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Bringing New Horizons to Therapy

SPARED CRN Meeting

EDAP TMS Update – May 3, 2018

Hugo Embert, CEO - EDAP Technomed Inc.

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EDAP TMS HIFU Technology – key figures

- 20 years of clinical usage
- 50,000 treatments
- 350 sites
- 90 peer-reviewed publications

Focal One® is not available in the US

Ablatherm® HIFU in the US

- 510(k)-cleared in Nov. 2015 for “Prostate Tissue Ablation” (Ablatherm Fusion 510(k)-cleared in Oct. 2017)
- High effort in physician education (300 US physicians phase 1-trained)
- Fixed and Mobile user sites
- Academic University Hospitals and Private Surgery centers
- CMS created reimbursement C-code available since July 1st 2017
- NCCN Guidelines have included HIFU as a salvage option (02/2017)

Data Collection initiatives

- Creation of a centralized database
- Based on RedCap Software
- Hosted at University of Miami (Dr Parekh, PI)
- Made available online for other US academic centers

FoR-UsA Registry

FOCAL ROBOTIC ULTRASOUND ABLATION

FoR-UsA Registry Project Update

- Database up and running
- U of Miami leading the project (D. Parekh, MD and B. Nahar, MD Principal Investigators)
- Common protocol validated (Cleveland Clinic, Duke, Weill Cornell/Houston Methodist, USC)
- Administrative challenges (local IRBs approval and Data Sharing Agreement)
- 50+ patients logged into the database (all from Miami)
- 35 patients in mirror RedCap database in Houston
- Other sites are pending administrative go.

FoR-UsA Registry
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1st scientific communication from FoR-UsA Registry

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

Functional and Oncologic Outcomes of High Intensity Focused Ultrasound (HIFU) for Focal Treatment of Prostate Cancer: A single Institution Experience

B. Nahar, DM. Lopategui, V. Venkatramani, NS. Prakash, ML. Gonzalgo, CB. Ritch, S. Punnen and DJ. Parekh

UNIVERSITY OF MIAMI
MILLER SCHOOL of MEDICINE

INTRODUCTION

- Focal therapy is emerging as potential alternative for localized prostate cancer (PCa), providing acceptable short-term oncological control with minimal adverse effects.
- There is a lack of data in the setting of focal HIFU ablation of the prostate, particularly in the United States.
- We report oncologic outcomes from the first prospective cohort of US patients treated with focal HIFU ablation.

METHODS

- Prospective data was collected on the oncologic and functional outcomes of the HIFU procedures performed from January 2016 to January 2018 at the University of Miami.
- Patients underwent a 12 core TRUS-guided biopsy, in addition to MRI-US fusion biopsy if a targetable lesion was identified on MRI.
- Patients eligible for focal (<50% of prostate volume) or subtotal (>50% but less than whole-gland) HIFU ablation were included in the study.
- Any Gleason Grade was considered for HIFU. However, patients with very low risk or high-risk and high-volume PCa were excluded.
- Follow-up included PSA every 3 months, and MRI-US fusion biopsy in 6 months or 12 months for high risk and low-intermediate risk PCa, respectively.
- Functional outcomes were assessed using IPSS, SHIM score and EPIC 26 every 3 months.

Figure 1: Dynamic Contrast Enhancement (DCE) MRI before treatment and 1 month post-HIFU in two patients. DCE shows the best correlation with treatment success and chance of recurrence or treatment failure

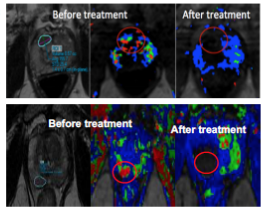


Table 1 (below). Perioperative Complications

Clavien-Dindo grading system score		N
I	Urinary tract infection	22
	Transient acute urinary retention	13
	Transient urge incontinence	7
II	>15 days of urinary retention	9
	Gross hematuria	3
	Orchitis	2
III	Obstruction requiring TURPT	3
	Abscess requiring incision and drainage	1
No complications		19

Figure 2: follow-up biopsy results

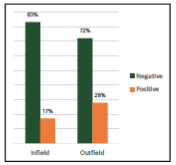
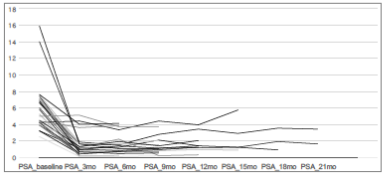


Figure 3: PSA values at pre-HIFU baseline and post-HIFU therapy during follow up.



RESULTS

- 50 men were included in this study. Median age was 68 years old, median baseline PSA was 5.5 ng/mL (3.2 – 25,9) and median prostate size of 31 cc on TRUS (11-73)
- 31 patients (62%) presented with Gleason 7+ PCa (26 with Gleason 7, 2 Gleason 4+4, 2 Gleason 4+5, and 1 Gleason 10)
- HIFU was performed as primary treatment in 46 patients (92%), and as salvage in 4 (8%)
- 46 (90%) men underwent focal ablation and 4 subtotal ablations. Mean follow-up was 13.3 months.
- 1-month post-HIFU MRI showed appropriate ablation in all cases (figure 1)
- Complications are summarized in table 1.
- Although we saw an increase in the IPSS in several patients, 78% went back to their baseline score after 3-6 months.
- 85% of patients maintained the erectile function and 15% referred de novo erectile dysfunction at 12 months
- At 3 months follow up, a nadir PSA <2ng/mL was achieved in 30 (83%) patients (figure 2)
- 18 patients underwent a protocol follow up biopsy, of which 15 (83%) were negative in the ablated area. However, 5 (28%) patients showed positive biopsy (Gleason 6) on the contralateral side (figure 3)
- In-field recurrence was seen in 3 (17%) patients; of note, all had Gleason 6

CONCLUSIONS

- Focal HIFU ablation of the prostate showed promising short-term oncological outcomes, even in clinically significant PCa.
- Longer follow-up and re-biopsy data are needed before reaching further conclusions regarding oncological efficacy.

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Thank you