

Randomized clinical trial of efficacy and costs of three dissection devices in liver resection

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Background: In recent decades a variety of instruments for liver dissection has become available. This randomized controlled trial analysed the efficacy and costs of three different liver dissection devices.

Methods: Ninety-six patients without cirrhosis undergoing liver resection were randomized to either ultrasonic dissection, waterjet dissection or dissecting sealer (32 in each group). Patients were unaware of the device used. The primary endpoint was dissection speed. Secondary endpoints were intraoperative blood loss, morbidity and mortality, and costs of dissection devices, staplers and haemostatic agents.

Results: Dissection was slower with the dissecting sealer ($P = 0.004$ versus waterjet dissector). The difference was more pronounced for extended resections (mean(s.e.m.) $1.62(0.36)$ cm²/min versus $3.42(0.53)$ and $3.63(0.51)$ cm²/min for ultrasonic and water dissectors respectively; $P = 0.037$). Costs were significantly higher for the dissecting sealer when atypical or segmental resections were performed. Four patients died after extended resections; postoperative complications did not differ between groups.

Conclusion: The dissecting sealer is slower than the ultrasonic dissector or water dissector. The three devices are equally safe in terms of blood loss, transfusions and postoperative complications. Ultrasonic and water dissectors might be more favourable economically than the dissecting sealer. Registration number: ISRCTN52294555 (<http://www.controlled-trials.com>).

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Introduction

Liver resection is the only potentially curative treatment for secondary liver tumours and is important in dealing with primary tumours. It has become the most effective therapy for primary and secondary liver malignancies in terms of costs and efficacy¹. A continuous effort is being made worldwide to improve the outcome after hepatic resection. Several well designed trials have compared ways to reduce perioperative bleeding, biliary leakage and ischaemia–reperfusion injury^{2–6}. It is now common knowledge that blood loss during liver dissection can be reduced by controlling hepatic inflow and outflow as well as by central venous pressure reduction^{7–11}.

More recently there has been growing interest in various dissection devices. The effect of dissection technique on perioperative and postoperative bleeding has been analysed in a number of retrospective studies^{12–18}. Only three randomized trials have prospectively compared dissection devices such as the ultrasonic dissector, waterjet dissector and/or dissecting sealers in terms of postoperative outcome as well as efficacy^{19–21}. Ultrasonic and waterjet dissection are clinically established dissection techniques^{12–18}. The dissecting sealer has been evaluated in a number of studies^{12–18}, but mostly without comparison to other dissection devices. The only study that compared ultrasonic and waterjet dissection with a dissecting sealer used inflow occlusion¹⁹, making comparison of the efficacy of the

devices regarding blood loss difficult. This prospective randomized trial compared ultrasonic dissection, waterjet dissection and dissection with a tissue sealer in 96 patients undergoing liver resection for primary or secondary malignancies.

Methods

Between September 2003 and June 2005, 96 consecutive patients with primary or secondary hepatic tumours undergoing liver resection were randomized to one of three dissection strategies: ultrasonic dissection (Selector®; Erbe, Tübingen, Germany), waterjet dissection (Helix HydroJet®; Erbe) and dissection with a tissue sealer (Dissecting Sealer 3.0®; TissueLink Medical, Dover, New Hampshire, USA). There were 32 patients in each group (Fig. 1). The study was approved by the local ethics committee of the University of Saarland and registered as a controlled clinical trial (ISRCTN52294555). Patients gave their informed consent before the study and were blinded to the type of dissection device throughout the trial. Randomization was by opening sealed envelopes before laparotomy. If the intended liver resection could

not be performed, which was the case in 25 patients, envelopes were resealed and returned to the pool of sealed envelopes.

Cirrhosis or cholestasis (serum bilirubin over 42 µmol/l; normal range 5–21 µmol/l) and chemotherapy within the preceding 6 months were exclusion criteria for the study. Patients with multiple liver tumours requiring a combination of hemihepatectomy or segmental/sectorial resection with atypical resection were also excluded.

