



HIFU PROSTATECTOMY FOR PROSTATE CANCER: THE USA EXPERIENCE

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Introduction

A non-invasive transrectal ultrasound device has been developed with the capacity to both image (TRUS) and treat the prostate with high intensity focused ultrasound energy for tissue ablation.

Objectives

Define safety and efficacy of the HIFU treatment under the FDA approved Phase I/II trials for the treatment of both localized primary (T1/T2) and recurrence prostate cancers those were first time treated with radical prostatectomy or EBRT.

Method

The Sonablate® 500 (SB-500) is a transrectal ultrasound device that provides both imaging (TRUS) and HIFU treatment of the prostate. The transverse, longitudinal and volumetric imaging provides three-dimensional ultrasound rendering of the prostate. The therapy planning software is used to outline treatment volume and the HIFU treatment is carried out under computer control producing coagulative tissue necrosis in the prescribed tissue volume. The process is repeated for the entire prostate ablation. The FDA approved protocols are to enroll twenty patients for each study. For the localized and recurrent studies, twenty (20) and three (3) patients have been respectively treated since 2002. Patients characteristics- Mean (range): Age-62.8 (44-75), PSA-5.36 (0.01-9.66), Weight-197 lbs. (130-400), Prostate weight 25.9 grams (20-45) and treatment time 183 min. (67-516). The outpatient procedure was conducted under general anesthesia. Patients were followed on at 48 hrs, 15, 30, 90 and 180 days post treatment. SP indwelling catheter 13 days (range 2-31 days).

Results

Recurrent prostate cancer patients showed no positive biopsy and PSA nadir of <0.5 ng/ml is maintained over 18 months. For the T1/T2 study, nine of twenty received second HIFU treatment.

Conclusions

Transient complications: 2 gross hematuria, 3 UTI. There was no rectal injury or BNC. The HIFU procedure was well tolerated, safe and efficacious that warrants a long term, multi-center Phase III studies.