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Researcher helps develop standards for safe use of histotripsy therapy

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University of Cincinnati researchers are working with the U.S. Food and Drug Administration to develop a set of regulatory standards to ensure the safe and effective administration of histotripsy therapy used to treat patients with an enlarged prostate.

Histotripsy is a novel form of therapeutic ultrasound that can be applied transcutaneously (across the skin) to liquefy tissue. In addition to treating the prostate, it has applications for treatment of fetal ventricular defects, deep-vein thrombosis, and renal and liver cancer.

Kenneth Bader, PhD, postdoctoral fellow in the division of cardiovascular health and diseases at UC, says the gold standard for treating benign prostatic hyperplasia (BPH, an enlarged prostate) involves physicians using electrocautery or sharp dissection to remove tissue that is restricting urination in patients.

"Although the procedure is highly effective, there is also a significant rate of impotence in patients," says Bader. "Histotripsy is highly targeted and will give physicians a less invasive option."

"Instead of heating the tissue like in most forms of therapeutic ultrasound, histotripsy mechanically deforms it," says Bader. "So what happens is you have the small gas nuclei that are in your body and the ultrasound hits it and causes it to expand very rapidly and it collapses in a process termed cavitation. The mechanical action of that expansion and collapse of the cavitation is what liquefies the tissue to generate the

therapy."

"It's like a scrubbing bubble, the same as a detergent breaking up dirt and grime, but in this case we are breaking up tissue," says Bader.

Currently, there are clinical trials in which surgeons use a histotripsy device to emit ultrasound pulses from outside the patient's body into the prostate. These pulses form a bubble cloud within the prostate that mechanically breaks up the cellular structure of the soft tissue. The surgeon can direct the bubbled cloud to the intended treatment location.

UC researchers are not part of those clinical trials, but are working with the FDA to determine ways to regulate the output of these histotripsy devices as part of a $107,000 grant from the Focused Ultrasound Foundation.

Bader is the principal investigator and Christy Holland, PhD, professor in the division of cardiovascular health and diseases at UC and associate director of research for the UC Heart, Lung and Vascular Institute, along with Kevin Haworth, PhD, assistant professor in the division of cardiovascular health and disease at UC, are co-investigators.

"Will there be any collateral damage using histotripsy?" asks Bader. "Is there a good way to monitor the cavitation and monitor the histotripsy therapy? Part of what we are going to do is look at different settings on the histotripsy device. We are going to consider a range of ultrasound pulse durations. We are going to try to see where there is potential for collateral damage with the shortest and the longest pulse duration typically used on a histotripsy device.

"We look at not only how long is the pulse, but also how loud is the pulse," adds Bader. "We are looking at a soft tone versus a very loud tone. It's the range over which you can generate cavitation that depends

on either how loud or how long the ultrasound pulse is."

"We will do numerical simulations to try and predict where the cavitation occurs and where the therapy occurs. These simulations will help with patient treatment planning," says Bader.

At some point what's helping to treat the prostate may help improve the cardiovascular health of patients. Histotripsy has been used in animal models to try and break up tissues in the heart for the treatment of congenital heart diseases, and breaking up clots to treat deep-vein thrombosis.

"Right now it is just helping the FDA understand histotripsy for BPH, but that will open up a whole other flood gate of applications."

Provided by University of Cincinnati