Study hypothesis and endpoints

The null hypothesis was that the three liver dissection devices would not differ with respect to dissection speed (square centimetre surface area per minute) and this was the primary endpoint of the study. Secondary endpoints were intraoperative blood loss, mortality and morbidity, comprising the most common postoperative complications after liver surgery: bleeding, bile fistula, cholangitis, liver abscess, pleural effusion, pneumonia and cardiac complications. The dissection devices were also compared with respect to intraoperative or postoperative blood transfusions, hospital stay and intensive care unit (ICU)

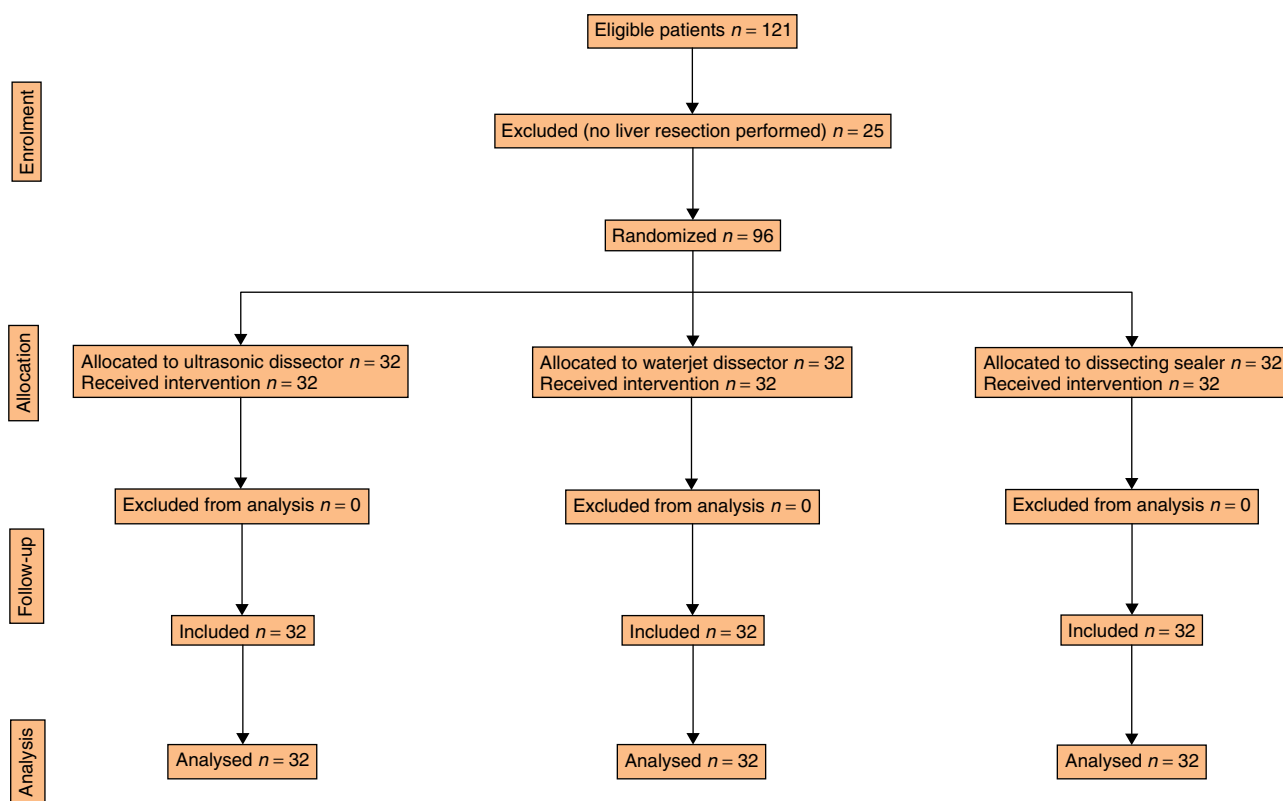


Fig. 1 CONSORT diagram for the trial

Table 1 Demographics and preoperative data for 96 patients undergoing liver resection with different liver dissection devices

