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A new single-instrument technique for parenchyma division and hemostasis in liver resection: a clinical feasibility study

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Abstract. The objective of this study was to evaluate the clinical feasibility of a new technique for liver resection based on a radiofrequency-assisted (485 kHz) device that has shown high performance in the animal setting in both transection speed and blood loss per transection area. Eight patients with colorectal hepatic metastasis underwent 11 partial hepatectomies using the proposed technique for both parenchyma division and hemostasis. Main outcome measures were blood loss per transection area and transection speed. No other instruments (including sutures or clips) were used in any of the cases; temporary vascular occlusion performed was not performed. No blood transfusions were required and no mortality or morbidity linked to the hepatic procedure were observed. The median blood loss per transection area and the median transection speed were .79 mL/cm^2 (range, .05–7.37 mL/cm^2) and 1.28 cm^2/min (range, .49–1.87 mL/cm^2), respectively. During the follow-up period (range, 4–12 mo) no late complications were detected and postoperative patients were free from hepatic recurrence. The proposed radiofrequency-assisted device was shown to achieve parenchymal division and hemostasis simultaneously, resulting in extremely reduced blood loss.

In liver surgery, efficient and safe parenchymal transection is dependent on the ability to simultaneously address 2 tasks: parenchymal division and hemostasis. Because no single instrument has yet been developed to achieve both tasks, most hepatic parenchymal transections are performed using a combination of instruments and techniques that usually include a dissection device (eg, a clamp or an ultrasonic dissector) and another instrument to achieve hemostasis (eg, suture ligatures, clips, or other devices).[1] This combination of instruments requires considerable training and skill to reduce intraoperative blood loss and increases costs.[2] In turn, intraoperative blood loss and perioperative transfusion not only increase the risk of surgical morbidity and mortality[3] but also jeopardize long-term survival because they actually increase the recurrence rate of the tumor

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Table 1 Clinical details of the patients

Patient	Hepatic surgery	Additional nonhepatic surgery	Days at hospital	Complications
1	Atypical resection	Stoma closure	9	Wound infection
2	Two atypical resections	Ligature of portal vein	6	None
3	Bisegmentectomy (segments 2 and 3)	Anterior resection + partial cystectomy + hysterectomy	33	Anastomotic leak requiring postoperative Hartman's procedure
4	Two atypical resections	None	6	None
5	Bisegmentectomy (segments 2 and 3) + atypical resection	None	6	None
6	Atypical resection	None	18	Enterocolitis
7	Atypical resection	Reparation of surgical hernia	4	Wound seroma
8	Bisegmentectomy (segments 6 and 7)	None	4	None

being resected.[4–6] Therefore, over the past decade many techniques have been tested and developed to minimize intraoperative blood loss during liver resection.

Several recent approaches, including saline-linked technology, use radiofrequency (RF) energy deposited on the liver tissue to achieve a coagulating effect before transection. Weber et al[7] pioneered the use of RF needle electrodes to obtain a 1- or 2-cm wide line of coagulation on the resection line before dividing the line with a scalpel, thereby permitting bloodless liver resection. Further application of this concept of precoagulating tissue with RF energy before transection has been achieved with more recent devices, such as Habib's method[8] or the InLine[9] device (Resect Medical, Inc, Fremont, CA), in which a range of RF electrodes are inserted in a monopolar or bipolar configuration. Once the plane of coagulation has been created with these RF-assisted devices, the coagulated tissue is cut with a straight scalpel without blood loss.

The aim of the present study was to evaluate the clinical feasibility of a new technique based on a RF-assisted device that has shown high performance in both transection speed and blood loss per transection area in the animal setting (through both an open[10] and laparoscopic approach[11]).

Patients and Methods

The study was approved by the local ethical committee and by the Spanish Agency for Medicines and Health Products and was registered and audited as a clinical trial of this institution (AGEMED 312/08 EC) according to the European Directive for Clinical Trials with Medical Devices (93/42/EEC). All patients signed an informed consent before surgery.

Between September 2007 and May 2008, 8 patients (5 men and 3 women) suffering from colorectal hepatic metastases underwent hepatic resection after the procedure described later. Their mean age was 70 years (range, 69–79 y). All patients underwent careful preoperative assessment of their disease, including spiral computed tomography, scanning, or magnetic resonance imaging, and showed no evidence of unresectable extrahepatic disease. The inclusion criteria were colorectal metastases to be resected by a partial hepatectomy, and ASA (American Anaesthesia Association) ranging from I to III. The exclusion criterion was hemihepatectomy (left or right). A total of 12 tumors were removed in a total of 11 partial hepatectomies (Table 1). Mean tumor diameter was 30.5 mm (range, 7–79 mm). Additional nonhepatic procedures were performed on 4 patients (Table 1). After discharge, a follow-up appointment was made of all the patients for the first month and then every 6 months. At each follow-up visit, in addition to a clinical examination and determination of the carcinoembryonic antigen level, computed tomography or magnetic resonance imaging was performed.

