

**Meeting Coverage**

# 'Cautious Optimism' for HIFU in Prostate Cancer

— Radical treatment avoided for 2 years in 90% of patients

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SAN DIEGO -- Almost 90% of patients with early prostate cancer remained free of radical intervention 2 years after treatment of a single lobe with high-intensity focused ultrasound (HIFU), according to a multicenter French study.

All but five of 101 patients had no evidence of clinically significant prostate cancer following a single HIFU treatment session, and all 14 had complete absence of any cancer in the treated lobe.

A year after surgery, 97.2% of patients did not require sanitary pads for urinary incontinence, and 78.4% had regained or preserved erectile function, as reported here at the American Urological Association meeting.

"Partial treatment of the prostate gland may fill the gap between active surveillance and radical treatments," said Pascal Rischmann, MD, of Rangueil University Hospital in Toulouse, France. "The treatment can be used for a homogeneous patient population and offers the potential to limit the risks of treatment-related morbidity. Hemiablative HIFU may be amenable to about 20% of patients who present with unilateral prostate cancer."

The results provide reason for "cautious optimism" that HIFU -- as well as other focal therapies -- can play a role in the treatment of early prostate cancer in the United States, said Marc Bjurlin, DO, of NYU Langone Medical Center in New York City.

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"One of the things the results highlight, as the presenter noted, is candidate selection is key," Bjurlin told MedPage Today. "The appropriate candidates for focal therapy at this time appears to be those patients with low to intermediate-risk prostate cancer. Candidate selection must include not only the tumor characteristics but also the location of the tumor within the gland, which the presenter also highlighted, because there may be some limitations of HIFU in terms of treating anterior-located tumors."

Moving forward, prostate cancer specialists and patients will need to weigh the potential benefits of HIFU against those of active surveillance as an initial approach to managing low-risk prostate cancer, he added.

Outside the U.S., HIFU has been used for about 2 decades to treat localized prostate cancer. Late last year the FDA approved the technology for "prostate tissue ablation." The approval did not specifically mention prostate cancer nor did it rule out use of HIFU for treating the disease. Bjurlin said several centers in the U.S. are evaluating to HIFU in studies designed to determine whether it has a role in treating prostate cancer and, if so, what is the most appropriate role.

Rischmann reported findings came from a multicenter trial of unilateral or hemiablativ HIFU in low- and intermediate-risk prostate cancer. Radical therapies have questionable benefits for that subgroup of patients and has carries a risk of potential functional consequences, said Rischmann. Active surveillance can carry a risk of understaging, undergrading, psychological stress, and delayed treatment. The trial aimed to evaluate HIFU as a potential intermediate option.

Investigators at 10 French centers enrolled patients older than 50 with stage T1C or T2 disease, PSA level <15 ng/mL, unilateral tumor, Gleason grade  $\leq 7$ , a maximum of two consecutive sextants involved, and  $\geq 5$  mm distance from the tumor apex to the urethra by multiparametric MRI. Follow-up PSA measurements occurred at 3, 6, 12, and 24 months, MRI-guide biopsy at 6 to 12 months, and functional-quality of life assessments at 3, 6, and 12 months.

The primary endpoint was absence of clinically significant cancer in the treated side, defined as Gleason score >6, more than two positive biopsy cores, or cancer-core length >3 mm, regardless of grade. Secondary endpoints included absence of any cancer on biopsy, biochemical response, functional results, and quality of life.

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Investigators enrolled 111 patients who had a median age of 64, mean PSA value of 6.2 ng/mL, and mean prostate volume of 31.6 g. Three-fourths of the patients had tumors that were Gleason grade  $\leq 6$ . The volume of the treated area of the prostate averaged 16.1 g.

Subsequently, 101 patients had follow-up biopsies and were evaluable for the efficacy analysis.

Among the 101 patients with paired biopsies, 95 (95%) had no evidence of clinically significant cancer on the treated side of the gland. Analysis of secondary outcomes showed that 87 (87%) had no residual cancer in the treated lobe, and 68 (67%) had no evidence of cancer in the entire gland.

Rischmann said two-thirds of patients with positive biopsies had tumors located at the apex of the prostate. The observation could represent a limitation of the treatment, need for a second treatment session, or other modifications of the technique or technology.

During 2 years of follow-up, eight patients had repeat HIFU treatments, six had radical prostatectomy, three had external beam radiotherapy, and 16 patients enrolled in active surveillance. Three patients had second-line treatment: One underwent radical prostatectomy and two had radiation treatment. None of the additional treatments was associated with complications.

Assessment of functional outcomes at 12 months showed that 2.8% of the men had persistent grade I stress incontinence, and the remaining 97.2% required no use of sanitary pads. Evaluation by the International Index of Erectile Function (IIEF) showed that 78.4% of the men had preserved erectile function (IIEF-5 score  $> 16$ ). Scores of quality-of-life measures remained stable or improved.

**The study was supported by the French Urological Association.**

**Rischmann disclosed no relevant relationships with industry.**

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