

The modern use of radiofrequency energy in surgery, endoscopy and interventional radiology

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Moderne Anwendung der Radiofrequenzenergie in Chirurgie, Endoskopie und interventioneller Radiologie

Zusammenfassung. *Grundlagen:* Der therapeutische Einsatz der Radiofrequenzenergie (RF) in der Medizin nimmt zu. Diese Arbeit beschreibt 4 neue RF-Instrumente für Chirurgie, Endoskopie und interventioneller Radiologie.

Methodik: Die 4 Instrumente sind: 1) Endoblate zur endoskopischen RF-Therapie beim Rektumkarzinom; 2) Hexablate, ein bipolares RF-Instrument zur Behandlung des Hepatoms; 3) VesCoag, ein bipolarer RF-Katheter zum interventionell-radiologischem Verschluss von Tumorgefäßen der Leber und 4) EndoHPB, ein endoskopischer bipolarer RF-Katheter zur endobiliären Ablation, derzeit im Schweinemodell getestet.

Ergebnisse: Endoblate, Hexablate and VesCoag zeigten im klinischen Einsatz keine technischen Probleme und unerwünschte Nebenwirkungen. Alle wurden bipolar verwendet bis auf VesCoag, welches nur monopolar Effizienz bei der Gefäßversiegelung zeigte. Bei EndoHPB zeigte sich im Schweinemodell, dass 5–10 Watt für 2 Minuten die ideale Einstellung war. Eine klinische Studie untersucht derzeit den Einsatz bei malignem Verschlussikterus.

Schlussfolgerungen: Die RF-Instrumente stellen eine faszinierende Entwicklung dar, welche vielversprechende therapeutische Methoden in Endoskopie, Chirurgie und interventioneller Radiologie erwarten lassen.

Schlüsselwörter: Radiofrequenz, Ablation, Endoskopie, endovaskulär, biliär, Hepatom.

Summary. *Background:* The potential applications of radiofrequency (RF) energy in medicine are an expanding field. This paper describes the development and early results of the application of four novel radiofrequency devices in surgery, endoscopy and interventional radiology.

Methods: The four devices that were designed and have been assessed were 1) Endoblate: a bipolar RF catheter for endoscopic use which was assessed in patients with rectal tumors, 2) Hexablate: a bipolar RF ablation/aspiration device which was used to treat liver cancers, 3) VesCoag: a bipolar RF catheter for endovascular ablation which was used by interventional radiologists to seal the blood vessels of tumors within the liver and 4) EndoHPB: an endoscopic bipolar RF catheter for endobiliary ablation which so far has been assessed in a porcine model.

Results: In the pilot clinical studies on Endoblate, Hexablate and VesCoag, all the devices could be used in the clinical situation for which they had been designed. There were no technical problems and no serious adverse events associated with their use. All were used in bipolar mode apart from VesCoag, where it was found that a monopolar current was required for effective vessel sealing. For EndoHPB in the porcine model, it was determined that the ideal power setting was 5–10 watts for 2 min. A clinical trial is to be undertaken to determine whether this power setting is applicable for when EndoHPB is used in the management of malignant obstructive jaundice.

Conclusions: It is an exciting time in the development of new RF instruments, and as they become more sophisticated their clinical applications will expand. These early data from the animal and pilot clinical studies are promising and larger studies with longer term follow-up needs to be undertaken to establish their true clinical worth.

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Introduction

The medical use of radiofrequency (RF) energy where a high frequency electric current is used to produce coagulative necrosis is an expanding field. The Hammersmith experience with RF technology started when a RF cool tip single probe was used to perform a right hepatectomy. The gain from approaching liver surgery in this way was to reduce intra-operative blood loss [1], but the drawbacks of using a single probe were that it was time consuming and monopolar, which has potential problems such as collateral tissue injury and unpredictable current pathways. To address the limitations of the technology, a number of modifications were made. The RF probe was changed to a bipolar arrangement of four stainless steel electrodes, so that the current is confined to the area to be treated thereby ablating a larger volume of tissue which shortens operative time. The resulting RF probe is now known as the Habib 4X and further development has led to two handsets, one for use at open and another for laparoscopic surgery [2]. At our institution, the use of the Habib 4X is now the standard for liver surgery, and in our hands shortens operative time and facilitates parenchymal sparing liver resections and non-anatomical resections without the need for inflow or outflow control [3–5].

