

HIFU FOR THE TREATMENT OF LOCALIZED PROSTATE CANCER: EFFICACY RESULTS OF THE EUROPEAN MULTICENTRIC STUDY

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INTRODUCTION AND OBJECTIVES: The safety and the efficacy of High Intensity Focused Ultrasound (HIFU) for the treatment of prostate cancer have been assessed in a phase II-III prospective multicentric clinical trial.

METHODS: Patients presenting with localized prostate cancer and non candidates for radical prostatectomy were included between 1995 and 1999 in 6 European sites. All patients were treated with HIFU under general or spinal anesthesia. During the follow-up, random sextant biopsies and PSA level measurements were performed. Any positive sample in biopsies performed after the last treatment session resulted in a "HIFU failure" classification.

RESULTS: In total, n=559 patients were enrolled in the study at data lock point. Of them, n=402 patients were staged T1-2 N0-x M0, and were treated with HIFU as primary prostate cancer care. Main patients baseline characteristics were (mean \pm SD): age 69.3 ± 7.1 years, prostate volume 28.0 ± 13.8 cc, PSA 10.9 ± 8.7 ng/ml. 92.2% of the patients were presenting 1 to 4 positive samples at the baseline biopsy. Gleason scores were 2 to 4 for 13.2% of the patients, 5 to 7 for 77.5%, and 8 to 10 for 9.3%. Patients received in mean 1.4 HIFU session. The mean follow-up duration was 407 days (Q1: 135 days, median: 321 days, Q3: 598 days). The negative biopsy rate observed in the T1-T2 primary care population is 87.2%. These results were also stratified according to the usual disease related risk classification, and are presented in the following table:

	Overall T1-2	LowRisk	Interm. Risk	High Risk
Neg. Biopsy Rate	87.2%	92.1%	86.4%	82.1 %

PSA results were strongly correlated to the completeness of the HIFU treatment, 83.8% of the complete prostate treatment resulting in a low (<1 ng/ml) and stable PSA level.

CONCLUSION: These short-term efficacy results obtained on a large cohort confirm that HIFU is an option to be considered for the treatment of localized prostate cancer.

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