

Haemostatic partial nephrectomy using bipolar radiofrequency ablation

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OBJECTIVE

To determine whether an electrode array with a bipolar radiofrequency ablation (RFA) energy source can be used to perform a haemostatic partial nephrectomy by simultaneously ablating and coagulating renal tissue.

MATERIALS AND METHODS

Lower-pole partial nephrectomy was performed in 12 porcine kidneys using a bipolar RFA system. Intraoperative ultrasonography was used to identify and avoid the collecting system. Tissues were positioned between opposing electrodes and tissue impedance monitored using a proprietary feedback and control algorithm.

Ablation time and power, lesion width and length, and tissue thickness were recorded. The kidneys were assessed *in vivo* to show haemostasis of the remaining renal unit. Collecting system integrity was assessed with methylene blue injection, and the resected tissue analysed histologically.

RESULTS

Partial nephrectomies were successful in all 12 porcine kidneys; the mean nephrectomy specimen was 3.2×2.6 cm. The total ablation time (SEM) per lesion was 211 (15) s and the mean power was 23 W. Methylene blue injection showed an intact collecting system in 11 of the 12 kidneys, and haematoxylin and eosin staining showed a mean zone of necrosis of 9 mm at the resection margin.

Ultrasonography revealed flow to the remaining kidneys after RFA and the *in vivo* assessment of haemostasis revealed no abnormal bleeding or haemorrhage from the kidneys.

CONCLUSIONS

Applying bipolar RF energy to an electrode array can enable transmural excision of renal parenchyma *in vivo* in a bloodless fashion without collecting system injury.

KEYWORDS

radiofrequency ablation, partial nephrectomy, haemostasis

INTRODUCTION

Clinical studies show that partial nephrectomy for renal tumours is an acceptable alternative to radical nephrectomy [1–3]. Traditionally, partial nephrectomy has been performed through an open incision, but recent advances have led to the development of minimally invasive approaches such as laparoscopy. A major limitation of the laparoscopic approach is the difficulty of maintaining haemostatic control during tumour excision. Furthermore, renal ischaemic injury and postoperative urine leakage remain a concern [2,3]. These complicating factors have led to innovations in minimally invasive technologies to assist or replace open or laparoscopic partial nephrectomy (LPN).

Recent preliminary studies have reported success using radiofrequency ablation (RFA) for small renal tumours [4–7]. RFA is

attractive because it is minimally invasive, haemostatic, and available in selected centres [4,5]. RFA produces controlled ablation by creating thermal energy in the target tissue due to resistive heating that results from ionic friction. Both monopolar and bipolar probes have been used for RFA, but to our knowledge, there are no reported studies evaluating bipolar RFA for a partial nephrectomy. Our goal was to show that bipolar RFA can be used for haemostatic partial nephrectomy, simultaneously ablating, coagulating and excising tissue.

MATERIALS AND METHODS

Following strict animal research committee protocol at our institution, six domestic female pigs (20 kg) were anaesthetized using tiletamine/zolazepam 6 mg/kg *i.m.*, followed by halothane 4–5% in oxygen for induction and 2–3% for maintenance, inhaled to effect and then prepared for surgery. The pigs were

placed supine, prepared in the midline and draped. Through a midline incision, one kidney was dissected free and the lower pole exposed. Ultrasonography was used to delineate the renal parenchyma from the collecting system. The prototype multiprobe bipolar electrode was inserted transmurally through a line demarcated by ultrasonography (Fig. 1). The probe consisted of an array of up to four electrodes (1×5 mm cross-section) placed 1.5 cm apart; this allowed treatment of all kidney widths encountered in the study. RF energy was applied between each pair of adjacent electrodes in bipolar fashion, but to only one electrode pair at a time. Bipolar power application was rapidly switched between different electrode pairs, with a period of 600 ms (i.e. power was applied between electrodes 1–2, then between electrodes 2–3, and so on). A proprietary control algorithm based on the impedance between each electrode pair was used to control the applied

