

# NOTES Transvaginal Cholecystectomy: Report of the First Case

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Natural Orifice Transluminal Endoscopic Surgery is a new development area with potential advantages for patients. However, technical and ethical challenges involved in perforation and closure of a healthy organ, as seen in transgastric access, and lack of comprehension of physiopathology of these approaches haven't allowed clinical application. The present study, based on previous animal experiments, describes the first clinical application of transvaginal Natural Orifice Transluminal Endoscopic Surgery. On March 13, 2007, a 43-year-old female patient with symptomatic cholelithiasis with surgical indication was submitted to elective Natural Orifice Transluminal Endoscopic Surgery transvaginal cholecystectomy using a colonoscope, endoscopic graspers, and vaginal platform instruments. Operative time was

66 minutes, and vaginal access and closure were obtained in 15 minutes. The patient had good postoperative evolution and was dismissed within 48 hours without complications. Recent literature and experience of the present study group suggest possibilities for preliminary clinical applications by transvaginal natural orifice surgery. The access may offer earlier benefits in the literature than the transgastric route because of lack of danger of fistula and peritonitis. Further studies regarding instrument development and physiology of natural orifice surgery are ongoing, possibly bringing solutions for more advanced procedures.

**Keywords:** natural orifice surgery; NOTES; laparoscopy; cholecystectomy; endoscopic surgery; endoscopy

## Introduction

Natural Orifice Transluminal Endoscopic Surgery (NOTES) is a new field of experimental research, potentially changing standard paradigms of surgery for diagnostic and therapeutic procedures. The promised benefits in creating even less invasive access can avoid incision-related complications and may be the logical progression of minimally invasive surgery.

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In their recent papers on endoscopic transgastric surgery, Kalloo et al<sup>1</sup> and Kantsevov et al<sup>2</sup> showed the possibilities of going beyond the gastric wall and working with a perorally introduced, flexible endoscope via a sterile overtube in the abdominal cavity. Paul Swain, a pioneer in endoscopic suturing, is also heading the search of new procedures, describing transgastric cholecystectomy, jejunostomy, and gastroenterostomy.<sup>3,4</sup> Even NOTES splenectomy was also described in an animal model.<sup>5</sup> The recognition of the limitations of technology for the access specially for a safe closure of the gastric wall have led to alternative technology developments to solve the danger of postoperative leakage and peritonitis.<sup>6</sup>

A small group of leading specialists founded the American Society of Gastrointestinal Endoscopy and the Society of American Gastrointestinal and Endoscopic Surgeons (ASGE/SAGES) Working Group on NOTES, defined standards for the experimental interdisciplinary development of instruments and coordinated interdisciplinary research,<sup>7</sup>

and is committed to safely developing and introducing a technology that may benefit patients. Following the directives, a safe process of gaining experience with transgastric access allied to safe closure by new devices should be the natural way to slowly apply NOTES to clinical use. Instead of other NOTES proposed accesses, however, natural orifice transvaginal surgery may be a less potentially dangerous alternative for diagnostic and therapeutic purposes.

Most abdominal NOTES proposed accesses have the potential for developing septic complications after the bowel incision, and a safe closure device will be critical for the evolution and clinical application of new methods. Results of new gastric suture devices in survival studies are still to be presented before clinical trials.<sup>3</sup> However, transvaginal NOTES could provide an easy-access, direct-vision closure, with available instruments, through a well-known access with reasonable disinfection possibility. The present study describes the initial clinical application of transvaginal NOTES — the first case of the literature — in a patient with indication for cholecystectomy using a transvaginal colonoscope and instruments for the abdominal procedure.

