

AUA 2021: Focal Ablation Proves Effective and Preserves Erectile Function and Continence Better Than Radical Prostatectomy

Patients preferred this less invasive treatment option for IR prostate cancer.

PracticeUpdate Editorial Team

September 10, 2021 — Las Vegas, Nevada — One year post treatment, focal ablation has achieved good oncological efficacy and preserved erectile function and continence better than radical prostatectomy in patients with intermediate-risk prostate cancer. This interim outcome of a randomized, controlled crossover study was reported at AUA 2021, the 116th Annual Meeting of the American Urological Association, from September 10 – 13.

Eduard Baco, MD, PhD, of the Oslo University Hospital, Norway, and colleagues set out to compare oncological and functional outcomes after 1 year between focal prostate ablation using in intermediate-risk prostate cancer.

Patients presented with unilateral prostate cancer (cT<3, International Society of Urological Pathology <4, and PSA<20 ng/mL) from 2017 to 2020 were randomized 1:1 to high-intensity focused ultrasound or radical prostatectomy. Median patient age was 63 (interquartile range 60 - 69) years. PSA was 7.1 (interquartile range 5 - 10) ng/mL. Tumor diameter as measured by MRI was 13 (interquartile range 10 - 17) mm. Prostate volume was 37 (interquartile range 27 - 47) mL.

Focal ablation was performed using the FocalOne® high-intensity focused ultrasound device. Robotic radical prostatectomy was

performed at high-volume centers using unilateral nerve-sparing surgery. Treatment failure in the focal ablation arm was defined as International Society of Urological Pathology >3 in MRI-targeted and/or systematic prostate biopsies 12 months post treatment and/or the need for whole gland treatment. Treatment failure in the radical prostatectomy arm was defined as PSA >0.2 ng/mL and/or a positive surgical margin.

Voiding and erectile function were assessed using patient-reported International Prostate Symptom Score and International Index of Erectile Function 5 questionnaires. De novo urinary incontinence was defined as the patient-reported need for at least one pad daily. One-hundred eighteen patients were randomized to focal ablation (n=56) or radical prostatectomy (n=62). The rate of crossover was 20% (24 of 118). Two patients declined treatment. Sixty-six percent (76 of 116) underwent focal ablation, 34% (40 of 116) radical prostatectomy and were included in the per-protocol analysis. Ninety-seven percent (74 of 76) of the focal ablation group underwent MRI and prostate biopsy after 1 year. The remaining two, whose MRI was negative, declined biopsy. Treatment failed after focal ablation in 5% (four of 76, 95% confidence interval 1% - 13%). Treatment failed after radical prostatectomy in 17% (seven of 40, 95% confidence interval 7% - 36%) (P = .022).

In the focal ultrasound group, salvage radiation treatment was performed in three patients. One patient was treated with salvage radical prostatectomy. Two patients required repeat focal ablation due to detected International Society of Urological Pathology 3 prostate cancer in untreated prostate zones. In the radical prostatectomy group, six patients exhibited positive surgical margins. One developed pelvic lymph node metastases. Median baseline International Prostate Symptom Score with focal ablation was 9 (interquartile range 5 - 12); with radical prostatectomy, 7 (interquartile range 4 - 18), difference not significant.

After 1 year, this score was 5 (interquartile range 3 - 11) with focal ablation; 7 (interquartile range 4 - 14) with radical prostatectomy, difference not significant. Median baseline International Index of Erectile Function 5 was 22 (interquartile range 12 - 25) with focal ablation; 23 (interquartile range 15 - 24) with radical prostatectomy,

difference not significant. After 1 year, median baseline International Index of Erectile Function 5 was 18 (interquartile range 10 - 23) with focal ablation; 5 (interquartile range 5 - 6) with radical prostatectomy ($P < .001$). After 1 year, 4% (three of 76, 95% confidence interval 1 – 12) of patients who underwent focal ablation had experienced de novo urinary incontinence; 35% (14 of 40, 95% confidence interval 19 - 59) who underwent radical prostatectomy ($P < .001$).

Dr. Baco concluded that 1 year post treatment, focal ablation was shown to achieve good oncological efficacy and to preserve erectile function and continence better than radical prostatectomy. The incidence of crossover in the radical prostatectomy group was high, demonstrating patient preference for a less invasive treatment option.

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