Laparoscopically Delivered HIFU for Partial Renal Ablation

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Our purpose is to develop a high intensity focused ultrasound (HIFU) probe to ablate kidney laproscopically. A Sonablate™ 200 HIFU system (Focus Surgery Inc., Indianapolis, IN) was used in acute (n=10) and chronic (n=5) experiments to ablate Yucatan mini-pigs' kidneys. A 5 Fr ureteral catheter was inserted into the renal pelvis and 10 cc of air was instilled into the kidney. The HIFU probe was inserted through a 30-mm trocar placed at the level of the umbilicus. The targeted renal pole was treated aiming to ablate a 21´17´10 mm^3 tissue volume. HIFU induced average lesion size of 23´17´11 mm^3. 10 animals were sacrificed at 4 days and 5 animals at 15 days following surgery. Gross and microscopic examination revealed homogenous and complete tissue necrosis throughout the entire volume of the lesion with sharp demarcation from adjacent normal tissue. We were able to refine a 15mm probe for laparoscopic HIFU delivery capable of simultaneous ultrasonic imaging. Partial renal ablation using this probe is feasible and safe, and results in homogenous, complete and reproducible lesions.

INTRODUCTION

There is an increasing interest in the laparoscopic techniques for performing nephrectomy. The uro-surgical community is currently investigating several laparoscopic techniques. Notable examples are: cryo-ablation, radio-frequency (RF) ablation, and high intensity focused ultrasound (HIFU) ablation (Gill et al., 2000). HIFU technology has demonstrated promising results in the treatment of benign prostatic hyperplasia and prostate cancer (Madersbacher et al., 1995; Sanghvi et al., 1999). A notable example of HIFU systems is the Sonablate™ device developed by Focus Surgery Inc., Indianapolis, IN (http://www.focus-surgery.com). The Sonablate™ makes use of a proprietary transrectal image-guided HIFU technology to treat prostate diseases by rapidly elevating tissue temperature about 90 °C to produce coagulative necrosis. In this feasibility study, we extended the application of the Sonablate™ device for laparoscopic kidney tumor ablation.

I. MATERIAL AND METHODS

A. Sonablate™ Device

The Sonablate™ 200 HIFU device (Focus Surgery Inc., Indianapolis, IN) was used to image and localize kidney tissue for ablation, and to monitor and control the treatment parameters during the laparoscopic procedure. A complete description of the device has already been given in several publications (Sanghvi et al., 1999).

B. Laparoscopic HIFU Probe

The probe consists of two main parts: (1) probe assembly, and (2) supporting sleeve.

B.1. Probe Assembly

The laparoscopic probe assembly parts are shown in Figure 1. Two major modifications were implemented to standard Sonablate™ prostate treatment probe.

(1) The probe tip was redesigned and built from Stainless Steel to adapt to laparoscopic surgery requirements.

(2) A new piezoelectric transducer (4.0 MHz, 30-mm focal length, 12×30 mm aperture) was built with a geometry that was adaptable to the new tip.

B.2. Supporting Sleeve

The supporting sleeve (Fig. 1A) made from Stainless Steel has two functions: (1) protection of the latex sheath during the probe insertion, and (2) providing an acoustic window to allow the latex sheath to extend in the desired plane only. It covers the latex sheath while its opening is aligned with the window on the probe tip (Fig. 1B).

B.3. Transducer Calibration

The transducer was fully characterized by measuring its electrical impedance, acoustic field, and total acoustic power output. It was able to generate acoustic power levels up to 35 W that corresponded to focal intensities over 2200 W/cm^2 in tissue that would be sufficient for tissue ablation through rapid temperature rise (>90°C) and possible vaporization.

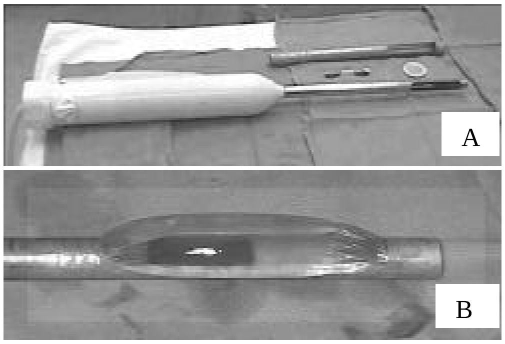

Figure 1. The laparoscopic HIFU probe. (A) The probe and the supporting sleeve. (B) A close-up of the probe tip including the supporting sleeve and the water-filled Latex sheath.

C. Animal Model

Fifteen female Yucatan pigs, weights ranging from 40 to 55 kg, were used in this approved study. The lower pole of the right kidney was treated in all the pigs.

D. *In Vivo* Experimental Procedure

Fifteen pigs were divided in two groups. The first group (n=10) was used for a sub-acute, 4 days survival study and the second group (n=5) was used for a chronic, 15 days survival study. All pigs were treated under general anesthesia and standard sterile surgical procedure. A urethral catheter was inserted into the kidney to be ablated and 10 cc of air was instilled before starting HIFU treatment. The air bubbles acted as a shield to block the ultrasound beam from propagating to the far end of the kidney.

Two laparoscopic trocars were inserted into the abdominal cavity. The probe tip was then advanced to the desired area of the lower pole of the right kidney. The kidney was imaged in the transverse and longitudinal planes. The treatment zone was selected on these images. The treatment was performed using 26 W of total acoustic output power and On/Off exposure cycles of 5/6 seconds.

At the end of the procedure, the abdominal openings were sutured and the animal was returned to the cage.

II. RESULTS

Immediately after the procedure a coagulated, blanched area appeared on the surface of the kidney. In both group of animals after sacrifice a well-defined necrotic lesion was found in the targeted region. The dimensions of the lesion were in good agreement with the desired dimensions set through the Sonablate™ treatment planning that was 22×17×11 mm ± 1 mm. Gross pathology (Figure 2) and histology showed well-delineated homogeneous lesions.

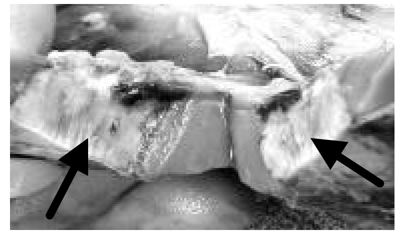

Figure 2. Cut section of the kidney shows sharp margins and uniformity of the lesion (indicated by arrows) extending from the pelvic system to the capsule.

III. CONCLUSIONS

Contiguous necrotic lesions were created in the lower pole of the kidney extending from the pelvic system to the capsule. The appearance of a hyperechoic region observed in the ultrasound B-mode images around the focus supports that cavitation may also have a significant role in this mode of tissue ablation. It is anticipated that necrotic tissue volume will significantly reduce bleeding during partial nephrectomy.

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