	Ultrasonic dissector (<i>n</i> = 32)	Waterjet dissector (<i>n</i> = 32)	Dissecting sealer (<i>n</i> = 32)	<i>P</i> †
Age (years)*	62.7(2.1)	56.8(2.9)	58.0(2.5)	0.275
Sex ratio (M : F)	21 : 11	18 : 14	15 : 17	0.323
ASA score*	2.4(0.1)	2.2(0.2)	2.4(0.1)	0.731
Liver tumour				
Primary	9	11	13	
Metastases	23	21	19	
Preoperative biochemistry*				
Bilirubin (μmol/l)	12.5(1.5)	22.4(9.9)	9.6(0.7)	0.105
INR	1.04(0.03)	0.95(0.05)	0.98(0.01)	0.183
APTT (s)	25.7(0.6)	25.1(0.7)	25.7(0.4)	0.677
Co-morbidities				
Cardiac	7	5	7	
Pulmonary	4	3	2	
Renal	2	2	1	
Other	28	14	10	

*Values are mean(s.e.m.). ASA, American Society of Anesthesiologists; INR, international normalized ratio; APTT, activated partial thromboplastin time.

†Kruskal–Wallis rank sum test and Dunn's test or Fisher's exact test.

Table 2 Intraoperative and postoperative data

	Ultrasonic dissector (<i>n</i> = 32)	Waterjet dissector (<i>n</i> = 32)	Dissecting sealer (<i>n</i> = 32)	<i>P</i> †
Intraoperative data*				
Blood transfusion (units)	0.38(0.26)	1.38(0.47)	0.19(0.14)	0.077
Fresh frozen plasma (units)	0.84(0.31)	1.22(0.41)	0.13(0.13)	0.059
Postoperative biochemistry*				
Bilirubin (μmol/l)	27.0(11.8)	33.7(11.6)	14.9(2.1)	0.217
INR	1.05(0.04)	0.95(0.05)	0.95(0.04)	0.076
APTT (s)	35.8(8.6)	37.2(5.8)	28.9(4.3)	0.056
Operator				
Surgeon 1	18	20	17	
Surgeon 2	9	7	11	
Surgeon 3	3	4	2	
Surgeon 4	2	1	2	
Morbidity				
Bleeding	1	2	0	
Bile fistula	2	3	3	
Cholangitis	0	1	0	
Liver abscess	3	0	2	
Pleural effusion	7	7	2	
Pneumonia	1	0	0	
Cardiac complications	1	0	0	
ICU stay (days)*	3.8(1.0)	4.3(1.1)	2.4(0.8)	0.059
Hospital stay (days)*	11.6(1.4)	12.9(1.3)	10.9(1.4)	0.166

*Values are mean(s.e.m.). INR, international normalized ratio; APTT, activated partial thromboplastin time; ICU, intensive care unit. †Kruskal–Wallis rank sum test and Dunn's test.

stay, costs of the dissection devices and supplementary costs to achieve haemostasis.

Liver dissection

Parenchyma-preserving resection²² was performed when possible and the extent of dissection was delineated by the senior surgeon in all patients. All procedures were

performed by one of four surgeons who had undertaken at least 15 major hepatectomies and had previous experience with the various dissection techniques. During dissection, small blood vessels and biliary radicals were coagulated, whereas larger vessels and bile ducts were ligated and cut. Hepatic veins were either dissected with a stapling device or cut and over-run with a 3/0 monofilament suture. Tangential resections of portal or hepatic veins were closed

