

## HIGH INTENSITY FOCUSED ULTRASOUNDS (HIFU) FOR PROSTATE CANCER: RESULTS ON CONTINENCE

### Hypothesis / aims of study

High Intensity Focused Ultrasound (HIFU) is a technique using ultrasounds to produce tissue heating and destruction. In HIFU, the ultrasound beam that is generated has a very high intensity in the focal area, which rapidly decreases in the surrounding zone of tissue. Focused ultrasound waves are capable of inducing sharp increases in temperature (up to around 70 °C to 100 °C) in a few seconds, destroying a well-determined zone of tissue while the surrounding region remains intact. The volume of tissue destroyed by a single burst of ultrasound is termed the elementary lesion. To create large lesions, several elementary lesions are made side by side, by mechanically moving the transducer. This technique has been shown to be effective in the treatment of localized prostate cancer or as salvage treatment after radiotherapy (1). Few data have been produced on functional outcomes after HIFU and, in particular, on continence. Aim of this study was to evaluate continence maintenance/recovery in patients treated with HIFU either as primary treatment of prostate cancer (PC), either as salvage treatment for local recurrence after radical prostatectomy (RP) or radiotherapy (RT).

### Study design, materials and methods

This is a prospective study aimed to analyse continence maintenance/recovery after HIFU performed as primary or salvage treatment for PC at our Institution; for this study only 268 patients who showed a minimum 12 month follow up were considered. 234 patients received HIFU as primary treatment and 34 as salvage treatment after RT (16) or RP (18). Mean age was 74,3 (±4,7) years; median PSA was 7,8 ng/ml; Gleason score range was 6-9. Mean prostate volume was 43 ml in patients receiving HIFU as primary treatment, whilst it was 21 ml in patients treated after RT. Mean volume of local recurrence after PC was 1,7 ml. HIFU was performed with the Ablatherm® (EDAP SA, Vaux-En-Veline, France) according to the technique described by Chaussy (2) if performed as primary treatment; all patients underwent a trans-urethral resection of prostate (TURP) before HIFU. 9/16 patients treated after RT underwent TURP. In patients receiving HIFU as primary treatment the "standard" protocol was used, whilst in patients treated after RT or PC a less intensive protocol of treatment (e.g. using less energy for less time) was used. Patients were evaluated 1, 3, 6 9 and 12 months after HIFU by means of voiding diaries. After 3 month follow-up patients reporting incontinence were treated by means of pelvic floor muscle exercises. Patients who reported incontinence before HIFU were excluded from the study.

### Results

Results are reported in table 1.

Table 1

	All pats. (268)	Primary treatment (234)	After RT (16)	After RP (18)
% continent pts (1 month follow-up)	60,33	58	75	77,7
% continent pts (3 month follow-up)	79	79	75	83,3
% continent pts (6 month follow-up)	92,4	93	87,5	89,4
% continent pts (12 month follow-up)	95,8	96	93,8	94,7
Number of pads (12 month follow-up) (mean)	1,5	1,5	2,0	2,0

Legend: Number of pads was calculated considering only incontinent patients

### Interpretation of results

HIFU is a good therapeutic option to treat localized PC and local recurrence of PC. Negative biopsies are found in 80-93% of treated patients (1). This procedure is easily performed in loco-regional anaesthesia, even in older patients with co-morbidities. Urinary incontinence is a common complication of treatments for PC: it is estimated to be present in as much as 10-15% of patients after RP and 5% of patients after RT. According to our data transient urinary incontinence is quite common after HIFU, being present in around 40% of patients one month after HIFU. On the other hand, continence recovery is obtained in the majority of

patients within 6 months after HIFU: less than 8% of patients remain incontinent at this follow up. One year after HIFU only 4% of patients remain incontinent. It is worthy to note that these results were obtained in a quite old population, being the mean age 74,3 years. Patients treated for localized prostate cancer or after RP/RT show similar continence rates at one year follow up. Continence recovery seems to be faster in patients receiving HIFU for local recurrence of PC, probably because the treatment time is shorter and the dose of ultrasound administered lower.

#### Concluding message

HIFU is a good therapeutic option to treat PC which determines only transient in continence in a significant number of patients. Percentage of permanent incontinence is around 4% and seems lower than those reported after RP and similar to that reported after RT.

#### References

1. Nat Clin Pract Urol. 2005 Apr;2(4):191-8
2. Curr Urol Rep. 2003 Jun;4(3):248-52
3. Proceeding of the 3rd ICI, Incontinence, 2005

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<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require eithics committee approval because</i></b>	<b>Routine clinical practice; observational study</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>