

U.S. Study's First Oral Gallbladder Removal Compares NOTES to Laparoscopy

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As part of the only U.S. prospective multicenter clinical trial to compare natural orifice transluminal endoscopic surgery (NOTES) to laparoscopy, surgeons at the University of California, San Diego School of Medicine have performed the trial's first oral gallbladder removal. This landmark study will evaluate whether or not NOTES is safe and as effective as traditional laparoscopic surgery.



Santiago Horgan, MD,
Chief of Minimally Invasive Surgery

"This groundbreaking study is the first in the world to compare oral and transvaginal NOTES to traditional laparoscopy," said Santiago Horgan, MD, principal investigator of the UCSD study site and chief of minimally invasive surgery at UC San Diego Health System. "Laparoscopy first emerged in the late 1980's. Two decades later, we are evaluating NOTES — a technologically-advanced surgical technique that may one day allow lifesaving surgery with no external incisions."

This study uses the mouth and vagina as routes to the gallbladder. Rather than creating up to five incisions in the abdominal wall, tools are passed down the mouth and through a hole created in the stomach (transgastric) or through the vagina (transvaginal). Under this clinical trial protocol, a laparoscopic port is required. Horgan opted to make two tiny incisions, requiring no stitches, to pass a camera and to inflate the abdomen for optimal safety and visibility. The actual gallbladder removal was performed entirely through the mouth.

"What is unique about this trial is that we will not only evaluate the safety and efficacy of NOTES compared to laparoscopy but will also assess and compare pain levels, cosmetic outcomes, operative costs and logistical outcomes," said Horgan, who has performed more than 70 NOTES surgeries.

Horgan, director of UCSD's Center for the Future of Surgery, said that traditional laparoscopy is a highly effective technique but that there is always room for improvement in reducing post-operative infection, hernia, scarring and pain.

"We hypothesize that NOTES procedures may reduce pain and infection by eliminating abdominal wall incisions altogether," said Horgan. "Post-operatively, many patients experience pain while walking or coughing due to contraction of the abdominal muscles. This discomfort is absent following the natural orifice approach."

On a randomized basis, up to 200 patients will be enrolled in the clinical trial to obtain 70 NOTES cases (35 transgastric and 35 transvaginal) and 70 laparoscopic cases. The UCSD site plans to enroll 20 patients.

Cholecystectomy, or gallbladder removal, is one of the most common surgeries in the United States, performed on approximately 750,000 patients per year.

This trial is sponsored by the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) which represents the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Gastrointestinal Endoscopy (ASGE.)

The surgeon-scientists of UCSD's Center for the Future of Surgery have pioneered both scarless and single-incision surgery. The Center's surgeons were the first in the United States to perform an oral appendix removal. To date, the team has performed more than 70 NOTES cases to remove diseased appendix and gallbladders and obesity surgeries such as the sleeve gastrectomy.

To learn more about this clinical trial, email the Center for the Future of Surgery at misresearch@ucsd.edu

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