS is safe for transecting the liver parenchyma, and yields the same results as the stapler cutter technique on postoperative day 7 in terms of general fluid collection (hematoma, biloma, and abscess), necrosis, and histopathological examination at the transection surface of remnant liver. The different operation techniques do not influence the clinical course within 7 days, but further trials in humans are necessary to evaluate the LVSS in comparison to the standard transection and closure techniques in liver resection procedures over a longer time period following the operation. Additionally, although transection time is significantly longer, LVSS significantly reduces material costs. To confirm these findings within a clinical setting, well-designed randomized controlled trials are needed in the future. However, the estimates obtained in this study are useful in planning such a trial; and one such trial has already started running in our hospital.

Conflicts of interest The authors have no financial interests or other disclosures to declare. No external funds were used to perform the evaluation, and all of the technology tested was independently purchased to complete the study. In addition, the authors had full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

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