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ORIGINAL ARTICLE

Evaluation of a bipolar radiofrequency device for laparoscopic hepatic resection: technique and clinical experience in 18 patients

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Abstract

Background: The increased frequency of laparoscopic hepatic resection as a principal or adjunct component of patient care has driven the need for and development of efficient and safe hepatic parenchymal transection technologies. At present, various devices are available for pre-coagulation transection (PCT) of hepatic parenchyma with the intent of minimizing procedure-associated postoperative haemorrhage and bile leak. This report presents the evaluation of a novel bipolar radiofrequency (RF) energy device for PCT used for laparoscopic hepatic resection.

Methods: Patients undergoing laparoscopic hepatic resection using the Enseal™ device (SurgRx Inc.) were identified from the prospectively maintained hepatobiliary database. Information on patient demographics, procedures and postoperative complications was collected and analysed; complications were grouped into early (at <30 days) and late (at ≥30 days) events.

Results: A total of 18 patients, of whom 13 had malignant tumours (12 colorectal metastases and one hepatocellular carcinoma) and five had benign tumours (two hepatic adenomas and three haemangiomas) underwent 18 hepatic procedures, including two formal hemi-hepatectomies, four left lateral sections, three posterior sections and nine atypical non-anatomic resections. Estimated blood loss did not differ from institutional historical control data; no postoperative haemorrhage, bile leaks or hepatic abscess or necrosis were identified ($n = 18$).

Conclusions: This initial experience using the laparoscopic bipolar RF device demonstrates an acceptable safety profile in terms of the outcomes analysed.

Keywords

bipolar RFA, liver resection, laparoscopy

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Introduction

The rapid increase in the frequency with which laparoscopic hepatectomy is performed since its advent in the late 1990s has occurred without a consensus on 'standard' technique or instrumentation. It is clear, however, that varied forms of thermal energy derived from monopolar, bipolar, harmonic resonance and even microwave generators have been utilized and described as potential adjuncts to staplers or mini-laparotomy during laparoscopic hepatic resection.

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The Enseal™ device (SurgRx Inc., Redwood City, CA, USA) employs bipolar radiofrequency (RF) energy and is approved as a tissue cutting and sealing device for use during traditional open or laparoscopic procedures.[1] To date, no studies defining the role of this device in hepatic resection have been published, although several limited studies have reported the properties of the device in various other surgical domains. The most salient demonstrated capacities of the bipolar RF device include the sealing of blood vessels in the range of 1–7 mm[3] and a minimal (<1 mm) lateral thermal spread of energy.

We present a series of patients who underwent laparoscopic hepatectomy using the Enseal™ device and describe our clinical experience as a formal hepato-pancreato-biliary (HPB) team at a volume centre for laparoscopic hepatic resection.

Materials and methods

Patients undergoing laparoscopic hepatic resection using the bipolar RF device were identified from the prospectively maintained hepatobiliary database. Patient demographics, procedures and postoperative complications were collected and analysed; complications were grouped into early (at <30 days) and late (at ≥30 days) events.

Results

Eighteen consecutive patients (12 female, six male; mean age 50 years) undergoing planned laparoscopic hepatic resection for benign or malignant tumours were resected using the bipolar RF device for pre-coagulation transection (PCT).

For formal hemi-hepatectomy, lateral or posterior sections, the hepatic portal pedicles (using the pedicle isolation technique described by Cunningham *et al.*,[2] modified to laparoscopy) and/or hepatic veins were divided with an endomechanical stapling device (EndoGIA™; Covidien Corp., Norwalk, CT, USA) after PCT. In this cohort, the procedures performed included two formal hemi-hepatectomies, four left lateral sections, three posterior sections and nine atypical non-anatomic resections (defined as resections that do not respect anatomic boundaries of Couinaud liver segmentation and include subsegmentectomies, or resection of more than one segment). Twelve of the 18 patients underwent concomitant surgical procedures as follows: RF ablation of other liver lesions ($n = 9$); partial colon resection ($n = 2$), and reversal of Hartman's procedure ($n = 1$). Mean estimated blood loss per procedure was 178 ml ± 53 ml (Table 1). Estimated blood loss did not differ from institutional historical control. No patient required blood transfusion, and no postoperative haemorrhage (defined as haemodynamic instability, drop in haemoglobin >2 mg/dl or postoperative haematoma requiring surgical or interventional radiology drainage) or bile leaks were identified in the <30-day or ≥30-day postoperative periods. Additionally, no resection plane parenchymal necrosis or hepatic abscess was noted on routine 30-day postoperative imaging, although this has been previously described with other energy-based PCT devices.

