

Abdominal Surgical Procedures Without Skin Incisions

The US Food and Drug Administration (FDA) recently cleared for marketing the natural orifice linear cutter (NOLC), which enables surgeons to perform procedures through the gastrointestinal (GI) tract without cutting or puncturing the skin of the abdominal wall.

The NOLC combines a 12 mm-wide surgical stapling device with a flexible shaft. Powered digital controls within the NOLC give surgeons precise command of the stapling instrument at the end of the shaft, acting like a tiny robot to do remotely what they have done previously with sutures and manual staplers.

“The NOLC is a device that will enable surgeons to advance laparoscopic surgery and NOTES [natural orifice transluminal endoscopic surgery] to improve patient outcomes by reducing the pain, recovery time, and risk of wound infection associated with traditional surgical procedures,” stated Ninh Nguyen, MD, Chief of the Division of Gastrointestinal Surgery at the University of California Irvine Medical Center. “The NOLC allows us to maneuver through the GI tract, turn corners, and close internal wounds with precisely-fired staples—all without making an incision in the patient’s abdomen. The NOLC is an essential surgical device for NOTES, as the older devices we use to close internal incisions are too bulky and do not allow access through the body’s natural orifices.”

FDA Approves Self-administered Biologic Treatment for Crohn’s Disease

The FDA recently approved adalimumab (Humira, Abbott) for treating adults with moderate-to-severe active Crohn’s disease who have had an inadequate response to conventional therapy or who have lost response to or are intolerant to infliximab (Remicade, Centocor), the only other approved biologic for treatment of Crohn’s disease.

Approval was based on data from three trials in more than 1,400 adults with moderate-to-severe active Crohn’s disease. In the CLASSIC I trial, out of 299 anti-tumor necrosis factor (TNF)-naive patients, 36% of patients receiving adalimumab (160 mg at Week 0 followed by 80 mg at Week 2) achieved clinical remission at Week 4 compared to 12% treated with placebo ($P<.001$).

During the 4-week open-label induction phase of the CHARM trial, 58% of patients (499) demonstrated a clinical response to adalimumab. Of those who continued on adalimumab 40 mg every other week, 40% were in clinical remission at Week 26 ($P<.001$) and 36% were in

remission at Week 56 ($P<.001$) versus 17% and 12% of patients in the placebo group, respectively.

In the GAIN trial, a 4-week induction trial of 325 patients who lost response to or were intolerant to infliximab, three times as many patients taking adalimumab achieved clinical remission at Week 4 versus placebo (21% vs 7%, $P\leq.001$).

Adverse events reported by more than 5% of patients treated with adalimumab 160 mg or 80 mg during the CLASSIC I and GAIN induction trials with a greater incidence than patients taking placebo included injection site irritation (8% vs 6%), nausea (6% vs 4%), and joint pain (6% vs 3%). During the CHARM maintenance trial, adverse events reported by more than 5% of patients treated with adalimumab 40 mg every other week with a greater incidence than patients taking placebo included nasopharyngitis (9% vs 7%), abdominal pain (7% vs 7%), headache (7% vs 6%), and nausea (7% vs 6%).

However, serious infections, sepsis, tuberculosis, and opportunistic infections, including fatalities, have been reported with the use of TNF-blocking agents, including adalimumab. In addition, more cases of malignancies have been observed among patients receiving TNF blockers, including adalimumab, compared to control patients in clinical trials. There was an approximately 3.5-fold higher rate of lymphoma in combined controlled and uncontrolled open-label portions of adalimumab clinical trials. The potential role of TNF-blocking therapy in the development of malignancies is unknown. TNF-blocking agents, including adalimumab, have also been associated in rare cases with demyelinating disease and severe allergic reactions.

Anti-inflammatory Drugs and Postendoscopy Bleeding

Researchers at the McGill University Health Center (MUHC), Montreal, Canada, compared the use of anti-inflammatory drugs in patients who experienced bleeding postendoscopy with patients who did not experience any bleeding. Out of 126 endoscopy patients, the researchers found that exposure to anti-inflammatories was not significantly associated with postprocedure bleeding. These findings were published in the March issue of *Alimentary Pharmacology and Therapeutics*.

“Approximately 70% of individuals over the age of 65 are taking nonsteroidal anti-inflammatory medications or aspirin regularly. Our findings show that withholding these is not necessary for patients undergoing therapeutic endoscopic procedures,” said Alan Barkun, MD, MUHC Chief of Gastroenterology.