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%.