The bipolar RF device

The bipolar RF device allows surgeons to seal and transect small to large vessels and tissue bundles to achieve surgical haemostasis. We used the 5-mm-diameter laparoscopic bipolar RF instrument. According to the published literature, this device has the capacity to seal vessels of 1–7 mm in diameter and the seal created has been demonstrated to withstand over seven times normal systolic pressure.[3]

Table 1 Patient demographics, liver pathology, estimated blood loss and total surgical time

Patient	Age, years	Sex	Liver pathology	Liver procedure	Concomitant surgery	Estimated blood loss, ml	Total surgical time, min
1	66	F	CRM	Non-anatomic resection	RFA	100	60
2	57	M	CRM	Non-anatomic resection	None	100	70
3	68	M	CRM	Left lateral	RFA	180	120
4	54	F	CRM	Left hepatectomy	Hartman's reversal	200	300
5	46	F	CRM	Non-anatomic resection	Colon resection	250	180
6	52	F	CRM	Posterior sectorectomy	RFA	200	150
7	48	M	CRM	Left lateral	RFA	220	160
8	55	M	CRM	Right hepatectomy	RFA	250	200
9	47	F	CRM	Left lateral	Colon resection	200	170
10	65	F	CRM	Non-anatomic resection	RFA	150	120
11	51	M	CRM	Non-anatomic resection	RFA	50	180
12	53	F	CRM	Posterior sectorectomy	RFA	200	170
13	43	F	HCC	Posterior sectorectomy	None	200	120
14	47	F	Haemangioma	Non-anatomic resection	None	200	100
15	40	F	Haemangioma	Left lateral	None	200	110
16	51	M	Haemangioma	Non-anatomic resection	None	150	120
17	28	F	Adenoma	Non-anatomic resection	RFA	200	120
18	35	F	Adenoma	Non-anatomic resection	None	150	90
	50 ± 10*	12 F 6 M			12 concomitant surgery	178 ± 53*	114 ± 56*

*Average ± standard deviation
F, female; M, male; CRM, colorectal metastasis; RFA, radiofrequency ablation; HCC, hepatocellular carcinoma

Bipolar RF energy delivery in tissue occurs under the 'line of sight' principle, where energy is transferred only between the electrodes, or in this case, between the jaws of the device. As such, current flow and heat deposition are confined only to tissue held within the jaws of the instrument. An advantage of this approach is that lateral thermal spread is minimized.

For laparoscopic liver surgery, the 535 RH model was selected because it has a rounded tip, which allows soft atraumatic introduction into the hepatic parenchyma, and a 35-cm shaft length, which allows for comfortable handling and is sufficient to reach any target point on the liver.

Technique

Without inflow occlusion and under low central venous pressure (CVP) (<5 mmHg), the hepatic lesion is identified, guided by intraoperative ultrasound (IOUS), and the liver capsule is scored ≥1 cm away from the lesion borders, using a monopolar electrocautery device. The scoring is used as guide for the parenchymal transection, with further application of the IOUS as needed to assure an adequate margin. The bipolar RF device is then introduced into the parenchyma with the straight inferior blade penetrating the parenchyma. The jaws of the device are closed to compress the parenchyma without crushing. The device is activated (by either a pull trigger or a foot pedal); PCT begins and as the coagulation progresses with concomitant tissue desiccation, the jaws allow the deployment of an 'I' cutting beam in a manner similar to that of an endomechanical stapler. In our experience, each closure of the device, which represents a PCT of a 1-cm segment of parenchyma, takes 3–10 sec to perform. The variability is dependent on how thick a portion of tissue is grasped. As the energy delivery cycle propagates coagulation, 'time-out' impedance is reached and energy delivery ceases. The device cutting tip length is approximately 20 mm and, using sequential forward advancement, a PCT plane is achieved. After each cycle, the superior jaw is opened as soon as the transection is completed and the straight jaw is advanced into the liver parenchyma following the tract initiated and guided by the lines scored on the liver capsule. It is important to keep the straight jaw at the same level of depth and advance it gradually to obtain a uniform, consistent and rapid PCT plane. The 360-degree rotation capability of the device allows it to advance forwards without applying torque on the liver parenchyma, thus avoiding small parenchymal fractures.

