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Evidence lacking to support use of costlier biologic mesh for abdominal hernia repair

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A UT Southwestern Medical Center study comparing two types of materials used in abdominal wall hernia repair surgery found no evidence to support the use of costlier biologic mesh versus synthetic mesh.

The findings, reported online today in *JAMA Surgery*, were based on a comprehensive review of published studies on patient outcomes following surgeries that used the two types of materials.

"In the absence of evidence demonstrating superiority of biological mesh materials, the expense associated with their use cannot be justified," said Dr. Sergio Huerta, Associate Professor of Surgery at UT Southwestern, staff physician at VA North Texas Health Care System, and first author of the study.

Abdominal hernia repair is one of the most common procedures performed by general surgeons. Recurrence of the hernia is common, and inserting a synthetic mesh at the time of the repair has been shown in a randomized clinical trial to substantially reduce the likelihood of recurrence. However, there is a risk of infection associated with synthetic mesh materials, and the mesh can erode into the bowel. In the 1990s, a new class of biologic mesh materials was introduced. The new biologically derived meshes were costlier, but it was hoped they might reduce infections and erosions.

The biologic mesh materials are derived from sources such as porcine

skin and bovine pericardium derivatives. On average, biologic mesh costs 3½ times as much as synthetic mesh, the authors found.

In the study, researchers analyzed published results from the use of biologic mesh in abdominal wall hernia repair and reviewed the U.S. Food and Drug Administration approval history of these devices, a process known as 510(k) approval. This process included review of an FDA online database for 510(k) clearances for all commercially available biologic mesh materials.

The researchers screened 274 articles, and found three studies that compared biologics with synthetics. In total, outcomes were described for 1,033 patients. Studies varied widely in follow-up time, operative technique, meshes used, and patient selection criteria. The three comparative studies were not randomized clinical trials. Clinical outcomes, such as infection, were inconsistently reported across the studies. All of the biologic mesh devices were approved by the FDA based on "substantial equivalence" to synthetic devices, rather than in clinical trials, which is standard FDA practice for approval of medical devices. Taking all these factors into account, the study found insufficient evidence to support the use of costlier biologic mesh materials.

Dr. Edward Livingston, Clinical Professor of Surgery at UT Southwestern and senior author of the study, said that new technologies are a key contributor to the rising cost of health care. "Greater application of evidence-based medicine will help control these increasing costs," said Dr. Livingston, who also serves as a deputy editor for JAMA. "The use of biological mesh materials for hernia repair is one of many examples in which significant costs could be avoided by tailoring clinical practice based on careful review of the evidence."

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