Hepatic procedure

A modified right subcostal incision was performed under general anesthesia. The peritoneal cavity was examined and an intraoperative ultrasonogram was performed to reveal any previously undetected lesions. The liver then was mobilized according to the size and site of the lesion to be resected, as is usually performed in our hospital when other procedures for liver transection are used. After choosing the transection plane the lower liver surface was isolated by gauze. All the hepatic procedures were performed by the same surgeon (F.B.) in the same hospital (Hospital del Mar, Barcelona, Spain).

The RF-assisted device (485 kHz) manufactured by Medelec (Puidoux, Switzerland) was used in all liver transections. The device and its operating procedure have been described in detail elsewhere.[10–12] Briefly, it consists of a handheld instrument that conducts 2 surgical tasks simultaneously: coagulation and cutting of the hepatic tissue. Coagulation is provided by dissipating RF energy into the tissue through the proximal part of the probe (P in Fig. 1). The previously coagulated tissue then is cut by the sharp blade attached to the distal part of the probe (D in Fig. 1) as the surgeon moves the device back over the tissue. In addition, the bladeless part of the device can be applied onto

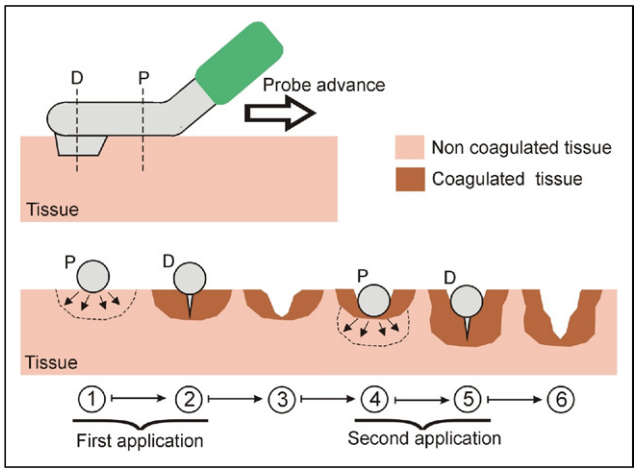

Figure 1 Main operating procedure with the proposed RF-assisted device. Top: lateral view of the probe showing the distal section (D) with the blade, the proximal section (P) joined to the insulated part of the probe, and the advance direction of the probe on the target tissue. Bottom: cross-sectional views of a fragment of target tissue showing 2 sequential applications. Each application consists of 2 steps: first, the tissue is heated (and coagulated) by applying RF currents (arrows) using the proximal section (① and ④), after which the distal section blade cuts the previously coagulated tissue (② and ⑤).

the tissue at any potential bleeding point or if the surgeon wants to increase the safety margin (Fig. 2).

Outcome measures

The outcome measures were as follows: (1) transection time: total transection time, including time for achieving complete hemostasis; (2) blood loss: total blood loss during transection (from suction device and blood-soaked gauzes); (3) transection area: obtained by delineation of the transection plane (digital photograph) using appropriate software (3D Doctor; Able Software Corp, Lexington, MA); (4) transection speed: the ratio of transection area to transection time; (5) blood loss per transection area; (6) deposited power during transection, using a computer switched to RF generator with appropriate software (Valleylab, Boulder, CO); and (7) biochemical data before and after resection.

All data were expressed as a median and range. A paired *t* test was used to compare biochemical data before and after surgery.

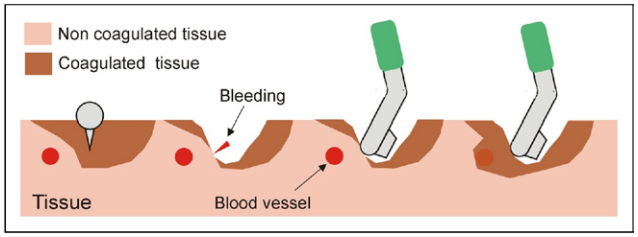

Figure 2 Secondary surgical procedure with the proposed RF-assisted device. Cross-sectional views of a fragment of target tissue showing an adjacent blood vessel that impedes complete coagulation. This secondary function may be used whenever a bleeding point appears or when the surgeon decides to increase the safety margin. The bladeless side of the instrument is moved continuously over the tissue in circular passes close to the bleeding point.