Table 3 Intraoperative data relating to dissection

	Ultrasonic dissector	Waterjet dissector	Dissecting sealer	P
All resections	32	32	32	
Dissection time (min)	37.5(3.5)	41.9(3.9)	40.0(4.0)	0.716
Resection area (cm ²)	78.2(7.7)	97.2(9.3)	56.6(5.2)*	0.003
Blood loss (ml)	516(101)	774(140)	301(47)*	0.005
Blood loss per unit area (ml/cm ²)	7.49(1.49)	8.19(1.36)	5.54(0.99)	0.145
Atypical resections	15	11	17	
Dissection time (min)	29.8(4.2)	42.2(7.7)	31.4(4.2)	0.243
Resection area (cm ²)	46.5(6.5)	91.2(21.4)	42.2(5.1)	0.077
Blood loss (ml)	431(191)	505(121)	245(55)	0.141
Blood loss per unit area (ml/cm ²)	9.54(2.95)	5.99(1.11)	6.17(1.71)	0.466
Segmental resections	11	9	10	
Dissection time (min)	46.8(6.0)	48.1(7.2)	47.7(6.7)	0.991
Resection area (cm ²)	100.5(10.4)	86.7(11.1)	71.4(9.7)	0.138
Blood loss (ml)	595(129)	829(203)	308(81)*	0.039
Blood loss per unit area (ml/cm ²)	6.16(1.43)	9.71(3.02)	4.17(0.91)	0.185
Hemihepatectomies	6	12	5	
Dissection time (min)	39.7(8.8)	36.9(5.4)	58.3(20.9)	0.341
Resection area (cm ²)	116.7(16.5)	110.5(13.2)	79.3(5.8)	0.241
Blood loss (ml)	583(122)	980(320)	587(170)	0.997
Blood loss per unit area (ml/cm ²)	4.82(0.48)	9.07(2.68)	7.41(2.13)	0.497

Values are mean(s.e.m.). Statistical analysis was by ANOVA and Student–Newman–Keuls test or Kruskal–Wallis rank sum test and Dunn's test.

**P* < 0.050 *versus* waterjet dissector.

with 7/0 Polypropylene (Prolene®; Ethicon, Norderstedt, Germany) running sutures.

Parenchymal transections were performed with the following instrument settings: ultrasonic dissector (Selector®): 80 per cent maximum power, 35 kHz frequency, 180 µm amplitude; waterjet dissector (Helix HydroJet®): 0.1 mm nozzle diameter, 30–40 bar water pressure; Dissecting Sealer 3.0® connected to a compatible electrosurgical generator (Force FX-8C; Valleylab, Boulder, Colorado, USA): 80 W output power, 480 kHz frequency, 4–6 ml/min flow of 0.9 per cent saline solution.

Before closure of the abdomen, a suction drain was placed below the resection area to measure postoperative serous, biliary or sanguinous drainage. Pringle's manoeuvre or vascular occlusion was not used in any patient, and central venous pressure was kept between 0 and 5 mmHg during resection^{7–9,23}. The use of techniques to achieve haemostasis, such as argon beam and/or tissue sealants (TachoSil®; Nycomed, Konstanz, Germany), was according to current surgical standards of the department.

Postoperative care

All patients were monitored in the ICU by means of standard laboratory tests and routine abdominal ultrasonography to exclude intra-abdominal haematoma.

Drainage fluid was collected every 8 h and its volume, bilirubin and haemoglobin concentrations were measured. A bilirubin concentration in the drainage fluid above twice the normal serum value for the individual patient was considered to indicate biliary leakage.

Data management

All demographic and operative data, information on postoperative outcome and complications, and economic data were collected and scored by a dedicated study nurse. The standard clinical data for each patient were recorded in a modified ISH-med® (SAP, Walldorf, Germany) database and later transferred to the study database by the study nurse.

Intraoperative blood loss was calculated from the suction volume after subtraction of rinse fluids and weighing the swabs used during dissection. It was assumed that 1 ml of blood weighed 1 g. Intraoperative and postoperative blood transfusions (red blood cell units) and fresh frozen plasma units were documented. The indications for blood transfusion were intraoperative haemorrhage of more than 1500 ml or a haemoglobin level below 4.5 mmol/l within the first 24 h after surgery.

