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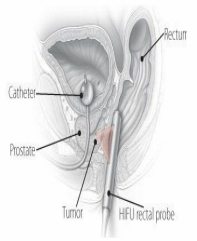
FDA Panel Disapproves Of HIFU For Prostate Cancer



The company marketing Ablatherm Integrated Imaging High Intensity Focused Ultrasound (HIFU), used to treat low-risk prostate cancer, has failed to get the nod of U.S. Food and Drug Administration (FDA) on its premarket approval application.

HIFU, which has been used in other countries for about 15 years, is marketed in Europe by EDAP TMS, a French company operating in the US as EDAP Technology. This robotic technology would be the first device of its kind to get approved in the USA.

HIFU consists of a treatment module designed to connect a control console to an endorectal probe device. After the patient has been anaesthetised, a urologist robotically controls the probe for insertion into the rectum, enabling the device to deliver ultrasonic energy to a focused portion of the prostate. In the process, high-intensity waves from an ultrasound imaging transducer in the probe generate intensive heat (85-95C). This causes ablation of cancerous tissue while preserving the apex, sphincter, and rectum, according to EDAP.

However, the Gastroenterology and Urology Panel of the FDA's Medical Devices Advisory Committee expressed concerns about the paucity of data available from HIFU sponsor's research findings that were presented as part of its US premarket approval application.

A majority of panel members voted 'No' to the question regarding a reasonable assurance that the therapy is safe. In addition, panel members voted unanimously against reasonable assurance that the treatment is effective.

During the hearing, EDAP presenters emphasised the "body of evidence" strongly supports the approval of HIFU in the US. The benefits of a noninvasive and localised therapy with exact energy delivery, they said, outweigh the risks for urinary obstructive morbidity. The side effects from HIFU are "not dissimilar" to those caused by other prostate cancer treatments, including radiation therapy, EDAP pointed out.

FDA presenters, however, reviewed EDAP's submission documents carefully, citing these deficiencies: lack of data and safety concerns (ie, a 28% cumulative positive biopsy rate two years after HIFU treatment among participants in a nonrandomised trial).

Inderbir Gill, MD, chair of the University of Southern California, Los Angeles, Institute of Urology, is among those who support the HIFU treatment. HIFU may not be perfect but all ablation technologies have similar biopsy rates, Dr. Gill told panel members. "It's about patient choice."

HIFU has been used in 40,000 patients during a 15-year period, said Dr. Gill, adding that the device has never been suspended or withdrawn from the market.

Source: Medscape
Image credit: Harvard Medical School

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