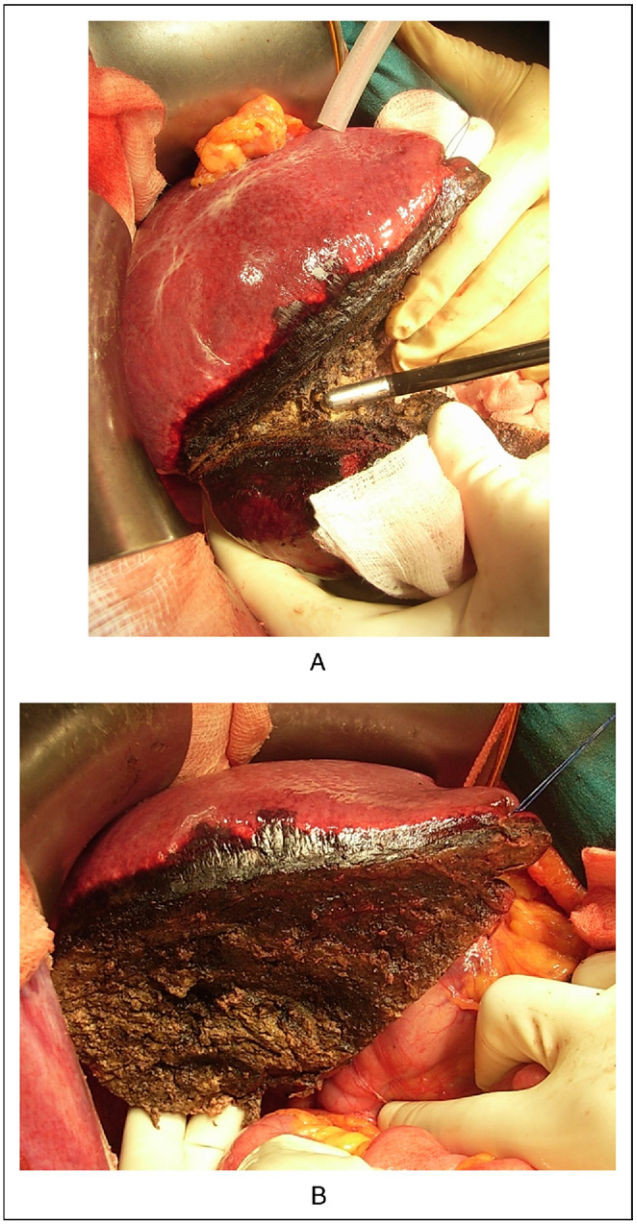

Figure 3 (A) Photograph showing transection of the liver after the described technique (bisegmentectomy 6–7; case 8). (B) Photograph taken immediately after concluding transection of the liver in the same patient after the described technique without temporary vascular occlusion and without using sutures, clips, or other instruments to occlude portal, hepatic vein, or biliary branches. Note the coagulated tissue on both surfaces of the transection plane.

Results

All the hepatic transections were performed with the proposed RF-assisted device, following the technique de-

Table 2 Biochemical changes before and after resection using the proposed technique

Patient	AST level before resection, U/L	AST level after resection, U/L (maximum value)	Bilirubin level before resection, mg/dL	Bilirubin level after resection, mg/dL (maximum value)
1	26	369	.35	1.03
2	14	1,826	.74	2.58
3	18	78	.50	.45
4	29	1,482	.47	1.97
5	14	1,175	.42	1.90
6	49	827	.74	2.43
7	32	815	.82	2.20
8	25	1,300	1.06	5.20
Mean	25.9	984.0	.64	2.22
SD	11.5	578.9	.2	1.4

AST = aspartate aminotransferase; SD = standard deviation.

scribed previously, at a deposited power range between 90 and 180 W. No other instruments (including sutures or clips) or temporary vascular occlusion (the Pringle maneuver) were used in any case for either parenchyma division or hemostasis (Fig. 3). Median resection time was 51 minutes (range, 38–87 min) and median transection speed was 1.28 cm^2/min (range, .49–1.87 cm^2/min). There was a significant change ($P < .05$) in the biochemical liver function after resection compared with previous data (Table 2), with subsequent progressive normalization.

