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Platinum Priority – Prostate Cancer

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Focal High-intensity Focused Ultrasound Targeted Hemiablation for Unilateral Prostate Cancer: A Prospective Evaluation of Oncologic and Functional Outcomes

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Abstract

Background: In selected patients with unilateral, organ-confined prostate cancer (PCa), hemiablation of the affected lobe might be feasible to achieve acceptable cancer control with fewer complications.

Objectives: To assess the oncologic and functional outcomes of focal high-intensity focused ultrasound (HIFU) hemiablation in unilateral organ-confined PCa.

Design, setting and patients: Single-center prospective evaluation of HIFU hemiablation for unilateral organ-confined PCa was performed from July 2009 through December 2013.

Intervention: Cancer localization was done with transrectal ultrasound-guided biopsy and multiparametric magnetic resonance imaging followed by HIFU hemiablation.

Outcome measurement and statistical analysis: Oncologic outcomes were analyzed with control biopsies and prostate-specific antigen (PSA) measurement. Functional outcomes were assessed with validated questionnaires for genitourinary symptoms.

Results and limitations: Of 71 HIFU hemiablation patients, 67 completed the study protocol. The mean age was 70.2 yr (standard deviation: 6.8 yr), and median PSA was 6.1 ng/ml (interquartile range [IQR]: 1.6–15.5 ng/ml). Median maximum cancer-core length was 3 mm (IQR: 2–10 mm), and total cancer length was 6.5 mm (IQR: 2–24 mm). Gleason score was 6 (3 + 3) in 58 patients (86.6%) and 7 (3 + 4) in 9 patients (13.4%). Median follow-up was 12 mo (IQR: 6–50 mo), and at 12 mo, 56 of 67 patients had a negative control biopsy in the treated lobe. At 3 mo, all patients were continent, and potency was maintained in 11 of 21 preoperatively potent patients (confidence interval, 0.18–0.69). Complications included 8% Clavien–Dindo grade 2 and 2.8% grade 3 events.

Conclusions: Focal HIFU hemiablation appears to achieve acceptable oncologic outcomes with low morbidity and minimal functional changes. Longer follow-up will establish future considerations.

Patient summary: This study showed that high-intensity focused ultrasound hemiablation in selected patients with unilateral organ-confined prostate cancer can be used for satisfactory cancer control with minimal effect on genitourinary functions.

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1. Introduction

The incidence of prostate cancer (PCa) is steadily increasing worldwide, and PCa is the most frequently diagnosed cancer in men [1]. Current screening strategies have led to earlier diagnosis of PCa at lower clinical stages, lower grades, and smaller volumes [2]. A wide variety of ablative methods have been introduced and applied in recent years as focal treatment (FT) alternatives with which cancer foci can be eradicated within the prostate gland, thus greatly reducing the associated side effects of radical treatment. Although FT is not yet the standard for organ-confined PCa, it is the therapeutic approach with the most important potential [3]. Among the multiple options for ablation, high-intensity focused ultrasound (HIFU) and cryoablation—the present authors have ample experience with both—have been clinically available during the past 15 yr and have undergone continuous development over time. In this context, HIFU is a promising technique that has proven medium- to long-term cancer control with a low rate of complications, comparable with those of established therapies [4]. In the present study, we assessed the oncologic and functional outcomes at 1-yr follow-up of patients with unilateral low-risk organ-confined PCa treated at our center with focal HIFU hemiablation.

2. Patients and methods

2.1. Study design and patients

From July 2009 to December 2013, focal HIFU hemiablation was offered to patients who had a diagnosis of unilateral localized PCa in our institution. Inclusion criteria were unilateral disease, clinical stage T1c–T2a, maximum positive biopsies <33%, Gleason score ≤ 7 (3 + 4), prostate-specific antigen (PSA) <15 ng/ml, no extraprostatic extension disease on multiparametric magnetic resonance imaging (mp-MRI), and life expectancy >10 yr. Patients with previous PCa-related treatment were excluded.

