



# HIFI Study : HIFU vs Radical prostatectomy in the curative treatment of localized prostate cancer GG 1 & 2 : Intermediate carcinologic results at 2 years



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## Method

Multicentre, prospective, non randomized, comparative study

Treatments : **HIFU** : total or subtotal ( $\geq 70\%$  prostate volume)  
Focal One<sup>®</sup>, Edap tms<sup>™</sup>, Vaux en Velin - France

Inclusion criteria **RP** : robotic, laparoscopic, open

T1-2 NxM0 , GG 1 (non eligible for AS) and GG 2, Gleason score  $\leq 7$ , restricted to the form [3 + 4] , PSA < 15 ng/mL , mpMRI

## Primary endpoint :

Survival rate without Salvage Treatment (SST)

## Secondary endpoints :

PSA, PM, biological recurrence, positive biopsies, metas, specific and overall survival

## Patients

**Treated patients** : 1988 HIFU / 1380 RP

**Age**: 75.2 in HIFU group / 64.4 in RP group

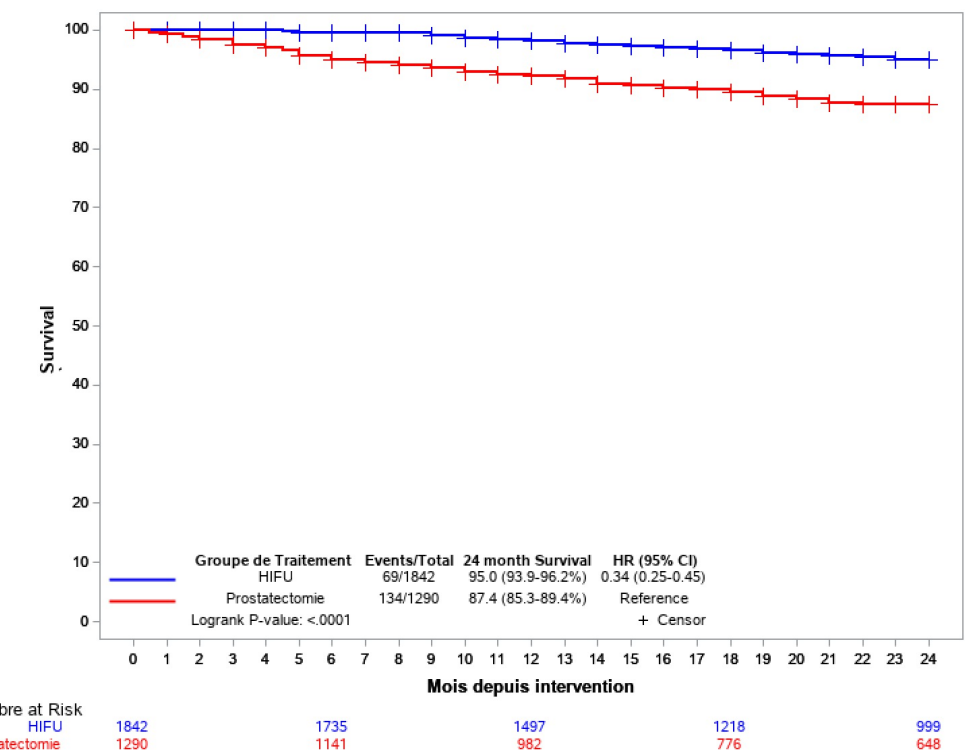
**GG1/2** : 41%/59% in HIFU group / 37% / 63% in RP group

**PSA**: 7.1 ng/mL in HIFU group / 6.9 in RP group

## Results

- Primary endpoint : Survival rate without salvage treatment at 24 months**

	Event	Hazard Ratio (95% CI)	Survival Estimates (95% CI)	p-value
<b>HIFU</b>	<b>69</b>	0.23 (0.16-0.33)	98.0 (97.3-98.7%)	<b>&lt;.0001</b>
<b>RP</b>	<b>134</b>	Reference	91.9 (90.3-93.5%)	



- Secondary endpoints :**

- PSA nadir** : 0.34 in HIFU group / 0.01 in RP group
- Positive margins after RP** : 277/1301 (**24%**)
- Biological recurrence (BR) after HIFU** : 202 /1224 (**16.5%**)
- Biopsies after HIFU** : Only 13.2 % of for-cause biopsies
- Salvage tt** : 2RP + 65Rxtt + 2AB

## Conclusion

Apparent superiority of HIFU (Focal One<sup>®</sup>, Edap tms<sup>™</sup>) on RP according to these intermediate data on 3368 patients

HIFU SST: 95% VS RP SST 87% , PM after RP: 24%, Radiation therapy often indicated for PM, BR after HIFU : 16.5%

Data not yet consolidated at 2 years: 30 months follow-up is necessary