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## Focal High Intensity Focused Ultrasound of Unilateral Localized Prostate Cancer: A Prospective Multicentric Hemiablation Study of 111 Patients.

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#### Abstract

**BACKGROUND:** Up to a third of patients with localized prostate cancer have unilateral disease that may be suitable for **partial treatment** with hemiablation.

**OBJECTIVE:** To evaluate the ability of **high intensity focused ultrasound (HIFU)** to achieve local control of the tumor in patients with unilateral localized prostate cancer.

**DESIGN, SETTING, AND PARTICIPANTS:** The French Urological Association initiated a prospective IDEAL multi-institutional study (2009-2015), to evaluate **HIFU-hemiablation** as a primary treatment.

**INTERVENTION:** Multiparametric magnetic resonance imaging and biopsy were used for unilateral cancer diagnosis and control, and **HIFU-hemiablation**.

**OUTCOME MEASUREMENTS AND STATISTICAL ANALYSIS:** Primary: absence of clinically significant cancer (CSC) on control biopsy at 1 yr (CSC: Gleason score  $\geq 7$  or cancer core length  $>3$  mm regardless of grade or  $> 2$  positive cores). Secondary: presence of any cancer on biopsy, biochemical response, radical treatment free survival, adverse events, continence (no pad), erectile function (International Index of Erectile Function-5  $\geq 16$ ), and quality of life (European Organization for Research and Treatment of Cancer QLQ-C28) questionnaires.

**RESULTS AND LIMITATIONS:** One hundred and eleven patients were treated (mean age: 64.8 yr [standard deviation 6.2]; mean prostate-specific antigen: 6.2 ng/ml [standard deviation 2.6]; 68% low risk, 32% intermediate risk). Of the 101 patients with control biopsy, 96 (95%) and 94 (93%) had no CSC in the treated and contralateral lobes, respectively. Mean prostate-specific antigen at 2 yr was 2.3 ng/ml (standard deviation 1.7). The radical treatment-free survival rate at 2 years was 89% (radical treatments: six radical

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prostatectomies, three radiotherapies, and two HIFU). Adverse events were Grade 3 in 13%. At 12 mo continence and erectile functions were preserved in 97% and 78%. No significant decrease in quality of life score was observed at 12 mo. One limitation is the number of low-risk patients included in this study.

**CONCLUSIONS:** At 1 yr, HIFU-hemiablation was efficient with 95% absence of clinically significant cancer associated with low morbidity and preservation of quality of life. Radical treatment-free survival rate was 89% at 2 yr.

**PATIENT SUMMARY:** This report shows that high intensity focused ultrasound half-gland treatment of unilateral prostate cancer provides promising results with high cancer control and low morbidity.

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**KEYWORDS:** Focal therapy; Hemiablation; High-intensity focused ultrasound; Prospective trial; Prostate cancer

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