## Case Report

This study was approved by the institutional review board for NOTES transvaginal clinical trials, and all methods were in accordance with the Helsinki Declaration, revision 1989. Study protocol criteria of inclusion were patients with low American Society of Anesthesiologists (ASA) risk, who could choose the transvaginal procedure instead of laparoscopy. Inclusion criteria for cholecystectomy were based on mild preoperative symptoms and a short duration of disease (2 years or less). The research group consisted of a multidisciplinary team of surgeons, gastroenterologists, endoscopists, gynecologists, and veterinary surgeons. A veterinary hospital facility was available, and NOTES technical possibilities were tested for the study group. Animal research in swine was carried out during the previous 14 months, solving problems of spatial orientation, insufflation, and instrument development. On March 13, 2007, a female patient with elective surgical indication for cholecystectomy was submitted to transvaginal NOTES procedure,<sup>8,9</sup> and intraoperative and postoperative parameters were documented. Informed consent was obtained after explanation of the method and disadvantages and complication possibilities. The patient chose the

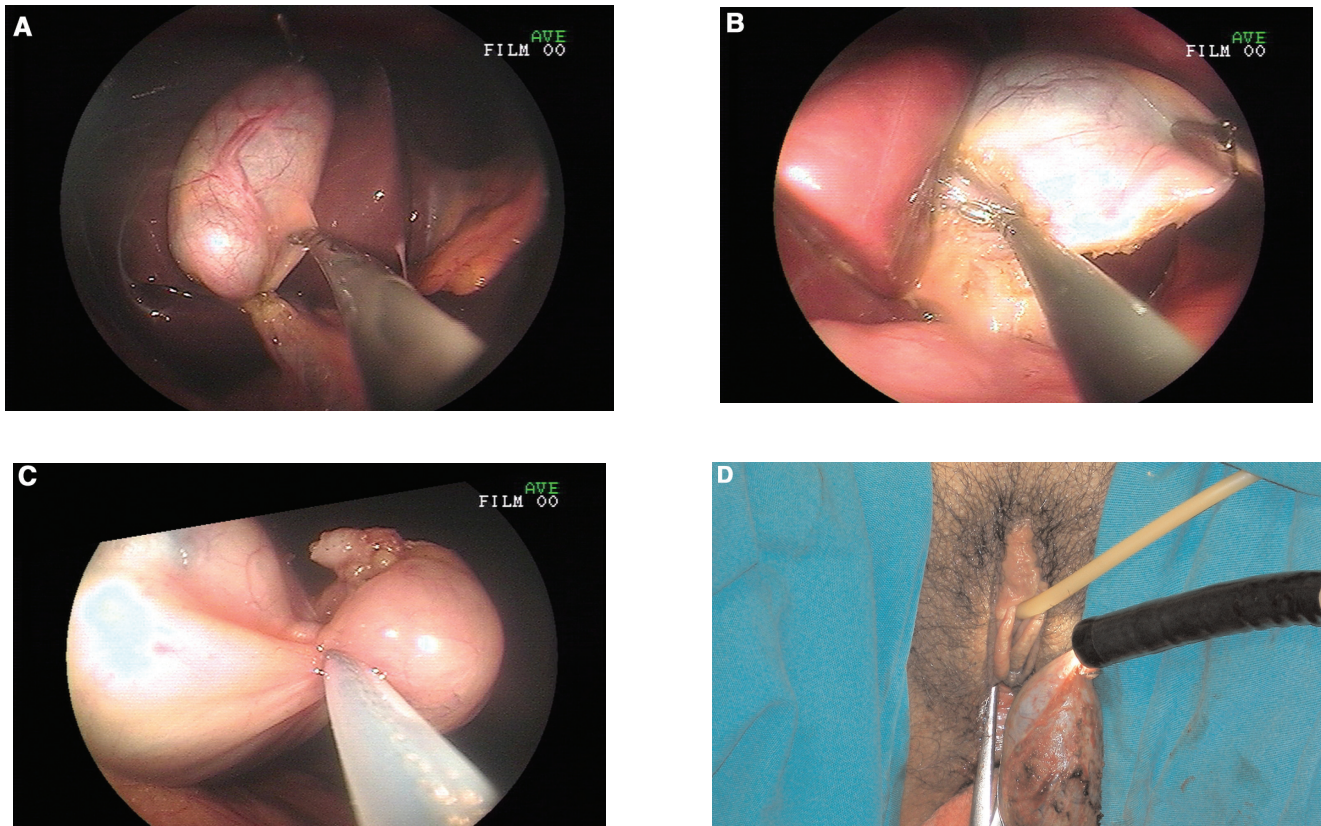
method instead of laparoscopy and was submitted to general anesthesia. The interventional team was composed of a general surgeon, a gastroenterologist, and a gynecologist.