Building on this experience in the design and demonstration of the clinical utility of RF energy in liver surgery, the technology has been further modified for application in alternative clinical situations. In total, four devices have been conceived and developed for use at either open surgery, endoscopically or during interventional radiology. This editorial gives a brief overview of this work, highlighting the device design, potential clinical application and some early data from animal experiments and pilot clinical studies.

Methods

For all the devices, either the Radionics Cosman Coagulator CC-1 or the RITA Medical Systems 1500 radiofrequency generators can be used. All the devices presented are CE marked and have FDA 510 (K) approval, and were provided free of charge by EMCision Ltd, London, UK. Professor Nagy Habib is a shareholder and the director of EMCision Ltd, which has developed all the devices described. All human studies have been reviewed by the appropriate ethics committee and have been performed in accordance with the Declaration of Helsinki.

Endoscopic rectal cancer RF ablation

The ideal management of patients with rectal cancers is surgical resection, but in 20–30% of patients local tumor advancement, metastatic disease or patient's comorbidity prevent curative resection from being undertaken. A number of different endoscopic techniques have been

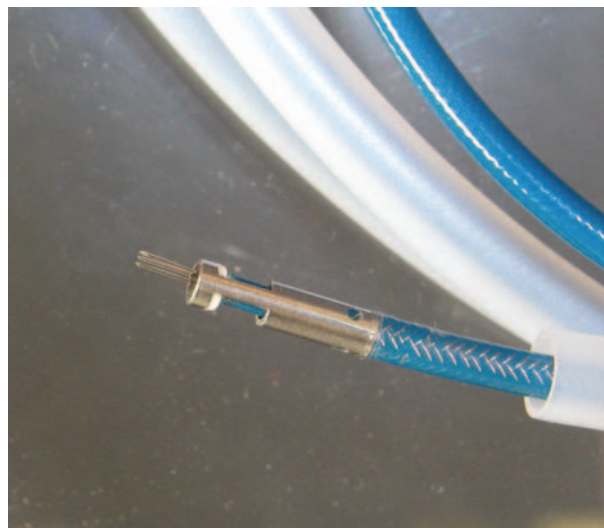


Fig. 1: A close-up of the distal end of Endoblate showing the arrangement of the electrodes

used to palliate tumors of the rectosigmoid, such as neodymium yttrium argon garnet (Nd:YAG) laser vaporization, argon plasma coagulation, electrocoagulation and cryotherapy. Alternatively, in selected patients, endoscopic metal stents can be used for long-term palliation [6–8]. However, endoscopic RF ablation has not previously been used.

The device (Endoblate) consists of three contact electrodes and one ring electrode, which is activated by bipolar RF energy, so no grounding pad is required (Fig. 1). The probe is designed to be introduced either through the working channel of an endoscope or via an operating proctoscope during transanal endoscopic microsurgery (TEM). In this small pilot study ($n = 12$), Endoblate was used during TEM under general anesthesia to ablate tumors of the rectum (Fig. 2). Under endoscopic visualization, the electrodes were advanced 2–3 mm into the tumor and the output of the RF generator started at 1 watt (W) and as required increased to 4 W. RF energy was



Fig. 2: Endoblate™ catheter being introduced through the instrument channel of the operating proctoscope during transanal endoscopic microsurgery (TEM)

delivered until impedance rose 10%, indicating that sufficient coagulation had been produced. The three electrodes of Endoblate were then retracted. Endoscopic ultrasound (EUS) was used to assess the depth of ablation in relation to tumor thickness and to minimize the risk of perforation during the procedure. After each application of Endoblate, a well-demarcated ablation zone was visible and the probe was reapplied step by step, to produce a confluent area of ablation. When technically feasible, the ablated tumor was then resected to assess the histologic effect of Endoblate.

