Clinical Update

FOCUS SURGERY, INC.

CLINICAL OUTCOME OF HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU) FOR THE TREATMENT OF LOCALIZED PROSTATE CANCER: 5-YEARS EXPERIENCE

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Objectives

Prostate cancer is the most common malignancy in men and second leading cause of death due to cancer in the United States. Recently, a number of alternative less invasive treatments have been developed to treat localized prostate cancer. High-intensity focused ultrasound (HIFU) is a noninvasive treatment that induces complete coagulative necrosis of a tumor at depth through the intact skin. We evaluated a biochemical disease-free survival, predictors of clinical outcome and morbidity for localized prostate cancer treated with HIFU.

Materials and Methods

A total of 152 HIFU treatments in 132 consecutive patients with stage T1c-2bN0M localized prostate cancer have undergone using Sonablate® HIFU device (Focus Surgery, Inc., Indianapolis, IN, USA). All patients followed more than 12 months. Disease freedom was defined according to the criteria recommended by the American Society for Therapeutic Radiology and Oncology consensus definition. The median age, serum PSA and follow-up were 70 years (range 45-87), 10.5 ng/ml (range 3.39-89.6) and 17.0 months (range 3 to 63). An average treatment time was 171 minutes (range 51-390). No adjuvant therapy was given after HIFU therapy.

Results

The biochemical disease-free survival rates by Kaplan Meier curves at 1, 3 and 5 years were in 83%, 69% and 69% of the patients. The biochemical disease-free survival rates at 3 years for patients whose pretreatment PSA less than 10 ng/ml, 10.01 to 20.0, 20.01-30.0 and more than 30 ng/ml were 88%, 67%, 61% & and 27% (logrank test, $p<0.0001$), respectively. The biochemical disease-free survival rates at 3 years for patients with low, intermediate and high risk group were 85%, 71% and 47% ($p=0.0004$), respectively. Final follow-up prostate biopsies showed 85% (112/132) of the patients to be cancer free. On multivariate analysis preoperative PSA (hazard ratio 1.061; 95%CI 1.040-1.083; $p<0.0001$) was a significant independent predictor of clinical outcome but age, stage, Gleason score, prostatic volume and neoadjuvant hormone therapy were not statistically significant for prognosis. Thirty-three (25%) patients developed a urethral stricture, 7 (5%) and 3 (2%) patients complained epididymitis and retrograde ejaculation. Four patients underwent transurethral resection of the prostate for prolonged urinary retention due to urethral stricture or bladder neck obstruction. One (1%) of each patient showed grade 1 incontinence for 1 month after HIFU and a rectourethral fistula. Twenty-two% (7/32) patients complained postoperative erectile dysfunction. Two of 7 erectile dysfunction patients were recovered with sildenafil citrate.

Conclusions

HIFU could noninvasively induce complete coagulative necrosis of the prostate without requiring surgical exposure or insertion of instruments into the lesion. Moreover, HIFU treatment is repeatable and, if needed, alternative options remain practicable. HIFU therapy appears to be safe and efficacious minimally invasive therapy for localized prostate cancer patients and pretreatment serum PSA was a useful predictor of clinical outcome.