A 43-year-old female patient with symptomatic, uncomplicated cholelithiasis with elective indication of cholecystectomy (cholelithiasis, 1 stone of 8 mm diameter) was informed of the possible advantages and complications of the new, still-experimental method, and the possibility of conversion to laparoscopic or conventional surgery. The patient signed informed consent, choosing the method instead of laparoscopy. Two other patients were also informed but preferred, and were submitted to, standard laparoscopic cholecystectomy. The first patient was operated on using transvaginal NOTES cholecystectomy at the Department of Surgery, University Hospital Teresopolis HCTCO-FESO.

## Surgical Technique

The patient was submitted to general anesthesia and installed in a Lloyd-Davies position. Disinfection of the vagina was achieved by topic iodopovidone, and a urinary catheter was installed. A single dose of intravenous bolus of 2 g cefalexin was given at the induction of anesthesia. Incision of the vaginal posterior sac was done after traction of the cervix with a conventional Posit instrument. The operator was positioned between the legs of the patient, with the first assistant behind and holding the controls of the colonoscope. A second assistant took position on the left side of the patient to retract the gallbladder. An original overtube platform was inserted through the posterior wound created and inserted into the abdominal cavity. A 2-channel videocolonoscope FUJINON EC 410-D (FUJINON, Japan) was inserted, and insufflation of the cavity with CO<sub>2</sub> was started through the colonoscope, using a laparoflator to control the pressure (Richard Wolf GmbH, Germany). After insufflation (5-6 mm/Hg), orientation of the colonoscope in the cavity was possible by initial localization of the abdominal wall, and following until the right upper quadrant by transillumination of the abdomen.

A single 3 mm laparoscopic trocar (Richard Wolf GmbH, Germany) was then inserted on the right upper quadrant under direct endoscopic vision, 2 cm from the median line, and a grasp forceps was used to retract the gallbladder. Endoscopic graspers, hot-biopsy forceps, snares, and original transvaginal



**Figure 1.** NOTES transvaginal cholecystectomy. (A) initial dissection using hot-biopsy forceps; (B) isolation of the cystic duct using transvaginal and endoscopic graspers after monopolar cauterization of the cystic artery; (C) retrieval of the gallbladder using a polypectomy snare; (D) extraction of the specimen through the vagina.

flexible instruments were inserted through the colonoscope and the overtube platform and initiated dissection of the Calot triangle (Figures 1A and B). Dissection of the cystic duct and artery were performed using hot-biopsy forceps, and the artery was coagulated with monopolar energy. Ligation of the cystic duct was achieved by 2 proximal endoclips using an original clipator and by changing the vaginal grasp to hold the gallbladder and ligating the distal duct with an external polipropylene 2.0 endoloop. After the artery and duct were cut by scissors, the gallbladder was dissected from the liver bed using a polypectomy snare. The gallbladder was retrieved transvaginally using the polypectomy snare to hold it intact, without any protection bag (Figures 1C and D).

Insufflation and spacial orientation were satisfactory, and surgery was possible even with low abdominal pressures of CO<sub>2</sub>. Insufflation was possible using the laparoflator or the colonoscope channel. Visualization of the whole cavity was of very good quality and permitted regular cleaning with sterile water instead of retrieving the scope from the

cavity. The patient recovered well without postoperative complications. Operative time was 66 minutes, and vaginal access and closure were obtained in 15 minutes. The patient had oral intake 2 hours after the procedure, and was dismissed after 48 hours. The patient did not require postoperative analgesia, nor oral or parenteral. At a 30-day follow-up, the patient was asymptomatic.

## Discussion

Laparoscopy has become the standard method for cholecystectomy and many other surgical indications. The concept of minimally invasive surgery is evolving recently to the goal of no-incision surgery, potentially obtainable by natural orifice surgery. As an emerging possibility, NOTES is still an experimental access, surrounded by discussion of the potential applications and the safety of the methods. Recent presentations at scientific meetings also described the first clinical human applications of the new method, after institutional review board (IRB) approval for



human trials on NOTES in different countries.<sup>10</sup> Despite efforts of researchers in experimental studies around the world, there was yet no clinical application of NOTES reported in the literature.