Liver cancer RF ablation/aspiration

Often tumors of the liver are unresectable, either because of extensive hepatic involvement, unfavourable localization in relationship to bile duct/blood vessel, extrahepatic spread, co-morbidity or limited liver reserve (volume/synthetic) [9]. Therefore alternative therapeutic approaches have been developed, e.g. percutaneous ethanol injection (PEI); transarterial chemoembolization (TACE); selective internal radiation therapy (SIRT); cryoablation, and in the last decade there has been a major interest in using heat to destroy tumors, for example, RF, laser, and microwave energies.

The use of RF energy to ablate the tumor is becoming a standard therapeutic option [10, 11] and it is predicted that the total number of thermal ablation procedures performed in the United States will grow from an estimated 47,600 in 2005 to 135,000 procedures in 2010 [12]. However, the technology can be developed further. Many devices (Valleylab, Angiodynamics, Boston Scientific Inc) are monopolar, which present the risks of collateral damage to adjacent organs, skin burn at the grounding pad site and unpredictable current pathways, which can reduce the area of ablation [13]. Another problem encountered is the discharge of vapor and fluid during ablation, and this may contribute to the patterns of recurrence observed after ablation, such as round the diaphragm or by promoting intra-parenchymal spread [14, 15]. Keeping these problems in mind, Hexablate was developed.

The Hexablate handset is bipolar and consists of a ring of six electrodes with a central electrode having a dual role as an aspiration channel and active electrode. Suction is achieved via an array of perforations along the shaft of the central electrode. Three alternative handsets are in the process of development: one for percutaneous use, one for use at open surgery, and one for laparoscopic surgery. In our first pilot study, the use of Hexablate was only assessed at open operation, allowing us to fully assess the utility and effectiveness of the device.

For tumors less than 2 cm in diameter the central needle of the device was centralized on the deposit. In tumors larger than 2 cm the device was applied at the periphery of the lesion, starting at the deepest part of the tumor, and then it was reapplied to produce circumferential ablation of the tumor. Finally, the central core of the tumor would then be ablated (Fig. 3). During ablation, the aspiration channel of the central electrode was kept open to remove tumor spume. The central electrode also has the potential to be used as a channel to deliver thera-



Fig. 3: Intra-operative photograph of Hexablate being used at open operation to ablate the outer edge of an intrahepatic cholangiocarcinoma

peutic agents into the central tumor space. The RF generator was activated at 40–80 W. On initial activation the current ran between the outer six electrodes to produce outer zone ablation. Ablation was then stopped after a 10% increase in impedance and the central electrode then activated at half the wattage used for the outer zone ablation, with the current then running from the outer ring to the central electrode to produce a 3 cm by 3 cm cylinder of ablation. When possible, the ablated lesion was then resected to allow histologic assessment.

Interventional radiology and endovascular RF ablation

The liver has a dual blood supply, with 80% derived from the portal vein (PV) and the remainder from the hepatic artery (HA). Both primary and secondary liver tumors are mainly supplied arterially and arterial occlusion with or without chemotherapy can be exploited to retard tumor growth or to allow staged surgical resection [16, 17]. This strategy is established in hepatocellular carcinoma (HCC), but it has the potential to be used in a variety of hepatic and extrahepatic solid tumors [18]. Presently available endovascular techniques rely on the delivery of embolic material and at the moment there are no data to suggest that one embolic material over the other has any advantage [19]. One recognized disadvantage in the use of embolic material is imprecision, leading to collateral damage to nontarget areas such as nontumoral liver which can lead to liver failure or other nontarget organ complications such as cholecystitis or upper gastrointestinal bleeding [19, 20]. To try and increase the therapeutic precision in target vessel occlusion, an endovascular RF catheter was developed.