Median blood loss was 42.5 mL (range, 5–420 mL) and the corresponding median blood loss per transection area was .79 mL/cm^2 (range, .05–7.37 mL/cm^2). However, the blood loss adjusted to transection area was markedly dependent on the case number (Fig. 4). None of the patients required blood transfusion during or after surgery, no mortalities occurred, and the described morbidity (Table 1) was not linked directly to the hepatic procedure. Median length of the postoperative stay was 6 days (range, 4–33 d) (Table 1).

Figure 4 Scatter-plot of the linear relationship between case numbers (patients) treated with the proposed technique and blood loss adjusted to the transection area during the clinical trial. The tendency of the adjusted blood loss to decrease may reflect the learning curve of the new technique.

Although the follow-up period was relatively short, ranging from 4 to 12 months, no late complications were detected and patients who underwent surgery are free from demonstrated hepatic recurrence.

Comments

This article describes an innovative technique using RF energy to achieve both parenchyma division and hemostasis with a single instrument without using sutures, clips, or other scalpels to occlude even portal, hepatic vein, or biliary branches. Several RF-assisted devices (such as Habib's[8] or the Inline method[9]) recently have been tested that may actually achieve bloodless transection usually require a limited number of sutures or clips to complete control of the portal or vein branches.[13] Furthermore, these instruments take the form of needles that are inserted blindly or under ultrasound guidance 2 or 3 cm into the liver to achieve an area of hepatic ablation,[7,14] which raises some concerns about possible thermal injuries to the hilar structures.[2] For the division of the parenchyma, these devices require an additional cutting instrument (usually a scalpel) that is applied to the middle of the supposed ablation area.[7] These shortcomings may explain why their use is restricted mainly to minor resection,[2] even though they occasionally have been used for anatomic or major resections.[15]

Interestingly enough, saline-link RF technology uses a handheld instrument (as in the proposed technique) that is easier to use and control. This technology may achieve parenchyma division and hemostasis in certain circumstances.[16] However, this instrument usually is unable to control openings made in the trunks of the hepatic vein[2] and usually is used in combination with other instruments.[16]

In the present report, similarly to previous experience in the animal setting,[10–12] we showed reduced blood loss adjusted to transection surface (median, .79 mL/cm^2; range, .05–7.37 mL/cm^2). Even though this was a clinical feasibility study and there was no control group, this number is encouraging if we keep in mind the results of several recent randomized studies with several methods of transection[17–19] (Table 3). In fact, blood loss in this procedure may be practically zero (around 5 mL) after completing the learning curve. In this respect, experience in using this device may be helpful to choose the appropriate speed during transection of the liver to achieve the best coagulating effect. There could be several explanations for the reduced blood loss: (1) parenchyma division automatically is adapted to the depth of the precoagulated tissue; (2) high power (90–180 W) is deposited, in contrast to other systems; and (3) the squeeze effect on the veins of the proposed handheld device may facilitate hepatic vein or portal vein coagulation better than other RF-assisted systems based on needle electrodes inserted into the liver.

Concerning the transection speed of the proposed technique in comparison with other studies (Table 3), it must be acknowledged that it is no faster or may be even slower than other techniques. Further clinical studies in the future may elucidate whether this transection speed can be improved, as in previous animal studies with this technique (in which a transection speed of 3 cm^2/min was achieved for open[10] and even for the laparoscopic approach[11]).

Several limitations or concerns of the proposed RF-assisted instrument also must be addressed. First, similarly to saline-linked technology, precoagulation of the tissue may preclude complete identification of the main blood vessels or main hepatic ducts. This could be an important issue and the device should therefore be used with caution near these structures because it is able to coagulate a higher amount of tissue than currently available saline-linked technology.[10] Second, the method sacrifices parenchymal tissue that usually is spared in other resectional techniques. This could be especially relevant in cirrhotic patients with limited remnant reserve. Third, some investigators have raised a concern about the destiny of the coagulated tissue on the transection plane (which could facilitate abscess formation or biliary leakage).[20] However, in our study we did not detect any complications that could be linked directly to the technique. Fourth, this was a clinical feasibility study, therefore it is mandatory that future research performed by other surgeons should compare the tested method with other available technologies.

