

PP-25

Nerve sparing HIFU as primary "focalized" treatment for localized prostate cancer: A single center study of 295 men with 7 years of follow up

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Introduction & Objectives: Nerve Sparing HIFU has been the first FOCAL strategy for prostate cancer. The objective of this study is to report biochemical and biopsy outcomes of 295 patients after unilateral nerve sparing HIFU as a primary treatment for T1c-T2b/c prostate cancer (largest nerve sparing HIFU series ever reported).

Material & Methods: Patients treated by Ablatherm (EDAP-TMS, Lyon, France) with single unilateral Nerve Sparing HIFU treatment strategy for their localized prostate cancer in the ZNA Middelheim in Antwerp. Patients with any previous local therapy for prostate cancer were excluded. Only patients with unilateral negative lateral biopsies were included for unilateral nerve sparing HIFU. Patients were stratified according to D'Amico's 2003 risk group definitions. Kaplan-Meier analysis was performed to determine biochemical survival with failure defined according to the 2006 Phoenix definition (nadir+2).

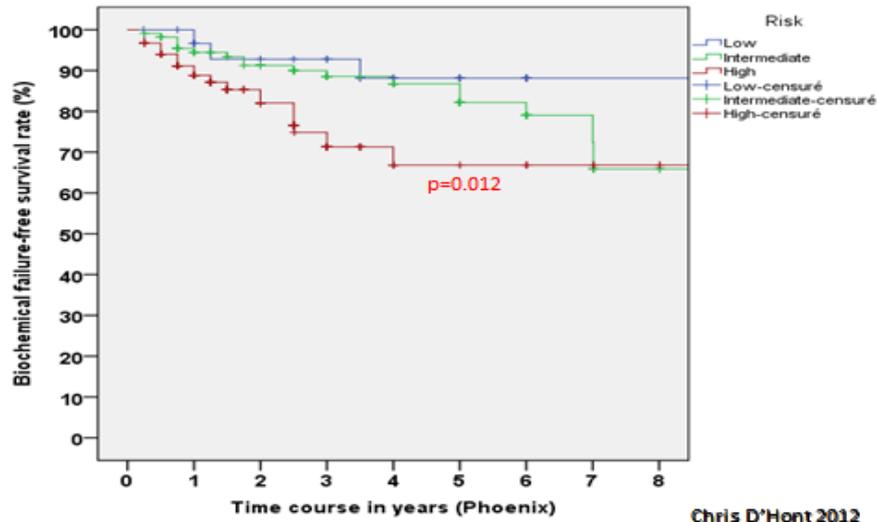
Results: A total of 295 consecutive patients - out of a series of 1000 pts - met the inclusion criteria. The average age was 60.0 ± 7.1 years. Pretreatment PSA was 9.3 ± 6.4 ng/ml, the median Gleason sum was 7 and 17.7%, 49.4% and 32.9% of patients were in the low, moderate and high risk groups, respectively. Patients were followed for 4.3 ± 2.2 years (range: 1 to 9 years). The median PSA nadir was 0.11 which was reached 15.7 ± 15.1 weeks after HIFU. Biochemical failure free survival rates at 5, 6 and 7 years are 80%, 74% and 70% respectively. A 2nd HIFU treatment is offered in case of bx proven local recurrence (10,1 % - most in the preserved untreated area).

Side effects are extremely rare, data are reported in the table. Only 1.3% of grade I stress incontinence (no grade III) and a potency preservation of > 85 % (63.3% without any medical support - IIEF-5 > 22).

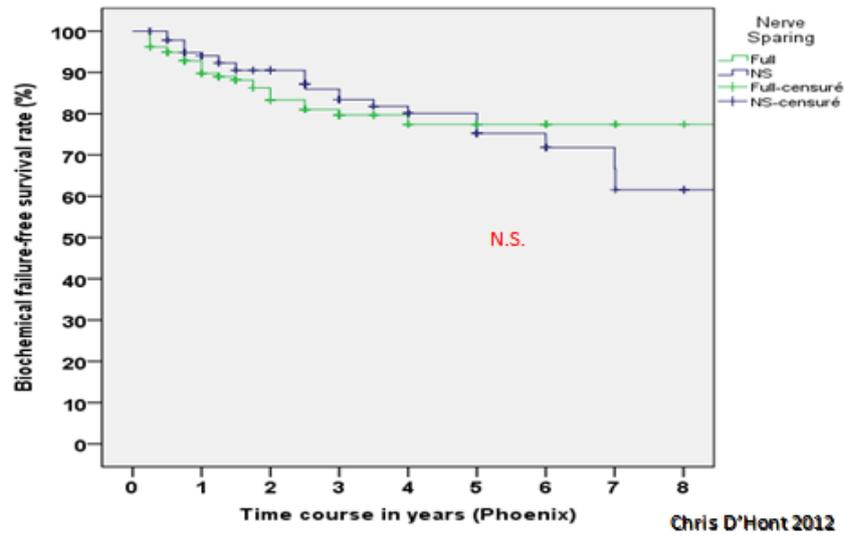
In case of bilateral nerve sparing HIFU (all lateral biopsies negative) > 98% of patients can preserve their potency (10 pts) - after a full HIFU treatment potency preservation is possible in > 50 % of patients (483 pts in our study). Even better results on QuOL in hemi-ablation (15 pts) and focal treatment (7 pts): see table.

Conclusions : Nerve sparing HIFU (Less ablation) provides good biochemical control through > 7 years of follow-up combined with a relatively low rate of side effects = excellent QuOL and good cancer control (same Quality of Treatment) in well selected patients. With more reliable imaging techniques more focalized HIFU treatment becomes a possible and safer first choice treatment in patients with limited and more focalized prostate cancer concerned about their Quality Of Life after treatment, knowing that in case of a local recurrence all salvage options (2nd HIFU & all other treatments) still remain possible. Hemi-ablation and focal treatment are technically possible with HIFU and offer excellent tumor control with even less comorbidity is well selected patients. We need more reliable diagnostic tools for selection.

Biochemical failure-free survival rates (Phoenix definition) dAmico risk groups



Biochemical failure-free survival rates (Phoenix definition) in patients treated with High-Intensity Focused Ultrasound according to treatment strategy ZNA Middelheim Antwerp



LESS = MORE

	n	Stress 1 1mnt%	Stress 1 6mnt%	Potent %	mPSA nadir	Salv %
full	483	6,2	2	50	0,41	15.2
Unilat/Bilns	295	3,8	1	85 / 98	0,2	10
hemi	15	1	0	87	1/3	15
focal	7	0	0	95	"normal"	short

complications		Unilateral Nerve Sparing (n=295)	
Incontinence, %		1 mth after HIFU	6 mnths after HIFU
Stress 1	3.8%		1,3 %
Stress 2	1.3%		0%
Stress 3	0%		0%
Urge	1.3%		0%
Potency, %		14.6%	< 7
- IIEF-5 score	61.4%		22-25
Impotent	20.9%		12-22 without aids
Fully Potent without aids	1.9%		17-22
Fully Potent with aids*	1.3%		12-22 with aids*
Diminished without aids			
Diminished with aids aids*			
* Use of PDE-5 Inh = choice of patient			
Total potency preservation		> 85 %	
Infection, %		5.1%	
Other			
TUIP, % (n)	2.5%		
Bladderneck sclerosis, % (n)	1.3%		
Stricture, % (n)	0.6%		
Retention, % (n)	0.6%		
pos. bx during follow up	10,1% = second HIFU		