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ORIGINAL ARTICLE

High intensity focused ultrasound with Focal-One® device: Prostate-specific antigen impact and morbidity evaluation during the initial experience☆

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KEYWORDS
Prostate cancer;
Focal therapy;
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Abstract
Objective: We report our initial experience in the treatment of prostate cancer (PCa) with high-intensity focused ultrasound (HIFU) using the Focal-One® device.
Material and methods: Retrospective review of the prospectively populated database. Between June 2014 and October 2015, 85 patients underwent HIFU (focal/whole-gland) treatment for localized PCa. Preoperative cancer localization was done with multiparametric magnetic resonance imaging (mpMRI) and transperineal mapping biopsies. Treatment was carried out using the Focal-One® device under general anesthesia. Oncological follow-up: PSA measurement and control biopsy with mpMRI according to protocol. Questionnaire-based functional outcome assessment was done. Complications were reported using Clavien classification.
Results: The median PSA was 7.79 ng/ml (IQR: 6.32–9.16), with a median prostate volume of 38 cc (IQR: 33–49.75). Focal and whole-gland therapy was performed in 64 and 21 patients respectively. Ten patients received salvage HIFU. Complications were encountered in 15% of cases, all Clavien 2 graded. Mean hospital stay was 1.8 days (0–7) and bladder catheter was removed on day 2 (1–6). Mean percentage reduction of PSA was 54%. Median follow-up was 3 months (IQR: 2–8). Functional outcomes: All patients were continents at 3 months and potency was maintained in 83% of the preoperatively potent.

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Conclusions: Focal-One® HIFU treatment appears to be a safe procedure with few complications. Functional outcomes proved no urinary incontinence and sexual function were maintained in 83%.

PALABRAS CLAVE
Cáncer de próstata;
Terapia focal;
Ultrasonido focalizado de alta intensidad;
Hemiablación

Ultrasonido focalizado de alta intensidad con el dispositivo Focal-One®: impacto sobre el antígeno prostático específico y evaluación de la morbilidad durante la experiencia inicial

Resumen

Objetivos: Reportamos nuestra experiencia inicial en el tratamiento del cáncer de próstata (PCa) con ultrasonido focalizado de alta intensidad (HIFU) utilizando el dispositivo Focal-One®.
Material y métodos: Estudio retrospectivo de datos recogidos prospectivamente. Entre junio de 2014 y octubre de 2015, 85 pacientes recibieron tratamiento HIFU (focal/total), para PCa localizado. La localización preoperatoria del tumor fue realizada con resonancia magnética multiparamétrica (mpMRI) y biopsias prostáticas mediante mapeo transperineal. El tratamiento fue realizado utilizando el dispositivo Focal-One® bajo anestesia general. Seguimiento oncológico: medición del PSA y biopsia control con mpMRI según protocolo. Los resultados funcionales fueron evaluados mediante cuestionarios validados y las complicaciones reportadas utilizando la clasificación Clavien.
Resultados: La mediana de PSA fue 7,79 ng/ml (6,32-9,16) con una mediana de volumen prostático de 38 cc (33-49,75). El tratamiento fue focal y total en 64 y 21 pacientes respectivamente. Diez pacientes recibieron tratamiento de rescate. La tasa de complicaciones fue del 15%, todas Clavien 2. La estancia hospitalaria media fue 1,8 días (0-7) y la sonda vesical fue retirada el día 2 (1-6). La media de reducción porcentual del PSA fue 54%. La mediana de seguimiento fue 3 meses (2-8). Resultados funcionales: todos los pacientes estuvieron continentes a los 3 meses y la potencia se mantuvo en el 83% de los previamente potentes.
Conclusiones: El tratamiento HIFU Focal-One® es un procedimiento seguro con pocas complicaciones. Los resultados funcionales no reportan casos de incontinencia y la función sexual se mantuvo en el 83%.

Introduction

Prostate cancer (PCa) treatment with high-intensity focused ultrasound (HIFU) began in the early 1990s by Dr. Albert Gelet et al.[1] This therapy is hyperthermia based and induces a coagulative necrosis of the prostate tissue by thermal and mechanical effect and the ablative zone is demonstrable as early as 2 h after the procedure.[2] Originally, HIFU was employed for patients with low or intermediate-risk localized PCa, who were not candidates for surgery, or as a salvage treatment for patients who were previously treated with external radiotherapy (EBRT), for whom a whole gland ablation was performed.[3]

Today, European Urology Association guidelines recommend active surveillance, radical prostatectomy, or EBRT as the standard treatment for localized PCa, depending on the tumor stage and the patient's life expectancy.[4] HIFU technology has evolved over the past decade and can be a viable treatment alternative in selected patients with low/intermediate-risk PCa as a focal treatment with promising oncological and functional results, in addition to low perioperative complication rates.[5,6] Currently, there are three devices available: Ablatherm® and Focal-One® from EDAP-TMS (France), and Sonablate® from SonaCare Medical (USA)[7] and Focal-One® represent the newer generation of HIFU devices with significant technical upgrade. In this paper, we report the initial clinical experience of Focal-One® device in the PCa treatment.

Methods and materials

Patients

We performed a retrospective analysis of our prospectively collected database of patients with localized PCa, treated with Focal-One® HIFU device between June 2014 and October 2015.

With Focal-One® we performed focal (hemiablation/subtotal) and whole-gland treatment. The clinical criteria for inclusion to perform focal treatment were: Clinical stage T1c-T2a, maximum positive biopsy: 33%, Gleason $\leq$7 (3 + 4), prostate-specific antigen (PSA) <15 ng/ml, absence of extraprostatic disease at the multiparametric magnetic resonance imaging (mpMRI), and life expectancy >10 y. Total treatment was performed for patients with a bilateral disease, or for those not candidates for surgery. Those in salvage treatment received focal or total treatment, according to an individual analysis for each case.