VesCoag is a bipolar RF endovascular catheter (5 F, length 110 cm) designed for insertion over a standard guide wire (0.014 inch) into either artery or vein. At the tip of the catheter are two platinum ring electrodes. When activated in bipolar mode, a high frequency current runs between these two ring electrodes to coagulate the blood

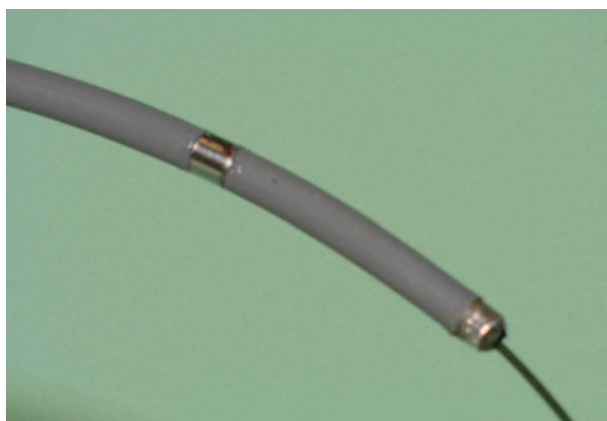


Fig. 4: A close-up of the radiofrequency vascular catheter (VesCoag) showing the two platinum ring electrodes at its tip

vessel wall so that it is sealed (Fig. 4). VesCoag can also be used in monopolar mode, and then grounding pads are required. Under fluoroscopic control, VesCoag was manipulated into the target vessel and the RF generator activated at 1 W, which was then increased till a 10% increase in impedance was achieved, to produce endovascular tissue coagulation. After endovascular RF ablation, a completion angiogram was performed to document whether the vessel had been sealed. If required, the central channel of the VesCoag catheter can be used to deliver chemotherapy, lipiodol or embolic material.

Endobiliary RF ablation

Patients with malignant biliary obstruction often have inoperable disease and will need relief of their jaundice. Endoscopic plastic stents are widely used, but clogging by sludge or tumor ingrowth often necessitates that the stent is changed every 3–6 months. Self-expanding mesh metal stents (SEMS) were introduced at the end of the 1980s, which have longer patency and lower occlusion rates [21]. However, tumor ingrowth is still problematic. Recently, photodynamic therapy (PDT) has been evaluated as a palliative and potential neoadjuvant modality for unresectable cholangiocarcinoma, with PDT treatment and subsequent stenting maybe improving survival, quality of life, and cholestasis compared with endoscopic stenting alone [22]. EndoHPB is an endoscopic bipolar catheter designed to be introduced across malignant strictures in the biliary tree, so that RF energy can be applied locally before stent insertion. Potential advantages gained from the use of the device could be longer stent patency by delaying tumor growth and endobiliary RF ablation may eventually compete with PDT as a form of neoadjuvant therapy in unresectable cholangiocarcinoma.

EndoHPB is a 8 F, 1.8 m coaxial over the wire catheter that is designed to be inserted through a 3.2 mm working channel of the endoscope. At the distal end of the catheter are two ring electrodes spaced 8 mm apart (Fig. 5) which produces a heating zone length of approximately 25 mm. A porcine model so far has been used to

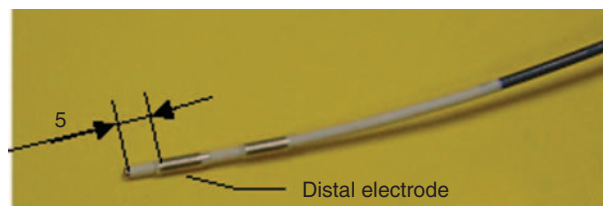


Fig. 5: A close-up of the distal end of EndoHPB showing the two ring electrodes, which are spaced 8 mm apart and the most distal electrode is 5 mm from the end of the catheter

assess 1) the ability of EndoHPB to heat and coagulate tissue in the common bile duct, 2) establish the power requirement and time parameters to achieve coagulation and 3) to assess the ease of operation via the side endoscope. Under general anesthesia, a side viewing endoscope was used to identify the opening of the common bile duct (CBD). After performing a sphincterotomy, EndoHPB was inserted over a guidewire (0.035" × 260 cm Hydra Jagwire, Boston Scientific) and its position was confirmed with fluoroscopy before activating the RF generator.

