

**CLINICAL OUTCOME OF TRANSRECTAL HIGH-INTENSITY FOCUSED  
ULTRASOUND FOR STAGE N0M0 POSTATE CANCER**

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**INTRODUCTION AND OBJECTIVES:** To report the clinical results of high intensity focused ultrasound (HIFU) therapy of N0M0 stage localized prostate cancer patients.

**METHODS:** We have performed HIFU treatments using the Sonablate™ 500 on 35 patients with N0M0 localized prostate cancer as of May 2004. Six month follow up was performed on these patients using PSA and biopsies with complete recovery (CR) being defined as success by ASTRO guidelines and a negative biopsy. Patients were classified by risk levels: Staging: over T2b, PSA over 10 ng/ml, and Gleason score over 7 were the thresholds. “Low risk” patients presented without being over any of these limits, “Intermediate risk” patients had indications over one of these levels, and “High risk” patients had two or more.

The patient characteristics were: Average age 67.9 years (range 57-87 years), 12 patients were stage T1C, 6 were T2a, 5 were T2b, 10 were T3a, and 3 patients were T3b. Therefore, 8 patients were Low risk, 9 were Intermediate risk, and 18 were High risk patients. Pre-operative PSA levels were 4.3 – 98.0 (average PSA 10.0, Mean PSA 17.2) ng/ml. Prostate size was 12.0 – 39.8 ml. (average volume 21.2ml, mean 24.2ml). Total treatment time was 68 – 425 min. (average time 157; mean time 171 min).

**RESULTS:** Serious complications included urethral strictures in 3 patients (8%). Of the 24 patients followed up for more than 6 months, 16 patients (67%) had both negative biopsies and met the ASTRO criteria for CR, while 19 patients (79%) met the ASTRO guidelines only for complete recovery. CR was segmented by risk class as follows: Low risk 5/5 patients (100%), Intermediate risk 4/5 patients (80%), and High risk 7/14 patients (50%).

**CONCLUSIONS:** Our early follow-up data suggests that HIFU therapy for localized prostate cancer produces satisfactory clinical results and we believe it to be very useful as a minimally invasive therapy for prostate cancer.

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