power for each electrode pair [8]. The power was increased steadily for each electrode pair, until an impedance threshold was exceeded due to tissue vaporization around the electrode, at which point power was reduced. No grounding is required for bipolar power application. Ablation was performed with a maximum applied power of 150 W, chosen on the basis of data from use of bipolar RF in the liver [9]. Tissues were clamped between opposing electrodes with steady pressure to ensure an intimate tissue–electrode interface. Applied power, lesion dimensions (width and length) and tissue thickness were recorded for each ablation. Although we did not occlude flow during the ablation, the renal hilum was dissected and a vessel loop was placed around the renal artery. A cold scalpel was used to excise the lower-pole segment. The margin of resection was visually observed for active bleeding and ultrasonography used to assess blood flow to the remainder of the kidney. The integrity of the collecting system was also assessed by direct ureteric injection of methylene blue dye. The identical procedure as outlined above was performed on the contralateral kidney.

Once harvested, the kidneys were completely perfused with 10% buffered formalin for immediate fixing, then removed and stored in formalin for 24 h to ensure complete fixation. Samples of lesions were embedded in paraffin wax, stained with haematoxylin and eosin (H&E), and reviewed by a pathologist blinded to the treatment (T.F.W.) to determine cell death, inflammatory changes and vascular thrombosis. The calculated volumes for all partial nephrectomy specimens and total treatment times were averaged. Statistical analysis was performed to compare the treatment times and the power used for each ablation.

RESULTS

The partial nephrectomies were successful in all 12 porcine kidneys. Grossly, *in vivo* assessment of haemostasis revealed no measurable bleeding from the kidneys after lower-pole nephrectomy (Figs 2 and 3). Ultrasonography after partial nephrectomy showed good flow in all 12 intact kidneys. None of the 12 procedures required renal artery occlusion after the procedure.

The mean (SEM) cross-sectional area of the partial nephrectomy specimens was $37.7 (9.5) \times 23.2 (5.7)$ mm, the length of the

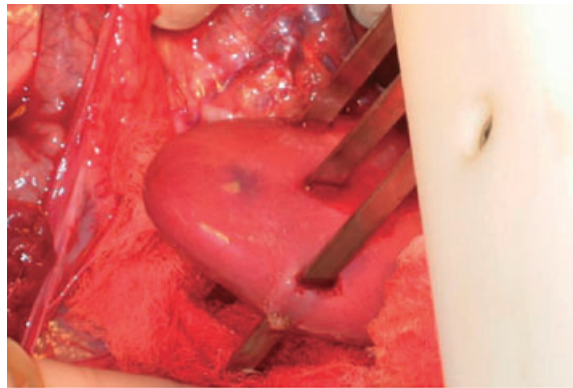


FIG. 1.
The prototype multiprobe RFA system deployed to perform lower-pole nephrectomy after ultrasonographic demarcation of renal parenchyma from the collecting system.

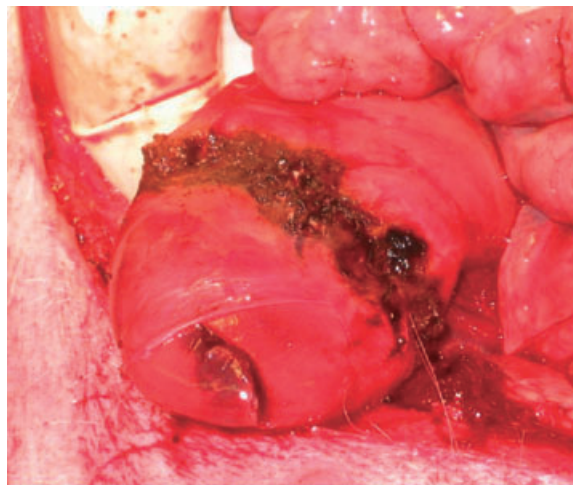


FIG. 2.
Transmural lesion after 180 s of treatment with the multiprobe prototype RFA probe.