Results

Endoscopic rectal cancer RF ablation

Twelve patients were treated with Endoblate. One patient underwent tumor ablation on two occasions for

Tab. 1: Summary of clinicopathologic data on the patients treated with Endoblate. Breakdown of patient age, gender and fitness according to the American Society of Anesthesiology (ASA) classification, grades I–IV. Endoscopic Ultrasound (EUS) was used to assess the relationship of the tumor to the anal verge, its thickness and its length. Characteristics of the rectal tumor treated with Endoblate further broken down according to stage of disease using the TNM system

Patient characteristics <i>n</i> = 12	
Age median (range) years	70.4 (54–82)
Gender Male/Female	6/6
ASA	
1/2/3/4	0/8/2/2
Tumor EUS assessment median (range) cm	
Distance from anal verge	7.2 cm (range 0.7–15 cm)
Tumor Thickness	3.1 cm (range 2.3–4.1 cm)
Tumor Length	4 cm (range 3–6 cm)
TNM	
T2	1
T3	10
T4	1
Nodal disease	8
Metastases (Liver)	3

palliation of bleeding. Table 1 summarizes the clinicopathologic characteristics of the patients. The mean total procedure and ablation time were 40 minutes (range 11–65 minutes) and 17 minutes (1–45 minutes), respectively. The average power setting used for ablation was 2.7W (range 1–4W). Surgical resection was subsequently performed in 10 patients, allowing intraoperative assessment of complications and for histologic effect of Endoblate to be determined. Only two patients were managed purely by endoluminal ablation to manage the symptom of bleeding. Surgical procedures undertaken were TEM ($n=3$), abdominoperineal excision ($n=3$) and anterior resection ($n=4$). At operation, there was no evidence of transmural thermal injury, pericolic fluid or any other adverse findings, such as bowel perforation.

In this series, there was no endoluminal ablation treatment related mortality or morbidity. The median length of stay was 8.4 days (range 3–12 days). In the two patients who underwent ablation only, the average length of stay was 3.5 days. Histology of the resected specimen showed that on average 82% (range 60–99%) of the tumor mass was destroyed in the ablation zone. In the two patients who had only been treated with Endo-

blate, there were no delayed complications relating to endoluminal RF ablation, or recurrent bleeding at clinical assessment three weeks following discharge.

Liver cancer RF ablation/aspiration

In total 17 Hexablate treatments were performed in 16 patients and followed up at 4 weeks after discharge. Table 2 summarizes patient clinicopathologic characteristics. Seventeen Hexablate treatment sessions were performed at open operation. In total 34 lesions were ablated in 16 patients. The mean number of lesions ablated per patient was 2 (range 1–6). The median diameter of lesion before ablation was 2.75 cm (range 1–10 cm), median volume aspirated during ablation 10 mls (range 0–25 mls) and the median operative time was 150 minutes (range 100–215 minutes). The only technical issue that arose was midway through one procedure the aspirator channel blocked, but this did not alter the procedure undertaken or lead to the device being exchanged for an alternative.

No patient required a blood transfusion and the only significant complication was a pleural effusion, which required a percutaneous drainage. Median length of stay was 7.5 days (range 3–14 days). There were no readmissions and there were no 30-day deaths. Cytological assessment of the aspirate obtained during ablation was done in eight patients. In all these cases malignant cells were demonstrated in the aspirate. Histology of the resected lesions after ablation was performed in 11 cases, there was no evidence of viable cancer at the tumor edge and overall, satisfactory ablation had been produced, on average 90% of the target tumor volume had been ablated. In the cases where ablation alone had been performed, the CT at two weeks demonstrated that the ablation zone produced by Hexablate had fully encompassed the tumor.