The beginning of the NOTES concept evolved with endoscopic invasive procedures in recent years. In 2000, transgastric endoscopic debridement of a necrotic pancreas was reported in 3 critical patients using a Dormia basket, without closing of the gastric wall, with good initial results.<sup>11</sup> Kalloo<sup>1</sup> and Kantsevoy<sup>2</sup> used a peroral transgastric route in a porcine model for diagnostic peritoneoscopy, liver biopsy, gastrojejunostomy, and for tubal ligation. Survival studies are of most importance to evaluate future potential clinical applications. Park et al<sup>4</sup> reported a survival study with pigs submitted to endoscopic full-thickness incision of the gastric wall and suture that were followed for a median of 22 days (range, 14-28 days) without complications. However, the gastric wound closure still represents a possible issue of complications, and indeed variable taxes of microabscesses, peritonitis, fistulae, and death are expected in the animal model.

Transvaginal NOTES may represent the most safe and applicable way for natural orifice routes, relatively independent of great development of technology, with a potential benefit of a controllable access and easy closure. In 1949, Bueno described the first case of successful performance of incidental vaginal appendectomy at the time of vaginal hysterectomy,<sup>12</sup> and at the present time, many operations were described for transvaginal open surgery, including a larger series of appendectomy.<sup>13</sup> Transvaginal extraction of the gallbladder, colon, spleen, and kidney were also previously described for laparoscopic operations.<sup>14-17</sup> Using a hybrid procedure, Tsin et al<sup>18</sup> described vaginal cholecystectomy and other operations after simultaneous hysterectomy with a vaginal trocar and formal laparoscopic instruments through the anterior abdominal wall, denominating the technique as "culdolaparoscopy." These studies using vaginal (contaminated) access to perform abdominal (sterile) operations showed small taxes of infectious complications. The available transvaginal access can avoid the potential risks of other NOTES approaches (transgastric, transcolonic, transurethral) of major contamination, fistulae, and peritonitis.

Insufflation problems are also a matter of concern in NOTES procedures in animal research. In a recent experimental study, effective intra-abdominal pressure monitoring could be assessed by the integration of pressure-monitoring capabilities

of laparoscopic insufflators into gastroscopes, avoiding the potentially deleterious effects of pneumoperitoneum during NOTES.<sup>19</sup> In this preliminary clinical experience, the procedure was possible also with low pressures (5-6 mm/HG) of capnoperitoneum. Infectious complications are in some degree expected using the access, and prophylaxis with antibiotics was indicated for cholecystectomy, similar to gynecologic vaginal surgery such as hysterectomy and transvaginal tube ligation.

The preliminary clinical application of transvaginal NOTES described for cholecystectomy is so far the first human application of NOTES in the literature. The access was easily created, and intra-abdominal inventory was performed without technical or orientation difficulty. Early problems with orientation, insufflation, and illumination were solved in the animal experimental phase. Closure of the vaginal wound is not a problematic issue of the approach, as it could be for other access propositions, such as transgastric, transrectal and transurethral approaches.<sup>20-23</sup> Unlike those other routes, transvaginal NOTES probably also has less potential for complications of fistula and peritonitis. The 30-day evolution of the patient was uneventful, and analgesia requirements can be a potential benefit for patients, reducing somatic parietal pain.

The future of clinical applications of transvaginal NOTES and its role in treating patients facing the standard techniques is still a topic of discussion. Development of proper instruments and platforms are needed for more advanced transvaginal procedures, and clinical trials should be performed only with previous valid animal survival experiments on each field. The specialist who will be performing NOTES in the future may have interdisciplinary training, creating a professional able to act at both sides of the intestinal wall.

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## References

1. Kalloo AN, Singh VK, Jagannath BS, et al. Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. *Gastrointest Endosc*. 2004;60:287-292.