Dissection time was calculated from the beginning until the end of liver parenchymal transection. The dissection area was analysed by transferring the liver specimen's resection surface on to a sheet of paper, which was then scanned and measured digitally using a standard

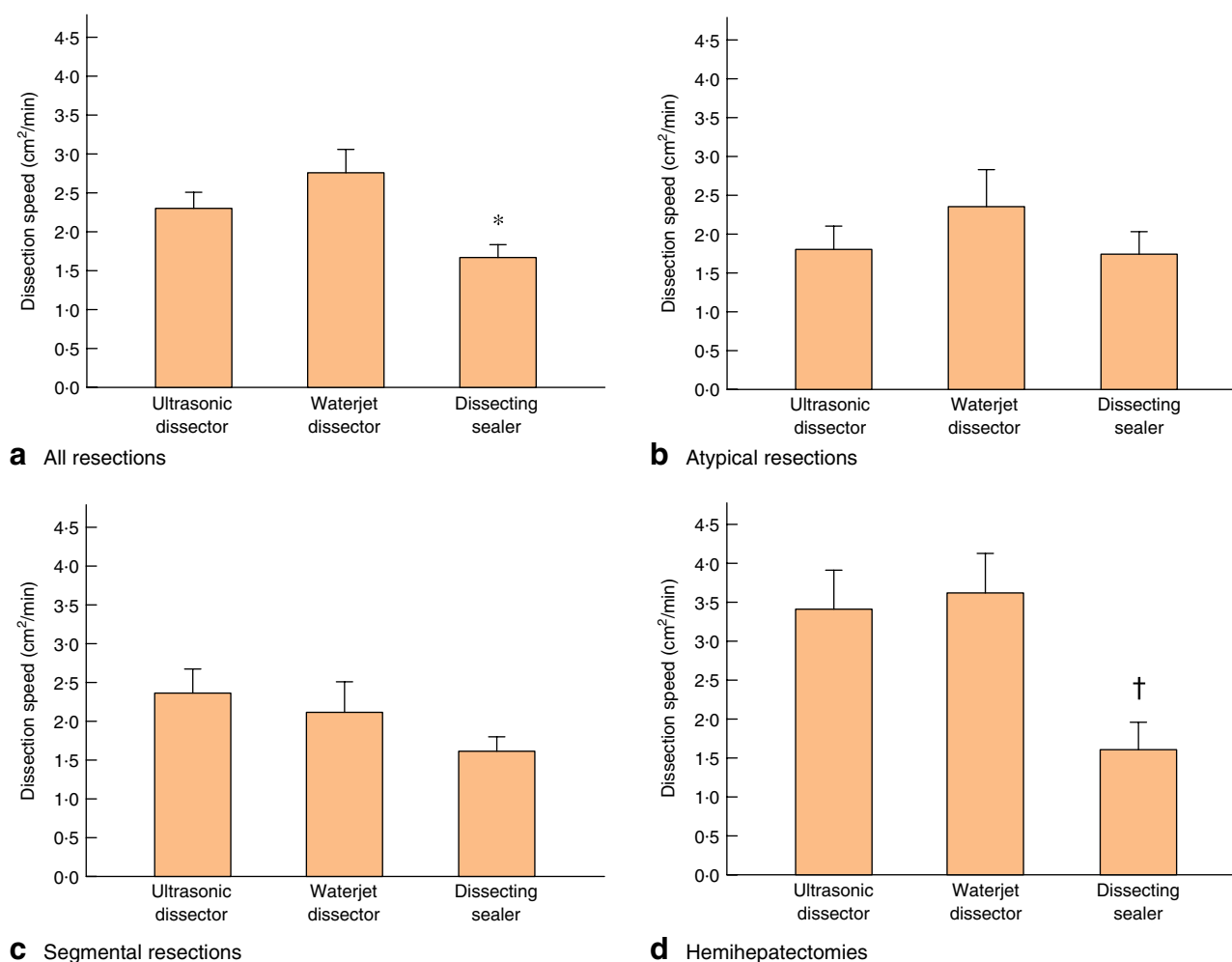


Fig. 2 Dissection speed for hepatectomies carried out using three dissection devices. Values are mean(s.e.m.) dissection speed for **a** all resections (32 with each device), **b** atypical resections (15 with ultrasonic dissector, 11 with waterjet dissector and 17 with dissecting sealer), **c** segmental resections (11, nine and ten respectively) and **d** hemihepatectomies (six, 12 and five respectively). * $P = 0.004$ versus waterjet dissector, † $P = 0.037$ versus waterjet and ultrasonic dissectors (ANOVA and Student–Newman–Keuls test)

computer program (Photoshop® CS2; Adobe Systems, Munich, Germany). Dissection speed (square centimetre surface area per minute) and blood loss per dissection area (millilitres per square centimetre) was calculated from these parameters.

