

**PP-37**

**Tolerance and efficacy of High Intensity Focused Ultrasound (HIFU) focal therapy as primary treatment for localized prostatic carcinoma: Preliminary results**

P. Conort, R. Renard-Penna, E. Comperat, S. Charlon, P. Mozer

*Pitié-Salpêtrière Hospital, Paris, France*

**Introduction & Objectives:** Improvements in prostatic carcinoma (PCa) detection with multi-parametric (mp) MRI and 3D prostatic biopsy (PB) mapping, allow new therapeutic alternative for low volume localized PCa. Early clinical studies of focal therapy (FT) have already demonstrated favorable outcomes. We report our initial experience regarding tolerance and efficacy of HIFU-FT for unifocal PCa, using a follow-up method similar to our practice for active surveillance.

**Material & Methods:** A prospective study was initiated on March 2010, for T1 to T2a patients with PSA  $\leq 10$  ng/ml, a visible nodule on mpMRI performed always before 3D PB mapping (Urostation®-Koelis) showing PCa only on the nodule. These inclusion criteria did not exclude Gleason grade 4. Patients signed informed consent form, agreeing HIFU-FT (Ablatherm Imagerie Intégrée®-EDAP TMS) and a follow-up based on mpMRI at 1 week, 6 & 24 months (mo), on PSA at 3, 6, 9, 12, 18 & 24 mo, on PB at 24 months or earlier in case of prostatic lesion (ESUR scoring  $> 9/15$ ) seen on mpMRI and/or increasing PSA after 6 mo, and on clinical control at 3, 6, 12 and 24 mo.

**Results:** 30 patients (72yo, 57-79) were prospectively included from March 2010 to September 2012. At baseline: PSA was  $6.5 \pm 2.0$  ng/ml, prostate volume  $45 \pm 27$ cc (15-150) with a nodule ( $11.7 \pm 3.8$  mm) on mpMRI; PB showed PCa only in this area [Gleason score: 3+3(18), 3+4 (9), 4+4 (3 with negative extraprostatic workup)]. All subjects received a limited TURP (anterior part) immediately before the HIFU treatment. Only 1 had PCa, Gleason 3+3 according well to mpMRI & PB. The HIFU application average time was 36 min (15-90) with a mean treated volume of 8.1cc (3.4-12.7), i.e. in average 30% (6%-50%) of the prostatic volume. Median follow-up was 15 mo (6-36). **Tolerance** was excellent: mean catheter time was 3.4 (1-25) days (2 temporary acute retentions), one epididymitis at D 15, no significant change for IIEF-5 and IPSS scores. **Efficacy** was assessed by early mpMRI which had always confirmed necrosis of the target and no other suspicious lesion or complication. At 6 mo mpMRI (n=30) demonstrated significant reduced prostatic volume ( $30 \pm 18$ cc) and 5 suspicious lesions; 3 negative PB (ESUR $<10/15$ ), 2 with ESUR score  $> 9/15$  and increasing 6 months-PSA: PB showed 2 PCa (G1 3+3), a second complete HIFU was planned. At 3, 6, 12 & 24 mo, mean(SD) PSA (ng/ml) was 4.0(2.9), 4.3(2.7), 4.9(3.4), 4.7(3.3) respectively. Patients with constant increasing PSA after 6 mo-mpMRI underwent new mpMRI and PB: 2 of them (28) had G1 3+3 and 1 4+3, and 3 had PB planned for ESUR  $< 10/15$  suspicious lesion. The 5 (16%) recurrences (2 ipsi-, 2 contro- & 1 bilateral) were treated by a new HIFU session (n=4) and 1 is on surveillance (5mm lesion).

**Conclusions:** The follow-up without systematic PB seemed to be a safe option. HIFU-FT is very well tolerated with preliminary encouraging oncological results. A longer follow-up is required to confirm the benefit of the HIFU-FT and the safety of this method of follow-up.