Tab. 2: Summary of patients ($n = 16$) clinicopathologic details and segmental distribution of deposits ablated ($n = 34$). American Society of Anesthesiology (ASA)

Patient characteristics $n = 16$	
Age median (range) years	66 (50–81) years
Gender	
Male	8
Female	8
ASA	
1	3
2	8
3	5
Tumor type	
Metastatic	
Colorectal	9
Breast	1
Pancreatic Adenocarcinoma	1
Primary	
Hepatocellular Carcinoma	4
Intrahepatic Cholangiocarcinoma	1
Segmental location of deposit ($N = 34$)	
II	2
III	5
IV	4
V	4
VI	5
VII	6
VIII	8

Interventional radiology and endovascular RF ablation

In this series ($n = 13$), VesCoag was used to occlude the tumor arterial blood supply. The average age of the patient was 68.5 years (range 48–80 years), five patients were female and eight were male. The indications for treatment were metastatic disease in 4, HCC in 7 and intrahepatic cholangiocarcinoma in 2. The mean diameter of the lesion targeted with VesCoag was 8.1 cm (range 2–18 cm) (Table 3).

In all cases VesCoag was able to be manipulated into the target vessel, with no technical problems such as vessel dissection or rupture. The average fluoroscopic time was 12.86 minutes and the mean duration of probe activation was 240 seconds (range 20–600 seconds). The lowest wattage used was 2W and the highest 120W (Table 3). Bipolar RF was found to be ineffective and monopolar RF was therefore used to produce vessel sealing. Problems encountered with endovascular RF were pain in 4 patients and failure of vessel occlusion in two patients, which was felt to be related to the

Tab. 3: Summary of clinicopathological data and therapeutic interventions on patients treated with VesCoag

Age (years)	Sex	Tumor	ASA	Child	Size (cm)	Duration of activation (sec)	Power (W)	Procedural compli-cations	Angiographic vessel occlusion	Additional therapy	LOS
72	F	RCC	2	n/a	5.1	215	20–60	none	Y	chemotherapy and lipiodol	1
59	M	HCC	3	A	5	156	20–60	none	Y	chemotherapy + DC	2
48	M	CC	3	n/a	13	130	40	none	Y	chemotherapy and lipiodol	1
69	F	HCC	3	B	8	66	40	none	Y	chemotherapy + DC	2
70	F	CLM	2	n/a	5.5	20	40	none	N	chemotherapy + DC	2
80	M	HCC	3	B	3.7	20	40	none	Y	None	2
79	M	CLM	3	n/a	2	240	10–40	Pain	Y	chemotherapy and lipiodol	1
72	F	HCC	3	B	2	240	10–40	Pain	N	Lipiodol	2
65	M	HCC	3	A	7	600	25–60	Pain	Y	chemotherapy and lipiodol	1
72	M	Laryngeal	2	n/a	2.2	480	60–120	none	Y	chemotherapy and lipiodol	1
63	M	HCC	3	A	10	360	35–50	Pain	Y	chemotherapy and lipiodol	1
74	F	CC	4	n/a	18	180	2	none	Y	chemotherapy + coils	6
68	M	HCC	4	A	15.6	240	2	none	Y	chemotherapy + PVA	5

Tumor type: renal cell metastases (*RCC*), hepatocellular carcinoma (*HCC*), intrahepatic cholangiocarcinoma (*CC*), colorectal liver metastases (*CLM*). Fitness of patient recorded using the American Society of Anesthesiology classification (*ASA*). When a *HCC* patient, Child classification used, otherwise not applicable (*n/a*). Size refers to the diameter of lesion treated (*cm*). Power VesCoag used at recorded in watts (*W*) and duration of its activation in seconds. VesCoag procedural complications and occlusion of targeted vessel on angiography after VesCoag therapy is summarized. Additional therapies used with VesCoag were polyvinylalcohol (*PVA*) and doxorubicin coated beads (*DC*). Length of Stay (*LOS*); Days.

period of activation (Table 3). In 12 of 13 cases an additional endovascular therapeutic maneuver was performed (Table 3). The median length of stay (LOS) after endovascular therapy was 2 days (range 1–6 days), LOS greater than 2 days occurred in 2 patients and they had the largest tumor diameters treated (Table 3). There were no cases of deterioration in liver function tests and there were no 30 days procedural deaths.