2.2. Study intervention

2.2.1. Cancer localization

Cancer grade and laterality were confirmed with transrectal ultrasound (TRUS)-guided biopsy and mp-MRI. For TRUS biopsy, a conventional two-dimensional gray-scale TRUS probe was used, and all patients had a minimum of 20 cores for cancer localization. For mp-MRI, all patients underwent 1.5-T MRI without endorectal coil for assessment of the prostate. The multiparametric components used were diffusion and perfusion images; however, all hemiablation was based on the TRUS biopsy results, including cases with a discrepancy in laterality between biopsy and MRI and “MRI-invisible” PCa.

2.2.2. Treatment

Hemiblation was carried out using the Ablatherm HIFU system (EDAP TMS, Lyon, France). This system includes a treatment table, a probe-positioning system, an ultrasound power generator, a cooling system for preservation of the rectal wall, a computerized control module with specific software, and an endorectal probe with a biplane imaging probe working at 7.5 MHz and a 3-MHz treatment transducer focused at a maximum of 45 mm. In addition, automatic applicator adjustment and multiple security circuits excluded accidental focusing on the rectal wall, avoiding rectal injury.

For this procedure, the transducer was inserted into the rectum and was covered by a condom through which cooled water was circulated to cool the rectal wall; multiple gland images were taken. Because of the proximity of the prostate, the focal lengths of the transducer could be kept short, permitting the use of ultrasound frequencies in the range of 3–4 MHz. They produced small but very precisely defined lesions, with the aim of treating the gland partially (hemiblation) by juxtaposition of elementary lesions. Larger areas were ablated by moving the transducer electronically and adding one lesion to another. The main sonication parameters were acoustic intensity, duration of exposure, on:off ratio, the distance between two elementary lesions, and the displacement path when multiple lesions were made. A safety margin of 4–6 mm from the sphincter was given to prevent sphincter damage. The entire procedure was carried out within 120 min, and an indwelling urethral catheter was placed after the procedure.

2.2.3. Follow-up

The Clavien–Dindo classification system was used to grade postoperative complications. Oncologic and functional outcomes were analyzed during follow-up. Control biopsies were performed within the first year of follow-up, constituting the primary end point. Prostate biopsies at 12 mo (12 core, bisextant, TRUS guided) were performed according to the mandatory protocol and directed at both treated and untreated portions of the prostate. Treatment failure was defined as a positive biopsy in the treated lobe or a need for salvage therapy.

Follow-up visits consisted of taking a history and a physical examination and completing International Continence Society (ICS), International Prostate Symptom Score (IPSS), and International Index of Erectile Function (IIEF-5) questionnaires, which were filled in at preoperative and follow-up visits. Continence was defined as the patient having no involuntary urine leak and being completely pad free. Potency was defined as an IIEF score ≥ 22 without any medications to improve erection. In addition, PSA evaluation was performed at 3, 6, and 12 mo and every 6 mo thereafter. Data were collected prospectively and analyzed retrospectively.

2.3. Statistical analysis

The Wilcoxon signed-rank test was used to compare variation in distribution of IPSS, ICS, and IIEF-5 scores between the preoperative and 3-mo follow-up scores. Box plot graphics were computed to describe PSA values over the follow-up period. Cross-tabs applying chi-square or Fisher exact tests were used to assess the relationships among categorical variables. A p value <0.05 was considered statistically significant. Statistical analysis was performed using PASW Statistics 18.0 for Windows (IBM Corp, Armonk, NY, USA).

3. Results

3.1. Demographic and cohort data

During the period of inclusion, 71 patients with localized PCa were assigned to the focal HIFU hemiablation single-institution protocol. Four patients (5.6%) refused the control biopsy and thus were excluded from the final analysis. Sixty-seven patients (94.3%) had complete follow-up data and formed the study population. The mean age at time of treatment was 70.2 yr (standard deviation [SD]: 6.8 yr). Mean body mass index was 25.5 kg/m² (SD: 6.5 kg/m²). The median number of biopsy cores was 22 (interquartile range [IQR]: 20–69). Median maximum cancer-core length (MCCL) was 3 mm (IQR: 2–10 mm), and the total cancer length (TCL) was

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