

# **Transrectal High-Intensity Focused Ultrasound (HIFU) using the Sonablate® 500 for the treatment of prostate cancer; the Perugia-Torino experience**

Mearini, L.1, D'urso, L.2, Collura, D.2, Zucchi, A.1, Formiconi, A.2, Muto, M.2, Porena, M.1  
1University of Perugia, Dept. of Urology, Perugia, Italy, 2Ospedale San Giovanni Bosco, Dept. of Urology, Torino, Italy

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## **Introduction & Objective**

High Intensity Focused Ultrasound (HIFU) is a relatively novel, minimally invasive therapy for prostate cancer. Data from other centres indicate that the early oncological efficacy is promising and that it appears to be well tolerated and associated with a favourable side effect profile. This study is a preliminary report on oncological outcomes of patients treated with Sonablate®500 HIFU device in our centre.

## **Materials and Method**

Between 2004 and 2007 163 men with T1-T3 N0M0 histologically proven adenocarcinoma of the prostate underwent transrectal HIFU in a Day Surgery setting. All patients gave informed consent, had HIFU under general or regional anaesthesia and were discharged with either a urethral or suprapubic catheter for at least 14 days. Follow up to determine oncological outcome included: PSA samples at 1 month and then every 3 months after treatment, and a prostate biopsy in all patients at 6 months. Failure was defined according to: positive findings at follow up biopsy and/or biochemical failure (according to American Society for Therapeutic Radiology and Oncology ASTRO criteria).

## **Results**

Median age was 72 yrs (SD 5.7); median baseline PSA value was 7.3 ng/ml (SD 3.3). Gleason score ranged 3-10; stage of disease was T1 in 72 pts, T2 in 69 pts and T3a in 22 patients. Median prostate volume was 32.4 ml (SD 15.9). Median treatment time was 189 minutes (SD 41.1). Median follow up was 23.8 months (SD 11.3). After HIFU treatment PSA dropped to a median nadir value of 0.18 ng/ml (SD 1.9). The median PSA value at three and six months were 0.30 ng/ml (SD 6.3) and 0.54 ng/ml (SD 3.7) respectively. At 6 months, percentage of negative biopsy was 73.4%. 22 patients were retreated with HIFU, while the others with EBRT or hormone therapy. According to ASTRO criteria, there was biochemically no evidence of disease (bNED) in 71.9% overall. Risk stratification using the D'Amico criteria show that just considering the low and intermediate risk group, the bNED is 87.2%. At univariate analysis, a negative biopsy at 6 months and bNED was statistically associated with a lower baseline PSA values and lower PSA nadirs at 1 month, T1-T2 stage and a lower Gleason score. At multivariate analysis, only baseline PSA is an independent predictor of a positive biopsy, while only clinical stage is an independent predictor of bNED.

## **Conclusion**

We have demonstrated promising early oncological outcomes using the Sonablate®500 for the treatment of prostate cancer. These data are in line with other European centres which attest to the reproducibility of the treatment regimen. We have found that outcome is positively associated with a lower baseline PSA, lower PSA nadir, lower Gleason score and lower tumour stage. As with any novel technology, long term data will be required before this technique gains widespread clinical acceptance outside of specialist centres.