



The 'Holy Grail' of successful prostate cancer treatment has been discovered
Authors: Ronald E. Wheeler, M.D., Gerald Grubbs, M.D.

-Abstract-

Introduction - Prostate cancer is the most prolific non-cutaneous cancer that men acquire in their lifetime. Presently, more than 250, 000 men are diagnosed with prostate cancer yearly through biopsy when the Prostate Specific Antigen reaches 2.5 ng/ml. or higher. Referencing the Surveillance, Epidemiology and End Results Data, there is an expectation that upwards of 500,000 men will be diagnosed within the next 10 years. To be sure, men and physicians alike are uncertain who should be treated and when they should be treated when a rising Prostate Specific Antigen (PSA) alerts us to a pending problem. Clearly this is a vexing proposition for physicians and patients alike when localized prostate cancer is diagnosed with either biopsy or a multi-parametric Magnetic Resonance Imaging (mp-MRI) scan or both! This study intends to demonstrate the efficacy of High Intensity Focused Ultrasound (HIFU) for all grades of prostate cancer including: low grade, intermediate grade and high grade complemented by the use of a multi-parametric MRI scan in all patients.

Methods – 147 patients diagnosed with prostate cancer from a biopsy or mp-MRI scan independent of a biopsy were treated with a total gland HIFU procedure. All men who had a biopsy confirmation were scanned without prior knowledge of a biopsy and/or results by Radiologists who read the scan. **Patients had to qualify for this retrospective study by having a PSA value \leq to 8.5 nanograms per milliliter, a Gleason Score \leq 4+4 = 8 while treatment had to be performed within 4 years of the diagnosis.** Specifically, 70 patients had biopsy diagnosed prostate cancer indicating Gleason scores of 3+3 = 6, 3+4 = 7, 4+3 = 7 or 4+4 =8. The total number of patients in each group were: 37, 25, 6 and 2 respectively. Additionally, 77 patients had cancer diagnosed with either a 1.5 Tesla Philips MRI (with an endorectal coil), a 3.0 Tesla GE HDX scan or a Siemens 3.0 Tesla Timm Trio magnet (with or without an endorectal coil). All scans were read by experienced Radiologists well educated in prostate scans relevant to sequences of MRI including T2Weighted Images (T2W), Dynamic Contrast Enhancement (DCE) and Diffusion Weighted Images (DWI) without assistance by spectroscopy. All men subsequently underwent treatment by one HIFU treating expert within 4 years of their diagnosis.

Results – The highest PSA value was recorded for each patient from the biopsy group with a mean PSA value of 5.1 ng/ml with a range of 0.5 to 8.5 ng/ml. The nadir PSA value in the entire biopsy group was 0.28 ng/ml while the breakdown for Gleason scores of 6, 7 and 8 was 0.28 ng/ml, 0.28 ng/ml and 0.15 ng/ml respectively. Likewise, the highest PSA value in the MRI diagnosed group was noted to be 5.5 ng/ml with a range of 0.39 to 8.5 ng/ml. The PSA nadir in the mp-MRI treated group was 0.24 ng/ml. Success from the HIFU treatment was judged using the Phoenix definition for cure, a criteria commonly used to determine the success of Radiation therapy. The percentage cure for the entire group was 99% with the range of follow up from 3 months to 72 months. The impressive cure rate is attributed to patient selection, physician expertise and the use of imaging diagnostically and for staging. Equally impressive is a lack of significant side effects with the HIFU procedure. Specifically urethral narrowing or bladder neck contracture (a very treatable condition) is present in approximately 15-20% of patients treated while long term issues with impotency and incontinence are absent, as was rectal wall injury.

Conclusion – Presently physicians are desperately trying to assist patients with making the correct treatment decision choice when prostate cancer is detected. The outcome data associated with this study should preferentially attract patients diagnosed with prostate cancer to HIFU thereby considering an outpatient procedure that is indicated as a single treatment. The inclusion of Gleason scores of 8 cancers magnifies the added value to a disease grade that heretofore had suffered from poor outcomes with any treatment choice. While encouragement is noted with a very aggressive cancer grade, long term follow up is needed. Beyond this notation, excitement within the health industry for HIFU as a definitive treatment for men with virtually all grades of prostate cancer promises to take more caustic and invasive commonly used procedures to the alternative category. Unfortunately, until FDA approval, only a small percentage of the patients diagnosed with prostate cancer will be able to access this level of treatment excellence as they are dependent on third party payers (insurance companies) to appropriately pay for their procedure. Without FDA approval, doctors will be reluctant to offer the HIFU procedure and ignore training programs while offering inferior treatment options with significant side effects. HIFU requires significant training to achieve excellence in outcome data. Doctors are encouraged to get involved and get educated now if they expect to compete with the best doctors in the world once approved. Expert status is defined by outcome statistics of at least a 95% cure rate in minimally 100 patients with an absence of significant side effects including impotency, incontinence and bowel injury.