The PCT plane is defined in an inferior (edge of the cystic fossa) to superior direction in the case of formal hepatectomy, or in a lateral to medial fashion in atypical resections. In our approach, the device is used for the first 2 cm of the circumference of the liver parenchyma as the parenchyma is divided, bridging or revealing hepatic veins, and endomechanical staplers are used to divide these particular structures. Thus, the objectives of the laborious procedures involved in the 'crush–clamp' technique for parenchymal transection can be accomplished without the need for ligature or clips.

Discussion

The resection rate of benign and malignant hepatic tumours has increased over the last decade and continues to do so. Various factors have contributed to this, including greater availability of hepatobiliary training, increased quality and frequency of body imaging, the refinement of operative techniques and the development of novel devices to facilitate hepatic parenchymal transection procedures. Laparoscopy and hepatic surgery have rapidly merged, with the result that laparoscopic hepatic resection as a principal or adjunct component of patient care is fairly common, even outwith major tertiary care centres.

Laparoscopic liver resection is inherently challenging on several fronts, but the fact that it precludes conventional blood vessel and bile duct ligation represents a key deterrent. Accordingly, techniques and technologies have been developed to overcome this limitation. Energy-based devices that are intended to allow for the simultaneous sealing, coagulating and cutting of blood vessels are used in preference to performing these procedures mechanically by tying, suturing, clipping or stapling, with the intention of minimizing procedure-associated morbidity such as postoperative haemorrhage and bile leak. However, the optimal device for these purposes has yet to be established.

Pre-coagulation transection is the term used to cover a broad use of energy devices in hepatic resection, whether by laparotomy or laparoscopy.[4] The PCT process is based on the response of hepatic parenchyma to thermal energy, most commonly monopolar, but, more recently, bipolar RF energy. Parenchymal protein denaturation occurs at high temperatures,[5] with resultant blood vessel wall and bile duct fusion, which translates into more controlled operative bleeding and potentially decreased postoperative haemorrhage or bile leak.

In the present series, 18 patients underwent laparoscopic hepatic resection procedures ranging from formal hemihepatectomy to atypical resection. The bipolar RF energy device was primarily utilized for PCT in a similar fashion to the crush–clamp technique. During PCT, minimal tissue charring on the active jaws of the device was observed, allowing for the sequential linear application of energy along a planned transection plane. The particular bipolar device employed provided efficient laparoscopic PCT in a smokeless field, thereby ensuring a continuous clear operative field and eliminating the smoke evacuation and cleaning of optical equipment that are required by other parenchymal transection systems.

The device was already in use in our institution for various other laparoscopic surgical procedures (i.e. colon-related and oesophageal procedures) and thus we did not need to climb a learning curve to expand its use for PCT of liver parenchyma. However, in recognition of the fragile character of liver parenchyma, we encouraged a consistent and slow transection technique to avoid the crushing or tearing of non-precoagulated tissues.

The subjective observations of the operating team included a comment that parenchymal haemostasis was excellent. There was no difference in estimated blood loss between the first patients and the rest of the patient group. No transfusions were required and no major postoperative haemorrhage was observed; however, this is more likely to reflect our strict adherence to the low CVP anaesthetic technique and the fact that our operating surgeons were senior, experienced and HPB-focused. There was also no clinical evidence of bile leak; to date there is no experimental or clinical study demonstrating the effectiveness of the bipolar RF device specifically for bile duct sealing. We note that it is possible that clinically insignificant bile leaks may have occurred, but it is not our standard practice to employ drains. Nonetheless, no patient in the series required an intervention for bile leak. In recognition of our numerically modest cohort, we make no observations on complications arising <30 days or ≥30 days post-surgery.