The costs of each dissection technique were calculated as the sum of the system costs (disposable parts) and the maintenance costs of the energy source. Costs associated with achieving haemostasis, such as staplers, stapler cartridges and other haemostatic agents (TachoSil®), were added. The preparation (mounting) time of each device was also assessed. Preparation by the operating theatre staff in parallel with the operation was not included in the cost analysis.

Statistical analysis

The required sample size was calculated with the expectation of a 25 per cent difference in dissection time during parenchymal transection in at least one group with a level of statistical significance of 0.05 and a power of 0.80, using a *post hoc* two-sample *t* test with Bonferroni correction. These calculations led to a sample size of 32 patients in each group.

Statistical analysis was performed using the software package SigmaStat 3.0® (SPSS, Chicago, Illinois, USA). For comparisons between groups, one-way ANOVA or Kruskal–Wallis rank sum test was used followed by the appropriate *post hoc* test (Student–Newman–Keuls or Dunn's test respectively). Data are presented as

Table 4 Costs directly related to the dissection technique

	Ultrasonic dissector	Waterjet dissector	Dissecting sealer	P*
All resections	32	32	32	
Mounting time (min)	7	5	3	
System costs (€)	66	139	934	
Maintenance costs (€)	62	0	0	
Cost of TachoSil® (€)	335.5(42.1)	355.2(44.8)	125.0(28.1)*†	0.001
Cost of staplers and cartridges (€)	153.8(49.6)	265.4(101.1)	120.8(51.9)	0.591
Total material costs (€)	617.2(64.7)	759.6(115.1)	1179.8(62.7)*†	0.001
Atypical resections	15	11	17	
Mounting time (min)	7	5	3	
System costs (€)	66	139	934	
Maintenance costs (€)	62	0	0	
Cost of TachoSil® (€)	364.9(56.1)	344.5(90.1)	123.8(36.3)*	0.004
Cost of staplers and cartridges (€)	95.3(67.5)	0	19.0(19.0)	0.396
Total material costs (€)	588.2(92.0)	483.5(91.0)	1076.8(43.4)*†	0.001
Segmental resections	11	9	10	
Mounting time (min)	7	5	3	
System costs (€)	66	139	934	
Maintenance costs (€)	62	0	0	
Cost of TachoSil® (€)	344.5(81.6)	304.1(86.7)	140.3(53.9)	0.119
Cost of staplers and cartridges (€)	222.6(111.4)	398.3(233.8)	268.5(125.1)	0.984
Total material costs (€)	695.0(157.9)	841.1(247.3)	1342.8(142.6)*	0.016
Hemihepatectomies	6	12	5	
Mounting time (min)	7	5	3	
System costs (€)	66	139	934	
Maintenance costs (€)	62	0	0	
Cost of TachoSil® (€)	245.6(100.5)	403.5(60.5)	70.2(70.2)	0.059
Cost of staplers and cartridges (€)	324.1(112.3)	409.1(195.1)	107.4(107.4)	0.512
Total material costs (€)	697.7(81.5)	951.5(221.6)	1111.6(177.6)	0.120

Values are mean(s.e.m.). Statistical analysis was by ANOVA and Student–Newman–Keuls test or Kruskal–Wallis rank sum test and Dunn's test.

* $P < 0.050$ versus waterjet dissector, † $P < 0.050$ versus ultrasonic dissector.

mean(s.e.m.). In addition, subgroup analysis was performed for the type of resection: extended resections (mostly hemihepatectomies), anatomical resection of one to three liver segments, or non-anatomical liver resection.

Results

Ninety-six patients were randomized to the three groups. The groups were similar in age, sex ratio and American Society of Anesthesiologists score (*Table 1*). There was no difference in the distribution of the four surgeons between the groups, but one surgeon operated on more than half of the patients in each group (*Table 2*). Preoperative bilirubin levels, international normalized ratio (INR), activated partial thromboplastin time (APPT) and comorbidities were similar in the three groups. Sixty-three patients (66 per cent) underwent resections for secondary malignancies and 73 (76 per cent) had a parenchyma-preserving resection.

