

Endoscopic procedure may result in better outcomes for patients with infected severe pancreatitis

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In a small, preliminary trial, patients with infected necrotizing pancreatitis (severe form of the disease involving devitalized pancreatic tissue) who received a less-invasive procedure, endoscopic transgastric necrosectomy (removal of the pancreatic tissue), had an associated lower risk of major complications and death compared to patients who had surgical necrosectomy, according to a study in the March 14 issue of *JAMA*.

"Acute pancreatitis is a common and potentially lethal disorder. In the United States alone, more than 50,000 patients are admitted with acute pancreatitis each year. One of the most dreaded complications in these patients is infected necrotizing pancreatitis that leads to sepsis and is often followed by multiple organ failure," according to background information in the article. "Most patients with infected necrotizing pancreatitis require necrosectomy. Surgical necrosectomy induces a proinflammatory response and is associated with a high complication rate." Endoscopic transgastric necrosectomy, a new technique, is a form of natural orifice transluminal endoscopic surgery (NOTES) that is performed under conscious sedation without the need for general anesthesia and potentially reduces the proinflammatory response and risk of procedure-related complications such as multiple organ failure. NOTES has not yet been compared with surgery in a randomized clinical trial for any disease.



Olaf J. Bakker, M.D., of University Medical Center Utrecht, the Netherlands, and colleagues conducted a study to compare the proinflammatory response and clinical outcome of endoscopic transgastric and surgical necrosectomy. The randomized controlled clinical trial was conducted in 3 academic hospitals and 1 regional teaching hospital in the Netherlands between August 2008 and March 2010. Patients had signs of infected necrotizing pancreatitis and an indication for intervention and were randomized to endoscopic transgastric or surgical necrosectomy. Endoscopic necrosectomy consisted of transgastric puncture, balloon dilatation, retroperitoneal (a space in abdominal cavity) drainage, and necrosectomy. Surgical necrosectomy consisted of video-assisted retroperitoneal debridement (surgical removal) or, if not feasible, laparotomy (surgical incision into the abdominal wall).

For the study, 22 patients were randomized, 2 of whom did not undergo necrosectomy following percutaneous catheter drainage and could not be analyzed for postprocedural proinflammatory response. The researchers found that following endoscopy, serum interleukin 6 (IL-6) levels (a measure of proinflammatory response) decreased, whereas these levels increased after surgical necrosectomy. "The composite clinical end point of death and major complications [new-onset multiple organ failure, intra-abdominal bleeding, enterocutaneous fistula (a connection between the intestine and the skin), or pancreatic fistula] was also reduced in the patients in the endoscopy group (20 percent vs. 80 percent). New-onset multiple organ failure did not occur after endoscopic transgastric necrosectomy (0 percent vs. 50 percent). Fewer patients in the endoscopic group developed pancreatic fistulas (10 percent vs. 70 percent)."

In total, 5 of 20 patients died (10 percent of patients in the endoscopy group, vs. 40 percent of patients in the surgical necrosectomy group). All deaths were attributable to persistent multiple organ failure.



"The transition from open to laparoscopic surgery over the past 25 years greatly reduced surgical morbidity. Natural orifice transluminal endoscopic surgery has the potential for another quantum leap in improved surgical outcomes," the authors write.

"In this first <u>randomized clinical trial</u> involving patients with infected necrotizing pancreatitis, endoscopic transgastric necrosectomy reduced the proinflammatory response as well as the composite clinical end point, including new-onset multiple organ failure, compared with surgical necrosectomy. However, these early, promising results require confirmation from a larger clinical trial."

In an accompanying editorial, O. Joe Hines, M.D., and Graham W. Donald, M.D., of the David Geffen School of Medicine at UCLA, Los Angeles, comment on the findings of this study.

"Although the difference in IL-6 levels between the NOTES group and the surgical group was statistically significant and scientifically compelling, IL-6 has limited utility as a clinical decision-making tool."

The authors add that the researchers with this study "are appropriately circumspect in describing their findings as preliminary because the results may have been more robust if the trial recruitment period had been longer and more <u>patients</u> had been enrolled."

More information: *JAMA*. 2012;307[10]:1053-1061. *JAMA*. 2012;307[10]:1084-1085.

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