Prostate Cancer: Localized: Ablative Therapy I

Podium 17

Friday, May 15, 2020 3:30 PM-5:30 PM

PD17-01

OUTPATIENT TRANS-RECTAL MR-GUIDED LASER FOCAL THERAPY PHASE II CLINICAL TRIAL: TEN-YEAR INTERIM RESULTS

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INTRODUCTION AND OBJECTIVE: In the United States alone, new prostate cancer cases for 2019 were estimated at 174,650 and deaths at 31,620. Focal therapies for low risk and intermediate risk localized prostate cancer are increasingly being explored. Our objective is to investigate the efficacy of using MR-guided laser focal therapy for MR visible prostate cancer utilizing a trans-rectal approach for laser applicator placement and therapy delivery in an outpatient setting for treatment naive and salvage patients.

METHODS: All MR-guided therapy was delivered using a 1.5 Tesla Philips Achieva XR system (Philips Healthcare, Best, The Netherlands) for both image acquisition and real-time thermometry. DynaCAD and DynaLOC (Invivo, Orlando, FL, USA) software were used for image analysis and laser fiber placement planning. Laser focal therapy was delivered using a Visualase (Medtronic, Minneapolis, MN, USA) 15W, 980 nm diode laser applicator introduced trans-rectally using the DynaTRIM (Invivo, Orlando, FL, USA).

RESULTS: Under an IRB-approved, HIPAA-compliant protocol, 158 men and 248 cancer foci were treated. No serious adverse events or morbidity were reported. Of the 122 men that underwent 6 mo. biopsy of the treatment site, 32/122 (26%) of men were positive and clinically significant*, while 71/122 (59%) of men were negative. The remaining 18 men (15%) were positive but clinically insignificant. In addition, while most of the positive results were of marginal recurrence, 6 men (5%) had clinically significant incidence cancers. We observed a 37% decrease in mean PSA at 12 months post therapy and no statistically significant change in IPSS and SHIM scores. At ten years, the metastasis free survival rate is 99%, the prostate cancer specific survival rate is 100%, and the overall survival rate is 98%. * *Excludes Gleason score 3+3 (Grade Group 1)*

CONCLUSIONS: Ten year outcomes data indicate that outpatient, trans-rectally delivered MRI-guided laser focal therapy for prostate cancer has similar oncologic control as whole-gland therapy without the associated morbidity. In 94% of the treatment naive patients, whole gland therapy was safely avoided. Focal treatment of prostate cancer may be an attractive option in a subset of men appropriately risk stratified. The precision and safety achieved using laser focal therapy under MRI-guidance may have a favorable impact on cost effectiveness and quality of life without eliminating the possibility of whole-gland treatment. We will continue to follow these men for twenty years as part of an IRB-approved clinical trial (NCT# $02243033)_3$.

Source of Funding: Patient funded research.

PD17-02

PIVOTAL TRIAL OF MRI-GUIDED TRANSURETHRAL ULTRASOUND ABLATION IN MEN WITH LOCALIZED PROSTATE CANCER: TWO-YEAR FOLLOW-UP

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INTRODUCTION AND OBJECTIVE: MRI-guided transurethral ultrasound ablation (TULSA) is a novel minimally-invasive procedure for prostate ablation. We report two-year outcomes from the pivotal TULSA-PRO Ablation Clinical Trial (TACT).

METHODS: The study enrolled 115 men with organ-confined prostate cancer ($\leq$T2b, PSA $\leq$15 ng/ml, Gleason Grade Group 1-2) across 13 centers in USA, Europe, and Canada. Treatment was whole-gland ablation with sparing of the urethra and urinary sphincter. Primary endpoints were safety and PSA reduction at one year. Secondary endpoints included one-year prostate volume reduction, mpMRI, and 10-core biopsy. Two-year outcomes include adverse events, quality of life (IPSS, IIEF, EPIC), and PSA stability.

RESULTS: Median (IQR) baseline age was 65 (59-69) years, PSA 6.3 (4.6-7.9) ng/ml, with Grade Group $\geq$2 (GG2+) disease in 72/115 men (63%). Targeted prostate volumes of 40 (32-50) cc were ablated in 51 (39-66) min, with 98% thermal coverage and $\pm$1.4 mm spatial precision on MRI thermometry. Grade 3 adverse events occurred in 9 (8%) men (all resolved before one year), with no rectal injuries or Grade $\geq$ 4 events. At one year MRI and biopsy, median prostate volume decreased from 37 to 3 cc, GG2 disease was eliminated in 54/68 (79%) men, and 72/111 (65%) had no evidence of any cancer. Two-year PSA and QoL are currently available for 48/115 patients. Median PSA decreased 95% to a nadir of 0.30 ng/ml, stable from 0.53 ng/ml at one year to 0.68 ng/ml (n=48) at 2 years. Median IPSS was unchanged from 7 to 6 at one year and 5 (n=47) at two years. Moderate urinary incontinence (Grade 2, pads) was reported by 3 patients (2.6%) at one year, with no new incontinence at two years. The rate of moderate erectile dysfunction (Grade 2, responding to PDE5) was 23% at one year, with one new onset at two years. Median change in IIEF-5 recovered from -3 at one year to -1 (n=46) at two years. Erections sufficient for penetration (IIEF Q2 $\geq$ 2) were maintained by 69/92 (75%) at one year, and for the patient subset with two-year follow-up, by 25/37 (68%) and 23/37 (62%) at one and two years, respectively. Three men whose one-year biopsy indicated incomplete ablation underwent uncomplicated salvage radical prostatectomy.

CONCLUSIONS: With two-year follow-up, the TACT pivotal study of MRI-guided transurethral ultrasound ablation (TULSA) in men with localized prostate cancer showed effective disease control in most patients with low toxicity and stable quality of life.

Source of Funding: Profound Medical

PD17-03

FIVE-YEAR OUTCOMES FROM A PROSPECTIVE PHASE I STUDY OF MRI-GUIDED TRANSURETHRAL ULTRASOUND ABLATION IN MEN WITH LOCALIZED PROSTATE CANCER

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INTRODUCTION AND OBJECTIVE: MRI-guided transurethral ultrasound ablation (TULSA) is a minimally-invasive procedure for customized ablation of benign and malignant prostate tissue. We