In conclusion, the proposed RF-assisted device has been shown to achieve parenchymal division and hemostasis si-

Table 3 Results of adjusted blood loss and transection speed in 3 recent randomized clinical trials with several methods of liver transection and results of the present feasibility study

	Clamp crushing	CUSA	Waterjet dissector	Dissecting sealer	Proposed technique
Blood loss per transection area, mL/cm^2	7[17] 1.5[18]	4[18] 7.5[19]	3.5[17] 8.2[19]	5.3[17] 3.4[18] 5.5[19]	.8
Transection speed, cm^2/min	.9[17] 3.9[18]	2.3[18] 2.3[19]	2.4[18] 2.8[19]	1[17] 2.5[18] 1.7[19]	1.3

Figures are mean values (except those for the proposed technique, which are median values).
CUSA = ultrasonic dissector dissecting sealer; saline-link technology (Tissuelink [Tissuelink Medical, Dover, NH]).

multaneously, resulting in extremely reduced blood loss. This could be more relevant in a laparoscopic approach. Further studies should confirm these results.

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References

1. Aloia TA, Zorzi D, Abdalla EK, et al. Two-surgeon technique for hepatic parenchymal transection of the noncirrhotic liver using saline-linked cautery and ultrasonic dissection. Ann Surg 2005;242:172–7.
2. Poon RT. Current techniques of liver transection. HBP (Oxford) 2007; 9:166–73.
3. Sitzmann JV, Greene PS. Perioperative predictors of morbidity following hepatic resection for neoplasm. A multivariate analysis of a single surgeon with 105 patients. Ann Surg 1994;219:13–7.
4. Stephenson K, Steinberg S, Hughes KS, et al. Perioperative blood transfusions are associated with decreased time to recurrence and decreased survival after resection of colorectal liver metastases. Ann Surg 1988;208:679–87.
5. Kooby DA, Stockman J, Ben-Porat L, et al. Influence of transfusions on perioperative and long-term outcome in patients following hepatic resection for colorectal metastases. Ann Surg 2003;237:860–9.
6. Yamamoto J, Kosuge T, Takayama T, et al. Perioperative blood transfusion promotes recurrence of hepatocellular carcinoma after hepatectomy. Surgery 1994;115:303–9.
7. Weber JC, Navarra G, Jiao LR, et al. New technique for liver resection using heat coagulative necrosis. Ann Surg 2002;236:560–3.
8. Jiao LR, Ayav A, Navarra G, et al. Laparoscopic liver resection assisted by the laparoscopic Habib sealer. Surgery 2008;144:770–4.
9. Yao P, Chu F, Daniel S, et al. A multicentre controlled study of the InLine radiofrequency ablation for liver transection. HBP (Oxford) 2007;9:267–71.
10. Burdio F, Navarro A, Berjano EJ, et al. A radiofrequency-assisted device for bloodless rapid transection of the liver: a comparative study in a pig liver model. Eur J Surg Oncol 2008;34:599–605.
11. Navarro A, Burdío F, Berjano EJ, et al. Laparoscopic blood-saving liver resection using a new radiofrequency-assisted device: preliminary report of an in vivo study with pig liver. Surg Endosc 2008;17: 295–9.
12. Burdío F, Berjano EJ, Navarro A, et al. Research and development of a new RF-assisted device for bloodless rapid transection of the liver: computational modeling and in vivo experiments. Biomed Eng Online 2009;18;8:6.
13. Hompes D, Aerts R, Penninckx F, et al. Laparoscopic liver resection using radiofrequency coagulation. Surg Endosc 2007;21:175–80.
14. Mitsuo M, Takahiro T, Yasuko T, et al. Radiofrequency (RF)-assisted hepatectomy may induce severe postoperative liver damage. World J Surg 2007;31:2208–12.
15. Navarra G, Spalding D, Zacharoulis D, et al. Bloodless hepatectomy technique. HBP (Oxford) 2002;4:95–7.
16. Poon RT, Fan ST, Wong JW. Liver resection using a saline-linked radiofrequency dissecting sealer for transection of the liver. J Am Coll Surg 2005;200:308–13.
17. Arita J, Hasegawa K, Kokudo N, et al. Randomized clinical trial of the effect of a saline-linked radiofrequency coagulator on blood loss during hepatic resection. Br J Surg 2005;92:954–9.
18. Lesurtel M, Selzner M, Petrowsky H, et al. How should transection of the liver be performed? A prospective randomized study in 100 consecutive patients: comparing four different transection strategies. Ann Surg 2005;242:814–23.
19. Richter S, Kollmar O, Schuld J, et al. Randomized clinical trial of efficacy and costs of three dissection devices in liver resection. Br J Surg 2009;96:593–601.
20. Lupo L, Gallerani A, Panzera P, et al. Randomized clinical trial of radiofrequency-assisted versus clamp-crushing liver resection. Br J Surg 2007;94:287–91.