This bipolar RF device is about 2 cm in length at the functional portion of the head, which is comprised of jaws. The head is designed to facilitate atraumatic dissection. The device has been approved by the US Food & Drug Administration for tissue sealing and several experimental studies have further characterized its properties. In a recent technology-comparative study, vessel burst pressures with this bipolar RF device were reported to be significantly higher than those of four other energy-based instruments. Interestingly, on histopathological analysis, the bipolar RF device demonstrated that porcine vessels sealed *in vivo* exhibited less radial adventitial collagen denaturation compared with those sealed by other similar devices.[3]

In further experimental support of the observation that decreased lateral thermal energy spread results in fewer potential tissue complications, a comparison among the bipolar RF device, a competitive vessel sealer and *in vivo* suturing on rat liver parenchyma demonstrated that necrosis, exudate formation, chronic inflammation, histiocyte and fibroblast scores were significantly lower in the bipolar RF group compared with the competitive vessel sealer and suture groups.[5] Bipolar RF was superior to both the competitive vessel sealer and to suturing in that it achieved a reduced inflammatory response, which is probably secondary to decreased lateral thermal injury and inflammatory response.[5] In a separate experimental study evaluating the effects of adhesion formation secondary to use of the bipolar RF device, the authors reported significantly lower adhesion formation in the bipolar RF device group compared with groups in which other energy-based vessel-sealing devices or suturing were used.[6]

The incentive to minimize lateral thermal spread in laparoscopic surgery is largely based on the need to prevent inadvertent tissue injury. Although this represents a positive feature for non-hepatic applications, the device has been criticized for failing to attain a wider ablation in the plane of resection, which some authors have proposed as desirable for malignant lesions.[7] A separate, but important, limitation of the technology concerns the width of the jaw aperture, which limits the amount of tissue that can be grasped for PCT.

We acknowledge that this study has limitations. It is difficult to estimate a potential benefit in limiting blood loss with the use of the device in our series for the following reasons: most of the cases included in this series involved combined surgical procedures where liver resections were concomitant with various other procedures (RF ablation, colon resection, Hartman's reversal) with an inherently wide range of potential blood loss. It would be unrealistic to construct a comparative study with a similar group of patients undergoing similar combined surgical procedures. Estimated blood loss is, by definition, estimated and thus subjective, and potential differences between different modalities can only by established by analysing a very large group of patients.

In order to evaluate the haemostatic role of the device in our study, we used objective data such as those pertaining to need for blood transfusion, haemodynamic instability, major decreases in haemoglobin (of >2 units) and postoperative haematoma requiring surgical or interventional radiology drainage.

It is difficult to compare the other beneficial aspects of this device with those of other devices, although its capabilities are very much appreciated. These parameters would include the absence of torque force within the parenchyma in conjunction with its 360-degree rotation capability, the fact that it allows for a smokeless surgical field during laparoscopy, and its inherent ease of use. In the present series, these beneficial effects are reported in terms of the absence of objective negative outcome parameters, rather than as beneficial effects: thus we note that no blood transfusion was required in any of our cases, and no postoperative haematoma, bile leak, abscesses or liver necrosis were observed.

For the reasons cited above, our study was not constructed to compare outcomes with this device with those of other similar devices by measuring estimated blood loss; consequently, the study does not claim that this device is superior to other sealing or haemostatic products. Rather, the goal of our study was to demonstrate the safety of using this device and to better define its application as an adjunct to laparoscopic hepatic surgery.

Our clinical experience with the bipolar RF device presented here demonstrates an acceptable safety and performance profile for its use in PCT for laparoscopic hepatic resection. The effect(s) of this device in cirrhotic liver have not been defined or addressed in the present report. The device can be used to transect liver without any inflow occlusion, which should be seen as an advantage that supports its inclusion in the armamentarium of technology available for use in laparoscopic liver resection.

The field of laparoscopic hepatectomy is in evolution and consensus is lacking about optimal instrumentation and technique. A wide array of devices and techniques for hepatic parenchymal transection have been reported by different teams and institutions. At present, laparoscopic hepatic surgeons should aim to define the technologies and techniques that are safe, as well as useful. The present series is the first to report the safety and efficacy of PCT of liver parenchyma using bipolar RF technology provided by the Enseal™ device. Further studies with multi-institutional collaboration may be useful to evaluate the various devices and techniques appropriate for these procedures, although it is unlikely than any single approach will emerge as superior to others as the field continues to be dynamic.

Conflicts of interest

None declared.

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