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**MRI-US FUSION GUIDED HIGH-INTENSITY FOCUSED ULTRASOUND WITH FOCAL-ONE® SYSTEM: IMPACT ON PSA, COMPLICATIONS AND GENITO-URINARY FUNCTIONS DURING INITIAL EXPERIENCE**

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**Introduction:** We report our initial experience in the treatment of prostate cancer (PCa) with high-intensity focused ultrasound (HIFU) using MR-US fusion guided Focal-One® system.

**Methods:** Between June 2014 to October 2015, 85 patients underwent HIFU (focal / whole-gland) treatment for localized PCa with low and intermediate disease. Preoperative cancer localization was done with multiparametric magnetic resonance imaging (mpMRI) and transrectal ultrasound-guided biopsy. Treatment was carried out using the Focal-One HIFU system under general anesthesia. Oncological follow-up includes PSA measurement (1,3, 6 and 12 months) and control biopsy with mpMRI at 1yr after treatment. Questionnaire-based functional outcome assessment (Pre-op and 1,3,6 and 12 months) was done. Complications were reported as Clavien-Dindo grade.

**Results:** The study cohort had a median age -70 yr (IQR 66-77 yr), and median PSA - 7,79 ng/ml (IQR 6,32-9,16 ng/ml). Median total cancer length was 7,50 mm (IQR: 4,25-14,50 mm). Biopsy characteristics are summarized in table 1. Mean prostate volume was 40 cc (range 15-70). Suspected lesions were observed in 71 pre-treatment mpMRI. Pre-operative TURP was performed in 22 patients. Focal and whole-gland therapy was performed in 64 and 21 patients respectively. Ten patients received salvage HIFU. Complications were encountered in 15% of cases, all Clavien I graded. Mean hospital stay was 1,8 d (range 0-7) and bladder catheter was removed on day 2 (range 1-6). Mean percentage reduction of PSA was 53% for first 40 cases and 56% for last cases. Nine patients had higher PSA post treatment. Median follow-up was 3 mo (IQR: 2-8 mo). At last follow-up, 8 patients had protocol control biopsy, 4 having residual disease in the treated area. Functional outcomes: all patients were continents at 3 mo and potency was maintained in 83% of preoperatively potent patients.

**Conclusions:** Focal-One® HIFU treatment appears to be a safe procedure with few low grade complications. Functional outcomes proved no urinary incontinence and sexual function were maintained in 83%.

**Table 1-Biopsy characteristics, no. (%)**

Variable	n=85
<b>Gleason score</b>	
3+3	52 (61)
3+4	30 (35)
4+3	2 (3)
4+4	1 (1)
<b>Tumor Side</b>	
Right	29 (34)
Left	43 (51)
Bilateral	13 (15)
<b>Localization</b>	
Base	30 (35)
Medial	20 (24)
Apex	13 (15)
Anterior	1 (1)
Multiple one-side	8 (10)
Bilateral	13 (15)