Excellence in High Intensity Focused Ultrasound (HIFU) Outcomes

PR Newswire

Currently more than 240,000 men are diagnosed yearly with prostate cancer while it is projected through SEER data that 500,000 men will be diagnosed within approximately 5 years. Additionally, prostate cancer is the most dominant (non-cutaneous) cancer diagnosed in men.

Since 2006 two specific HIFU treatment centers have provided procedures for organ confined prostate cancer in North America. The treating centers are Maple Leaf HIFU, represented by William L. Orovan, M.D. (Toronto, Canada) while PanAm HIFU™ has been represented by Ronald E. Wheeler, M.D., of Sarasota, Florida; treating in Cancun, Mexico and London, England. Heretofore, there has been no comparison of North American HIFU treatment outcome data.

Dr. Orovan's data comes exclusively from Ablatherm™ technology while Dr. Wheeler's work comes from the Ablatherm™ technology as well as the Sonablate 500™ technology. **This comparison is warranted based on the public perception that all institutions are equal regarding outcome data when HIFU is performed.** The following data will demonstrate that the treatment outcome data from PanAm HIFU™ is superior to that performed by Maple Leaf HIFU. Because many men may choose HIFU based on location or price point alone, this report gives reason to reconsider where they treat for HIFU and with whom they treat.

Methods –Dr. Orovan's outcome data can be found in the British Journal of Urology, International Edition published in 2012. His research article is entitled, "Single-session primary high intensity focused ultrasonography treatment for localized prostate cancer: biochemical outcomes using third generation-based technology". In total, Dr. Orovan reported on 402 patients treated between 2005 and 2010. 100% of Dr. Orovan's patients received biopsy confirmation while no patients were identified as having had an MRI (Magnetic Resonance Imaging) scan prior to the HIFU procedure. Dr. Wheeler's outcome data is noted in a study of 147 patients who qualified by virtue of preselected study criteria associated with a PSA value of ≤ 8.5 ng/ml, a Gleason Score of ≤ 8 (4+4) with subsequent treatment within 4 years of diagnosis. All patients in Dr. Wheeler's research had been diagnosed with either a biopsy or an MRI scan or both. Specifically, 70 patients had a confirmational biopsy (either proceeded by a scan or followed by a scan), while 77 patients were diagnosed by MRI (+ or – Spectroscopy) alone.

Results – Dr. Orovan qualified his group in accordance with the D'Amico stratification criteria as low and intermediate risk. Of 402 patients treated and followed to 4 years, 183 (45.5%) were low risk and 219 (54.5%) were intermediate risk. For clarity purpose, a low grade cancer in Dr. Orovan's treatment group was a

Gleason score 6 (3+3) while the intermediate group comprised a Gleason score 7 (3+4, 4+3). Depending on which classification for success was utilized Dr. Orovan's data reflected a cure rate of 76% for the Gleason 6 cancers while his cure rate was 69.5% for the Gleason grades of 7 (3+4, 4+3). Cure was defined by biochemical stability of the nadir (= .36 ng/ml) reached while failure was defined when a PSA value that reached the nadir and then rose to some point consistent with failure as defined by the Stuttgart or Horowitz definition. In Dr. Wheeler's data 147 patients received HIFU and followed for up to 6 years. In his data using a nadir (˂ .30 ng/ml) all but one patient succeeded with a cure rate of 99%. Specifically, the biopsy group (N= 70) noted the following characteristics: 37 patients had a Gleason score of 6, while 31 patients had an intermediate cancer of 7 (3+4, 4+3) and 2 patients had a very aggressive cancer of 8 (4+4). The men diagnosed with a MRI scan alone (N= 77) did as well as the biopsy group with a 99% cure.

Conclusion –It is clear that treatment outcome data varied significantly and must be understood by the patient when prostate cancer is diagnosed. It is quite possible that the MRI findings used by Dr. Wheeler gave him an additional diagnostic component or possible that individual treating physicians have treatment characteristics or qualities unique to themselves, allowing one to succeed more often while another may fail. Without question no matter the reason for success, Dr. Orovan had a success rate that must be improved upon if Maple Leaf HIFU™ expects to compete within the US population of organ confined prostate cancer patients. Patients will not accept failure when success has been defined as definitely and conclusively as this comparison represents. At this point in time, it is clear that location and cost should not be the controlling factor in deciding where patients are treated for prostate cancer. Patients interested in knowing more about PanAm HIFU™, and the diagnostic protocol developed by Dr. Wheeler, are encouraged to view their website: www.PanAmHIFU.com [1] or visit with our staff by calling: Dr. Ronald Wheeler at 941-957-0007.

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[1] http://www.panamhifu.com/