

First US surgery to compare NOTES vs. 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.

"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.

Provided by University of California - San Diego

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