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Study finds mixed results for use of mesh for hernia repair

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Among patients undergoing incisional hernia repair, the use of mesh to reinforce the repair was associated with a lower risk of hernia recurrence over 5 years compared with when mesh was not used, although with long-term follow-up, the benefits attributable to mesh were offset in part by mesh-related complications, according to a study published online by *JAMA*. The study is being released to coincide with its presentation at the American College of Surgeons Clinical Congress 2016.

Elective incisional hernia repair is one of the most commonly performed general surgical operations. In the United States alone, there were about 190,000 inpatient abdominal wall hernia repairs performed in 2012. Prosthetic mesh is frequently used to reinforce the repair; it's done in at least half of the abdominal wall hernia repairs performed in the United States. The benefits of mesh for reducing the risk of hernia recurrence or the long-term risks of mesh-related complications are not known.

Dunja Kokotovic, M.B., and Frederik Helgstrand, M.D., D.M.Sc., of Zealand University Hospital, Køge, Denmark, and Thue Bisgaard, M.D., D.M.Sc., of Hvidovre Hospital, Hvidovre, Denmark, conducted a study that included 3,242 patients with elective incisional hernia repairs in Denmark from January 2007 to December 2010. The researchers compared outcomes for hernia repair using mesh performed by either open or laparoscopic techniques vs open repair without use of mesh.

Among the patients (average age, 59 years; 53 percent women), 1,119 underwent open mesh repair (35 percent), 366 had open nonmesh repair

(11 percent), and 1,757 had laparoscopic mesh repair (54 percent). The median follow-up after open mesh repair was 59 months; after nonmesh open repair, 62 months; and after laparoscopic mesh repair, was 61 months. The researchers found that the risk of the need for repair for recurrent hernia following these initial hernia operations was lower for patients with open mesh repair (12 percent; risk difference, -4.8 percent) and for patients with laparoscopic mesh repair (10.6 percent; risk difference, -6.5 percent) compared with nonmesh repair (17.1 percent).

For the entirety of the follow-up duration, there were a progressively increasing number of mesh-related complications (such as bowel obstruction, bowel perforation, bleeding, late abscess) for both open and laparoscopic procedures. At 5 years of follow-up, the cumulative incidence of mesh-related complications was 5.6 percent for patients who underwent open mesh hernia repair and 3.7 percent for patients who underwent laparoscopic mesh repair. The long-term repair-related complication rate for patients with an initial nonmesh repair was 0.8 percent (open nonmesh repair vs open mesh repair: risk difference, 5.3 percent; open nonmesh repair vs laparoscopic mesh repair: risk difference, 3.4 percent).

"Mesh implantation prevented the need for subsequent reoperation in relatively few patients, suggesting that the benefits associated with the use of mesh are partially off¬set by long-term complications associated with its use. This observation, however, should be interpreted with caution because of the risk of selection bias. Larger, more complicated hernias are likely to be repaired with mesh, and small, simple hernias with little likelihood of long-term problems tend to be repaired without mesh," the authors write.

"The present study highlights the need to assess the long-term safety of interventions before making definitive conclusions about their benefits. Demonstration of long-term safety is required for drugs in the United

States but not for some devices, such as hernia meshes, which are not subject to similarly strict documentation. In the United States, most hernia mesh is approved for use by the 510(k) mechanism. This requires only that these materials have similarity to existing products on the market without the need for clinical trials to demonstrate safety or efficacy. Thus, the complete spectrum for the risks and benefits of mesh used to reinforce hernia repair is not known because there are very few clinical trial data reporting hernia outcomes as they pertain to mesh utilization. This highlights the need for more long-term studies of mesh repair using high-quality registries such as the one in Denmark."

"Although the study by Kokotovic and colleagues is one of the most comprehensive long-term studies in hernia surgery, many questions remain about the optimal approach for repairing ventral hernia," writes Kamal M. F. Itani, M.D., of the VA Boston Health Care System, Boston University, West Roxbury, Mass., in an accompanying editorial.

"To provide more rigorous data to better understand optimal approaches to this common clinical problem, surgeons will need to design large multicenter pragmatic trials with long-term follow-up. When commercial entities want to test a product, they should fund an independent research group to conduct the trial to avoid the perception of bias. Because hernia is so common and the evidence base supporting its treatment is so limited, there is a pressing need to design, fund, and conduct these trials."

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