2. Kantsevoy SV, Jagannath BS, Niiyama H, et al. Endoscopic gastrojejunostomy with survival in a porcine model. *Gastrointest Endosc.* 2005;62:287-292.
3. Sclabas GM, Swain P, Swanstrom LL. Endoluminal methods for gastrotomy closure in natural orifice transenteric surgery (NOTES). *Surg Innov.* 2006;13:23-30.
4. Park PO, Bergström M, Ikeda K, Fritscher-Ravens A, Swain P. Experimental studies of transgastric gallbladder surgery: cholecystectomy and cholecystogastric anastomosis. *Gastrointest Endosc.* 2006;61:601-606.
5. Kantsevoy SV, Hu B, Jagannath BS, et al. Transgastric endoscopic splenectomy. Is it possible? *Surg Endosc.* 2006;20:522-525.
6. Swanstrom L, Kozarek R, Pasricha PF, et al. Development of a new access device for transgastric surgery. *J Gastrointest Surg.* 2005;9:1129-1137.
7. Rattner D, Kalloo A. ASGE/SAGES Working Group on Natural Orifice Transluminal Endoscopic Surgery. *Surg Endosc.* 2006;20:329-333.
8. Brasil inova e retira vesícula de paciente pela vagina. Estado de São Paulo, 23rd March 2007. Available at: <http://www.estadao.com.br/ciencia/noticias/2007/mar/23/4.htm>. Accessed March 27, 2007.
9. Equipo medico brasileño retira la vesícula de un paciente pela vagina. *Madrid Reporter Digital*. Available at: <http://reporterodigital.com/madrid/ciencia/object.php?o=605699>. Accessed March 23, 2007.
10. NOSCART. 2nd International Conference on NOTES. Boston, Massachusetts, July 13-14, 2007.
11. Seifert H, Wehrmann T, Schmit T, Zeuzem S, Caspary WF. Retroperitoneal endoscopic debridement for infected peripancreatic necrosis. *Lancet.* 2000;355:653-655.
12. Bueno B. Primer caso de apendicectomía por vía vaginal. *Tokoginec Pract (Madrid)*. 1949;8:152-154.
13. Reiner IJ. Incidental appendectomy at the time of vaginal surgery. *Texas Méd.* 1980;1:46-50.
14. Delvaux G, Devroey P, De Waele B, Willems G. Transvaginal removal of gallbladders with large stones after laparoscopic cholecystectomy. *Surg Laparosc Endosc.* 1993;3:307-309.
15. Zornig C, Emmerman A, von Waldenfels HA, Felixmuller C. Colpotomy for specimen removal in laparoscopic surgery. *Chirurg.* 1994;65:883-885.
16. Gill IS, Cherullo EE, Meraney AM, Borsuk F, Murphy DP, Falcone T. Vaginal extraction of the intact specimen following laparoscopic nephrectomy. *J Urol.* 2002;167:238-241.
17. Abrao MS, Sagae UE, Gonzales M, Podgaec S, Dias JA Jr. Treatment of rectosigmoid endometriosis by laparoscopically assisted vaginal rectosigmoidectomy. *Int J Gynaecol Obstet.* 2005;91:27-31.
18. Tsin DA, Sequeria RJ, Giannikas G. Culdolaparoscopic cholecystectomy during vaginal hysterectomy. *JSLs.* 2003;7:171-172.
19. McGee MF, Rosen MJ, Marks J, et al. A reliable method for monitoring intra-abdominal pressure during natural orifice transluminal endoscopic surgery. *Surg Endosc.* 2007;21:672-676.
20. Hochberger J, Lamadé W. Transgastric surgery of the abdomen: the dawn of a new era? *Gastrointest Endosc.* 2005;62:293-295.
21. Lamadé W, Hochberger J. Transgastric surgery: avoiding pitfalls in the development of a new technique. *Gastrointest Endosc.* 2006;63:698-700.
22. Malik A, Mellinger JD, Hazey JW, Dunkin BJ, MacFadyen BV Jr. Endoluminal and transluminal surgery: current status and future possibilities. *Surg Endosc.* 2006; 20:1179-1192.
23. McGee MF, Rosen MJ, Marks J, et al. A primer on Natural Orifice Transluminal Endoscopic Surgery: building a new paradigm. *Surg Innov.* 2006;13:86-93.