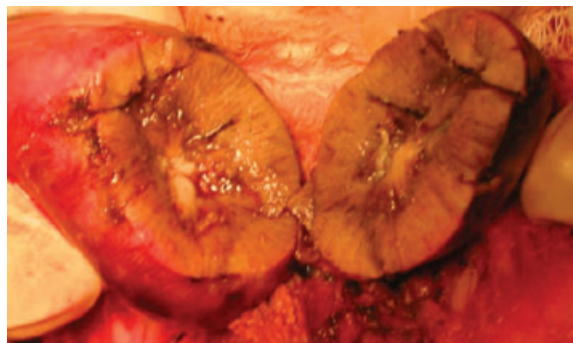


FIG. 3.
Partial nephrectomy shows haemostasis of the kidney *in vivo*.

cut specimens was 26.2 (9.5) mm, and the length of remaining kidney after partial nephrectomy was 68.9 (14.2) mm. Methylene blue injection showed an intact collecting system in all 12 kidneys. H&E staining showed that all the lesions were transmural and the zone of necrosis was 9.6 (1.9) mm at the resection margin.

In all 12 specimens cellular injury in the zone around probe sites consisted of coagulation

of protein manifested by basophilia of collagen, distortion of tubules and interstitial cells, and lysis of red blood cells (Figs 4 and 5). Nuclei were pyknotic and cell borders effaced, although the outlines of the collecting tubules and peritubular capillaries were recognisable. The mean length of these changes was 9.6 mm into the parenchyma. A zone of congestion with intact red blood cells in the vessels marked the zone of viable kidney tissue. Glomerular structures were

FIG. 4.

A section of a kidney showing the lesion area with compressed basophilic collagen (C), interstitial basophilic material (I) and lysed red blood cells in the vein (H). H&E $\times 100$.

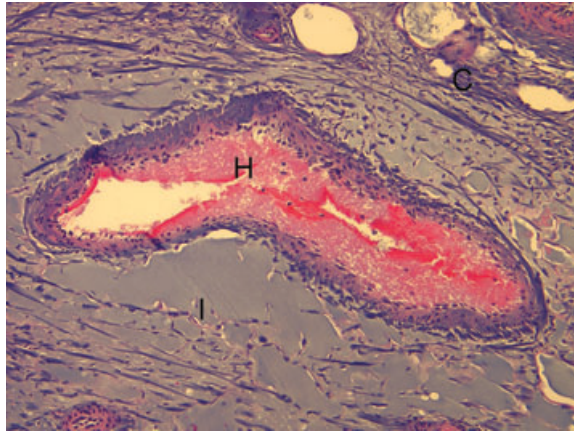
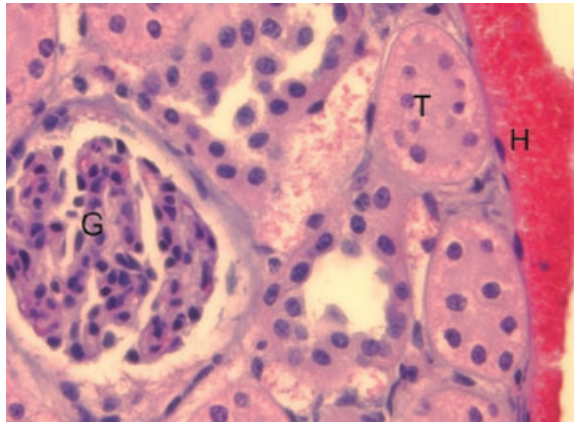


FIG. 5.

A section of a renal lesion showing the glomerulus devoid of red cells (G), tubular cells with absent cell borders (T) and lysed red blood cells (H). H&E $\times 100$.



identifiable in the damaged zone, but intracapillary red blood cells were totally lysed.

There was no significant relationship between power values and treatment times for the 12 kidneys. The mean (SD) initial power during RFA was 28.2 (12.0) W; the maximum power was 43.8 (5.7) W and the mean power used was 23.1 (5.9) W. The mean time for RFA treatment was 210.8 (53.8) s, and the time for the impedance rise was 104.5 (40.1) s.

