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DEVELOPMENT OF CONVECTIVE WATER VAPOR ENERGY FOR TREATING LOCALIZED PROSTATE CANCER: FIRST-IN-MAN EARLY CLINICAL EXPERIENCES

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Introduction: Earlier work has confirmed the unique thermodynamic properties of phase-change convective ablation using water vapor (steam) to conform to the anatomical zones of the prostate. The objective of this study was to assess in vivo treatment of prostate cancer and the early clinical effects using water vapor.

Methods: A total of 18 patients have been treated at 2 centers using the Reviv™ System and 6 have completed 6 month follow up biopsy. All patients had clinically localized prostate cancer as determined by biopsy, DRE, PSA and prostate MRI (non mp3). Treatment was performed using a urethral cooling catheter and a transperineal, ultrasound guided approach for needle placement and water vapor delivery. Several doses of vapor were tested depending on prostate size. Follow-up monitoring included serial, gadolinium enhanced MRI's performed pre-procedure and at 1 week, 1, 3, and 6 months post-procedure and a surveillance biopsy at 6 months post-procedure. Standard AE reporting was used to evaluate clinical outcomes.

Results: 18 patients have been treated. 10 patients underwent hemiablation, 5 whole gland ablation (3 staged), 2 unilateral PZ treatment and 1 hemiablation with contralateral PZ ablation. Serial MRI's confirmed tissue ablation in all patients. Ablation was seen to the prostatic apex, capsular boundaries and the anterior zones of the prostate. Six-month surveillance biopsies have been completed on 6 patients. Four had completely negative biopsies for cancer and two had positive biopsies that were in untreated zones. Catheterization and adverse events will be reviewed. There has been no incontinence, bladder neck contractures or rectal injuries.

Conclusion: The zonal anatomy of the prostate is ideal for phase change convective ablation using water vapor. The thermodynamics and physical principles validated by MRI indicate that effective ablation can be safely delivered anywhere in the prostate including the apex, capsular margins and anterior prostate. Partial, focal, zonal or whole gland ablation can be performed. These early and limited data confirm that effective tissue ablation to all areas of the prostate is feasible using convective water vapor.

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