There was no difference in postoperative morbidity between groups (*Table 2*). This was true for resection-associated and other complications. A total of four patients

died (ultrasonic dissection, two; waterjet dissection, one; dissecting sealer, one). All deaths were due to hepatic failure after extended resection.

Mean intraoperative blood loss was 530 ml; there was no difference in postoperative blood loss or transfusion requirements between groups (*Table 2*). Postoperative liver function, indicated by serum bilirubin level, PTT and INR, was not significantly different between the groups. Patients in all three groups required an equally long stay in the high/intermediate dependency unit and normal hospital care.

Dissection data

The mean transection area was 77.3(4.7) cm² overall, 78.2(7.7) cm² for ultrasonic dissection, 97.2(9.3) cm² for waterjet dissection and 56.6(5.2) cm² for the dissecting sealer. The mean resection area overall was significantly greater in the waterjet group than in the dissecting sealer group, but no differences were found when analysing atypical resections, segmental resections or hemihepatectomies.

Blood loss was lowest in the dissecting sealer group, and was significantly less than with waterjet dissection (*Table 3*). Blood loss per resection area, however, was similar for the three devices and a subgroup analysis for the three different resection types did not show any significant differences.

Dissection was significantly faster with a waterjet dissector ($2.76(0.29)$ cm²/min) than with the dissecting sealer ($1.68(0.17)$ cm²/min), but not compared with ultrasonic dissection ($2.30(0.22)$ cm²/min) (*Fig. 2*). There was no difference in dissection speed between the three dissection devices in patients undergoing parenchyma-preserving resection (non-anatomical or segmental/sectorial resections). However, ultrasonic and waterjet dissection ($3.42(0.53)$ and $3.63(0.51)$ cm²/min respectively) were significantly faster than the dissecting sealer ($1.62(0.36)$ cm²/min) when hemihepatectomy was performed.

Dissection-associated costs

The mounting time of the dissection device did not extend the dissection time or prolong total operating time. Therefore, costs in this study were mostly attributed to system costs of the individual device and to the use of sealants. For atypical resections, use of the dissecting sealer reduced the need for haemostatic agents, but the higher system price of €934 led to nearly twofold higher total costs compared with ultrasonic or waterjet dissection (*Table 4*). For segmental resections, the total material costs were also significantly higher for the dissecting sealer than for the ultrasonic or the waterjet device. In patients undergoing hemihepatectomies with ultrasonic or waterjet dissectors, the costs of staplers and cartridges increased, raising the total cost of dissection from €600 to €950. This amounts to 9–14 per cent of the total revenues for the whole hospital treatment, which was a mean of €6617 per patient.

Discussion

The main finding of this study was that the dissecting sealer was slower than the ultrasonic dissector or waterjet dissector. From an economic point of view, ultrasonic dissection and waterjet dissection appeared favourable compared with use of the dissecting sealer.

Liver dissection devices have been evaluated in a considerable number of studies^{12–18}, but few randomized clinical trials have been conducted^{19–21}. These trials were slightly different from the present study. Takayama and colleagues²⁰ compared dissection in both normal and cirrhotic livers, using intermittent 15-min total or 30-min selective vascular occlusion. Both cirrhosis and ischaemia time may affect outcomes such as bleeding

and postoperative liver function. To minimize differences between patients in the present study, cirrhosis or cholestasis and preceding chemotherapy were defined as exclusion criteria, and Pringle's manoeuvre or other vascular occlusion techniques were never used. In this context, it is important to note that Lesurtel and co-workers²¹ performed liver resections in patients without cirrhosis or cholestasis, always using inflow occlusion with the crush-clamp technique, but only occasionally (20–36 per cent) with other dissection methods. The study by Rau and colleagues¹⁹ did not include a sample size calculation. In addition, the liver ischaemia times were not standardized and there were significant differences in the duration of Pringle's manoeuvre between the groups¹⁹. It is well known that the duration of hepatic vascular occlusion may affect liver injury²⁴, especially in patients with underlying liver disease²⁵. Although intermittent vascular clamping is frequently proposed as an alternative to continuous Pringle's manoeuvre^{26–28}, it has not been proven to reduce liver injury significantly compared with continuous clamping¹⁰.

