FDA Warns Against Using Robotic Surgery to Treat Cancer

Agency wants doctors and patients to be aware of the lack of evidence of safety and effectiveness so they can make informed decisions.

February 28, 2019 By Food and Drug Administration (FDA)

Today, the U.S. Food and Drug Administration issued a safety communication to patients and health care providers urging caution when using robotically-assisted surgical devices for mastectomy and other cancer-related surgeries. Robotically-assisted surgical devices enable surgeons to perform a variety of surgical procedures through small incisions in a patient's body. This type of surgery may help reduce pain, blood loss, scarring, infection and recovery time after surgery in comparison to surgical procedures that do not use these devices. Computer and software technology allow a surgeon to control surgical instruments attached to mechanical arms through small incisions while viewing the surgical site in three-dimensional high definition.

The FDA has not granted marketing authorization for any robotically-assisted surgical devices for use in mastectomy or for the treatment or prevention of cancer. However, the FDA is aware of scientific literature and media publications reporting poor outcomes for patients, including one limited report that describes a potentially lower rate of long-term survival when surgeons and hospital systems use robotically-assisted surgical devices instead of traditional surgery for hysterectomy in cases of cervical cancer. In addition, the FDA has received a small number of medical device reports of patient injury when these devices are used in cancer-related procedures.

The safety communication warns patients and providers to be aware that the safety and effectiveness of robotically-assisted surgical devices for mastectomy and any cancer-related surgery has not been established. In addition, the FDA urges health care providers to complete the appropriate training for the specific robotically-assisted surgical procedures performed.

The FDA also recommends that patients and health care providers discuss the benefits, risks and alternative procedure options to make informed treatment decisions. The agency also advises patients to ask their health care providers about training, experience and outcomes related to the use of robotically-assisted surgery.

"Certain patients with cancer may require surgical procedures to treat or prevent the spread of cancer in their body. These procedures are often associated with improved survival outcomes for these patients. However, today we are warning patients and providers that the use of robotically-

assisted surgical devices for any cancer-related surgery has not been granted marketing authorization by the agency, and therefore the survival benefits to patients when compared to traditional surgery have not been established," said Terri Cornelison, MD, PhD, assistant director for the health of women in the FDA's Center for Devices and Radiological Health. "Our surveillance using multiple tools—medical device reports, patient registries, scientific literature—helps us monitor and identify potential problems with medical devices as they arise. In the case of robotically-assisted surgical devices and cancer-related uses such as mastectomy, we are aware of scientific literature reporting that surgeons have been using the device for uses not granted marketing authorization by the FDA. We want doctors and patients to be aware of the lack of evidence of safety and effectiveness for these uses so they can make better informed decisions about their cancer treatment and care. This safety communication issued today reflects the agency's commitment to enhancing our oversight of device safety as part of our Medical Device Safety Action Plan, as well as the agency's ongoing commitment to advancing women's health."

This announcement was originally published on the Food and Drug Administration website.

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