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Irreversible electroporation (IRE), a novel technique for focal ablation of prostate cancer (PCa): Results of a interim pilot safety study in low risk patients with PCa

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Introduction & Objectives

IRE is a new non-thermal ablation modality that uses short pulses of DC electric current to create irreversible pores in the cell membrane, thus, causing cell death. The primary objective of the study was to test the procedural and short term safety of the Device to ablate localized microfocal, low grade PCa. A secondary objective was to evaluate the effectiveness of the treatment and its impact on quality of life of our pts.

Material & Methods

11 pts with PCa were enrolled after the Ministry of Health, Ethical Committee approval and pt signed informed consent. Mean age was 70.2 yrs (range 60-78 yrs). Eligibility Criteria: unilateral PCa on template perineal guided biopsies (1.37 cores per cc), Psa < 10 ng/ml, Gleason score <7, stage cT1c/T2a. Mean pre-op Psao was 6.43 (range 2.7-9.75ng/ml) mean prostate volume on TRUS was 62.3cc (range 33-120cc). The mean N of cores biopsies was 85.4. Pre-op continence rate =100%. Mean pre-op I-PSS = 9.54 (range 0-23). Mean pre-op IIEF = 16.18 (range 14-24).Stage: cT1c =10 cT2a =10. The procedure was performed under general anaesthesia using the brachytherapy grid to reach the same area were PCa was detected at biopsy. Mean N of needles used to treat tumour area was 6.3 (range 4-10). Mean treatment time was 7.8’ (range 2’-18’).

Results

All the pts were evaluated for toxicity and response. No major complications occurred during the procedure. Hospital stay was 1 day for all the pts. Pts were controlled after 14, 30, 90 and 180 and 525 days (19.2 months) from IRE with PE, Psa, I-PSS and IIEF. Prostate biopsy of the treated area was performed after 1 month using local anaesthesia. The mean N of biopsies taken was 24.72 (range 15-41). No major complications were observed after 14, 30, 90, 180 days and 19 mounths (m). 1/11 pts (9%) had acute urinary retention. 3/11 pts. (27%) had a transient urge incontinence. Mean Psa after 30-90, 180 days and 19.2 m. went down to 3.5, 2.9, 3.3 and 3.12 ng/ml respectively. Continence rate was 100%. I-PSS was reduced to 7.72, 7, 6.12, 4.28 and 4 respectively while IIEF was 13.18, 10.45, 10.5, 11 and 17.3 m. Pathological report after 30 days was negative in 8/11 pts (73%). Coagulative necrosis, granulomatosis,
fibrosis and hemosiderosis was commonly reported. 3/11 pts (27%) had a persistent adenocarcinoma (1, 1 and 2 foci) respectively. 1 received radical prostatectomy, 1 was retreated and 1 is waiting for re-treatment.

Conclusions

IRE is a safe procedure for focal therapy in localised low risk PCa. It is relatively simple, mini invasive and effective. Further larger studies with longer follow-up are needed to confirm these preliminary results.

Provided in response to an unsolicited request for scientific communication. The NanoKnife System has been cleared by the US FDA for the surgical ablation of soft tissue;
It has not been cleared for the treatment or therapy of any specific disease or condition.
This material may discuss uses of the System which have not been cleared by the FDA.