Ultrasonic dissection, regarded as the standard technique for liver dissection in many centres²³, is comparable with waterjet dissection regarding its use of energy to fragment and aspirate the liver parenchyma. In the study of Rau and co-workers¹⁹ waterjet dissection was superior to ultrasonic dissection in terms of dissection time and requirement of postoperative blood transfusions, whereas Lesurtel and colleagues²¹ failed to show any difference between these two devices. This is in line with the present study, in which the dissection speed of both devices was comparable for all categories of dissection. Furthermore, there were no differences between ultrasonic and waterjet dissection concerning blood loss, blood transfusions, postoperative complications, ICU stay or hospital stay.

Dissecting sealers have been evaluated in liver surgery by several groups^{14,16–18}. However, there are few clinical or experimental studies comparing radiofrequency coagulation-based techniques with other liver dissection devices^{19,21,29,30}. The present study showed a significantly reduced dissection speed for the dissecting sealer compared with ultrasonic or waterjet dissection. This was particularly apparent in major resections. Despite the randomization process, only a few hemihepatectomies were performed using this device, leading to a smaller mean resection area than for ultrasonic or waterjet dissection. Therefore, dissection speed, defined as the area per dissection time, must be regarded as the most important parameter when comparing the three devices. The coagulation–sealing properties of the dissecting sealer require time beyond dissection, as noted previously^{17,29}. So far, no study has

accounted for the extent of resection bearing in mind that, while parenchyma-preserving resections may have smaller resection areas, they may be prone to increased blood loss compared with anatomical resections if inflow occlusion is omitted. In the present study, blood loss per unit area was no different for the three devices, regardless of the type of resection performed.

Costs of each device were calculated with respect to the type of resection performed. For major resections with large resection areas there were no differences in costs between the devices. However, for parenchyma-preserving segmental and atypical resections, the dissecting sealer became unprofitable owing to the high system costs. This is in apparent contrast to the findings of Lesurtel and colleagues²¹, but they did not distinguish between resection types, or consider the additional costs for haemostatic agents and staplers. Furthermore, system and device prices may vary between countries, and high- and low-volume centres, so that it is difficult to compare cost analyses in different studies. In the present study, acquisition costs and maintenance costs for the system consoles or power generators of the three devices were omitted. Use of the dissecting sealer was more expensive than both ultrasound and waterjet dissection, especially for small resection areas, which can be explained by the high cost of the disposable parts. However, the cost analysis provided here may not be applicable to other hospitals or healthcare systems.

Use of the dissecting sealer was associated with less use of haemostatic agents. The dissecting sealer is based on radiofrequency energy that heats and coagulates the surrounding parenchyma, whereas ultrasound and waterjet devices fragment, irrigate and aspirate the liver tissue without coagulation. Although all three devices represent selective liver dissection devices, their mode of operation is different, probably explaining the increased use of supplementary staplers and TachoSil® when ultrasound or waterjet dissection was used.

The present study has some potential limitations. Patients with liver cirrhosis were excluded. On the other hand, the trial included a relatively high proportion of patients with co-morbidities, mainly with colorectal liver metastasis, reflecting the referral base of the unit. Extrapolating the present data to younger patients with cirrhosis and primary hepatic malignancies may not therefore be justified. A reliable cost analysis is not currently possible owing to the different costs of system consoles, disposable parts and maintenance between hospitals. Furthermore, a postoperative cost analysis, including intensive and/or intermediate care, was not included owing to a lack of appropriate intermediate-care facilities.

The use of an ultrasonic dissector, waterjet dissector or dissecting sealer for resection of non-cirrhotic liver produced a similar outcome in terms of postoperative complications, intraoperative blood loss and blood transfusion requirement, when carried out by experienced surgeons. From an economic point of view, ultrasonic and waterjet dissection may be favourable compared with use of a dissecting sealer.

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