DISCUSSION

Clinically accepted techniques of nephron-sparing surgery include partial nephrectomy via open or laparoscopic approaches [10]. The primary concern using any extirpative nephron-sparing approach is maintaining haemostasis during tumour excision. While surgical control during open surgery is through traditional suturing, maintaining a bloodless field laparoscopically can be

challenging. Currently, haemostasis during LPN is obtained with argon-beam coagulation, harmonic scalpel coagulation, fibrin glue, and/or suturing with surgical bolster devices, limiting the use of LPN to small exophytic lesions. To expand the role of LPN across a wider range of lesions an alternative means for providing haemostasis is desirable.

For selected patients, renal RFA is a promising therapeutic option [2–5]. Experimental studies show that RFA is efficacious [4,5]; clinical studies are ongoing, but early evidence suggests that RFA is safe and oncological results are encouraging [5,7–11]. These studies used monopolar RF; in monopolar RFA, applied current flows from an active electrode (located in the target tissue) to a large dispersive ground pad located on the skin. The high current density near the active electrode causes heating due to ionic friction, resulting in cell death by coagulative necrosis in the target tissue (typically in 3–5 min).

Recent studies have also attempted to use RFA for haemostasis. Gettman *et al.* [11] reported their experience in using monopolar RFA as a coagulation-assisted technique; they treated 10 patients with RFA-assisted LPN. The tumour and a rim of normal renal parenchyma was treated with monopolar RFA and the specimen excised. Blood loss was ≤ 300 mL in all but one patient, who lost 900 mL of blood. Additional haemostatic measures, e.g. fibrin sealant and bolstering devices, were required to maintain haemostasis. Similarly, Jacomides *et al.* [12] also studied the laparoscopic application of RFA as a tumour ablation and excision-assist device; they treated 13 patients with a mean tumour size of 1.96 cm, and the estimated blood loss was < 150 mL in 12 of the 13. Although the results of these studies are compelling, monopolar RFA has not been widely adopted for assisting in minimally invasive partial nephrectomy.

For this application, bipolar RFA has advantages over the traditional monopolar method. In bipolar RFA, applied current flows between two electrodes in the target tissue, which results in simultaneous heating near both, and producing significantly higher temperatures between the two electrodes than monopolar RFA [13]. In the present study we assessed a prototype bipolar RFA probe for partial nephrectomy. We hypothesized that controlled ablation of tissue between the electrodes would create an effective zone of necrosis to excise tissue with good haemostasis. Additionally, by using a multiprobe system, transmural treatment would result in a complete ischaemic zone. Furthermore, computerized impedance monitoring allowed for efficient control of the applied power. Impedance spikes during treatment signified tissue vaporization and temperatures of > 100 °C.

Using impedance technology to monitor the length of treatment, all 12 RFA-treated kidneys had complete haemostasis with a pathologically confirmed transmurally-ablated zone. There was no substantial bleeding in any of the 12 kidneys. Histopathological findings confirmed a necrotic zone, defined by inflammatory cells, vascular ectasia and congestion. The lack of viable vasculature on pathology is an important finding, as it eliminates the possibility of delayed bleeding after treatment.

The present results show that an electrode array with RF energy applied using the bipolar method can be used as a haemostatic tool to transect normal renal parenchyma without having to clamp the renal artery. As a margin of normal tissue is mandatory during partial nephrectomy, we think this technology provides a safe, easy and effective means of maintaining haemostasis during excision of normal renal parenchyma, while protecting the collecting system. Although we did not use a minimally invasive study design we think that the findings from this study will be transferable to laparoscopy. We are in the process of creating an electrically insulated template to deploy the prototype RFA device percutaneously. We postulate that percutaneous application of bipolar RFA in conjunction with laparoscopic mobilization and exposure of the kidney will be one means of performing a haemostatic partial nephrectomy.

In conclusion, an electrode array in conjunction with applied bipolar RF power can be used to excise transmural renal segments *in vivo* without blood loss, and impedance monitoring is a reliable predictor of lesion transmural and surgical margin status. Additional *in vivo* studies are underway to evaluate the efficacy and safety of bipolar RFA technology for renal tumour excision [14].

CONFLICT OF INTEREST

None declared.

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Abbreviations: (RF)A, radiofrequency (ablation); H&E, haematoxylin and eosin; LPN, laparoscopic partial nephrectomy.