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Meta-analysis supports TIF procedure for GERD

By Amanda Pedersen, Senior Staff Writer

Technology supported by a lot of different clinical studies is a good thing, especially the more robust the data is and the longer the follow-up is, but it also can make it difficult to see the forest from the trees. That's why some researchers prefer to pool all the available studies together and analyze the collective data for a bird's-eye view of the outcomes. One doctor who uses this research technique, called a meta-analysis, presented her findings on the trans-oral incisionless fundoplication (TIF) procedure at Digestive Disease Week (DDW) in San Diego.

"So if one study has 30 patients and another study has 100 patients, in order to summarize what the overall effect is you can use meta-analysis," Lauren Gerson, a gastroenterologist at California Pacific Medical Center in San Francisco told *Medical Device Daily.* "This is a way to take a large amount of data and show it in a quantitative fashion."

The TIF procedure is a treatment option for patients with gastroesophageal reflux disease (GERD) that is performed with the Esophyx device from Endogastric Solutions Inc., of Redmond, Wash. According to the company, more than 60 peer-review papers from more than 50 centers have been published on more than 1,100 TIF patients. The Esophyx device was cleared by the FDA in 2007 and earlier this month the company reported FDA clearance for the Esophyx Z, the third generation of the device.

For the meta-analysis, Gerson and Karim Trad, a clinical professor of surgery with The George Washington University School of Medicine and Health Sciences, used research databases to examine data from three randomized clinical trials and seven cohort studies from the past eight years that examined the TIF procedure and outcomes at least six months after the procedure. In total, 492 patients and 426 TIF procedures were included in the analysis. The results showed the procedure effectively treats the underlying cause of GERD while, in most cases, ending patients' reliance on proton pump inhibitor (PPI) drugs. The pooled prevalence for complete discontinuation of PPI therapy was 70 percent, Gerson said, and the confidence interval of the studies that measured that was about 66 percent to 75 percent.

"What we tried to look at was basically did patients' quality of life get better, did their erosive esophagitis heal and did their PPI usage change significantly," Gerson said.

For most of the patients included in the analysis, the answer to all of these questions was yes. Gerson said there was a significant difference in overall quality of life scores in the randomized controlled trials as well as the cohort studies. The researchers also noted that after the TIF procedure a greater number of patients had a reduction of distal esophagus acid exposure and healing of erosive esophagitis. Going forward, the researchers plan to look at the data at 12-month follow-up for as many patients as possible, she said.

She noted that one question that remains is how long these treatment benefits will last.

While the reduction in PPI reliance is an important benefit of the procedure, Gerson said she is less concerned than other physicians may be about the safety of PPI therapy.

“PPIs now are getting a lot of bad press,” she said. “The latest thing that came out was [a link to] dementia. In the past, PPIs have been blamed for bone density loss and infections.”

Gerson said there is about a two-fold increased risk for certain types of infection but “all the other major risks that have been attributed to PPIs, like heart attacks, are not a major factor when you look at meta-analysis.”

Still, the TIF procedure offers GERD patients many quality of life benefits that are important to consider, given that this is a disease that wakes patients at night, interferes with their diet and can reduce their work productivity.

“People want to feel better and not be bothered by this and be able to consume regular meals and have a normal lifestyle,” Gerson said.

In other DDW news, Cdx Diagnostics, of Suffern, N.Y., reported results from a multi-center, prospective, randomized clinical trial demonstrating that wide area transepithelial sampling with 3-D tissue analysis (WATS3D) sharply increases, by four times, the detection of esophageal dysplasia (pre-cancer). The study compared WATS3D with the Seattle random forceps biopsy protocol used for the endoscopic surveillance of patients with Barrett’s esophagus. According to Cdx, the Seattle protocol leaves “the vast majority of the esophagus untested and is completely random.”

For the study, which was conducted at 14 academic GI centers, 160 high-risk patients undergoing Barrett’s esophagus surveillance received both Seattle protocol random forceps biopsy and WATS3D. WATS3D found 4.1 times more high-grade dysplasia and esophageal adenocarcinoma than the Seattle protocol biopsies, detecting 29 cases while the Seattle random biopsies method detected only seven cases.