Endobiliary RF ablation

So far this device has only been used in the pig model but based on this work a pilot clinical study is to be undertaken. This animal work established that the ideal power usage of EndoHPB in the biliary system to be 5–10 W for a maximum duration of 2 minutes. At higher power settings and longer ablation times problems were observed with heating effect extending beyond the target area and technical problems were encountered in reintroducing EndoHPB into the biliary tree.

Discussion

The application of medical RF will continue to grow as the technology evolves. At Hammersmith we have an established experience in adapting RF technology according to clinical need, which started with the development of the Habib 4X to assist in liver resection [1–5]. Each of the new devices described in this paper was conceived with a given clinical problem in mind, with the aim to try and approach the problem in a different way and perhaps be more effective. All these RF devices were designed for bipolar use, where the current is confined between the active electrodes of the instrument thereby avoiding some of the problems associated with monopolar instruments, such as heat sink and collateral tissue injury. So far, only data from small pilot studies or animal work are available to assess the utility of these devices in the clinical scenarios they were intended for, but the data collected so far have been promising, and it is hoped that larger scale studies and when appropriate, with longer periods of followup will establish their true clinical worth.

The pilot study on Endoblate is the first description of the application of bipolar RF to palliate rectal tumors, and our initial findings are encouraging. However, larger studies, including controlled trials are needed in order to compare this technology with other palliative techniques available. Whereas in the design of Hexablate, the attempt was to try and address some of the technical problems encountered in liver tumor ablation. At present, the majority of devices available for liver ablation are monopolar which can have problems with unpredictable current pathways that can reduce the area of ablation and run the risk of collateral tissue injury [13, 23]. Other problems that can arise, irrespective of whether monopolar or bipolar energy is used, is tumor "smoke", which may contribute to local (intra-parenchymal or intra-abdominal) and systemic spread of disease [14, 15]. Therefore, the handset was bipolar and had an aspirator channel incorporated. The initial clinical data show it to be an effective and safe way to ablate. However, this work needs to be repeated in a larger group of patients, with a longer period of follow-up, to see if the design features of Hexablate truly impact the pattern of recurrence after tumor ablation.

The endovascular application of RF energy at present is limited to the treatment of varicose veins [24] but endovascular RF energy could be used in a number of other clinical scenarios where the blood vessel needs to be sealed. Embolization is the standard approach in interventional radiology but it has potential problems such as collateral damage. To try and avoid this problem and to ensure that a given vessel is precisely sealed VesCoag was developed. From the initial pilot study, a number of issues were raised such as the need to increase the flexibility of the device so it is easier to manipulate down tortuous vessels, and effective sealing of the vessel was only achieved in monopolar mode. Despite this, the work highlights that there is a need to continue to develop endovascular technology to ensure precise localization of treatment so that the outcome of transarterial therapies will improve.

Currently, only animal data are available on EndoHPB and a pilot clinical study is to start soon, with the primary objective to see if the device is effective at ablating malignant biliary strictures and the secondary objective on whether it has an impact on the patency of stents in malignant obstructive jaundice. If the results of the pilot study are favourable, then the intent is to undertake a formal randomized control trial to determine whether endobiliary RF is more effective than PDT in patients with unresectable cholangiocarcinoma.

All the described devices are at an early stage of their development, but they illustrate the wide variety of clinical situations in which RF energy can be applied. At present, there are limited data on the clinical utility of these devices but it is hoped as more data are acquired from larger series of patients, with longer periods of followup, then the evidence will be available to define the position of these RF techniques in patient treatment.

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