

NOTES transvaginal hybrid cholecystectomy: the United States human experience

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Abstract

Background “Pure” NOTES and “hybrid” NOTES procedures have gained popularity during the past few years. However, most of these published series have been documented outside the United States.

Methods This is a prospective, nonrandomized series of patients. Female subjects who presented to the University of California at San Diego surgery clinic for elective cholecystectomy were offered participation in this study. Patients met the following criteria: aged 18–75 years; diagnosis of gallbladder disease that required cholecystectomy and American Society of Anesthesiology (ASA) class 1. Hybrid NOTES transvaginal technique was used for cholecystectomy.

Results A total of 27 women underwent hybrid transvaginal NOTES cholecystectomy during a 43-month period. The median age was 40.1 (range 23–63) years. The mean body mass index was 25.2 (range 16.4–34.1). All patients had an ASA I–II classification. The mean operative time was 92 (range 38–165) min. There was no conversion

to an open operation. The mean hospital stay was 1.07 (range 1–2) days. Patients were followed for a mean of 3.32 (range 0.06–12.2) months. There were no postoperative complications. No scars were visible on the abdominal wall.

Conclusions This study is the largest series of hybrid transvaginal cholecystectomy published in the United States. With our experience, we demonstrate that this technique is safe and clinically viable.

Keywords NOTES · Hybrid cholecystectomy · Transvaginal

Natural orifice transluminal endoscopic surgery (NOTES) has been established as a potential alternative to classic approaches to the abdominal cavity, such as laparoscopy and laparotomy, as a part of the rapid development of minimally invasive surgical techniques. The NOTES concept was introduced by the American gastroenterologist, Kalloo et al. [1]. Using a porcine model, their group demonstrated the feasibility of “pure” (defined as a procedure performed with only translumenally placed instrumentation and no laparoscopic or needleoscopic assistance) transgastric NOTES procedures [2]. This was followed by Rao et al. [3] who demonstrated the first human NOTES procedure in India. The first “hybrid” (defined as a procedure that involves any transabdominal needles or laparoscopic instruments) transvaginal cholecystectomy was performed by Bessler et al. [4] and the first “pure” transvaginal cholecystectomy followed in France in August 2007 by Marescaux et al. [5]. The initial clinical experience with NOTES in the United States was published by Horgan et al. [6]. Pure NOTES and hybrid NOTES procedures have since been gaining popularity. However, most

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of these published series have been documented outside the United States [7–12].

In this paper, we present our institutional experience with transvaginal hybrid NOTES cholecystectomy. This is the largest U.S. hybrid cholecystectomy experience. The purpose of this study was to report the safety and efficacy of this novel technique.

Methods

This prospective, nonrandomized series of patients was operated on between September 2007 and April 2011. This study was approved by the institutional review board. Female subjects, aged 18–75 years, who presented to the University of California at San Diego (UCSD) surgery clinic for elective cholecystectomy were offered participation in this study. Patients met the following criteria: aged 18–75 years, and diagnosis of gallbladder disease that required cholecystectomy and American Society of Anesthesiology (ASA) class 1–2.

They were excluded if any of the following conditions existed: (a) pregnancy, (b) morbid obesity (BMI > 35), (c) presence of severe medical comorbidities (ASA > 2), (d) gallbladder polyps, masses, or tumor, (e) history of prior open abdominal or transvaginal surgery, (f) prior history of peritoneal or vaginal trauma, (g) history of ectopic pregnancy, pelvic inflammatory disease, or severe endometriosis, (h) known common bile duct stones, (i) patients on anticoagulants, antiplatelet drugs, or with abnormal blood coagulation tests, and (j) immunocompromised patients.

Informed consent was obtained by a physician in the presence of a witness, and an authorization for Use of Protected Health Information (PHI) for Research Purposes was signed to comply with HIPAA. Eligibility was determined at the time of screening. Patients were asked to read the Informed Consent and the Patient Bill of Rights; a copy of the each was given to the patient and a copy was placed in the medical record.

The surgeons have had extensive experience with flexible endoscopy and are fellowship-trained in minimally invasive surgery. All procedures were first performed in an animal laboratory at the UCSD using a pig model. Translation to the human setting was only performed after all potential problems were appropriately addressed and the procedure perfected in the animal model.

Technique of hybrid transvaginal cholecystectomy

Preoperative antibiotics per Surgical Care Improvement Project (SCIP) guidelines are administered 30 min before

incision. The abdomen is prepped in the standard fashion for a laparoscopic cholecystectomy using chlorhexidine solution. The perineal region is prepped using Betadine solution. Both areas are draped in a standard sterile fashion.

The first incision is placed in the umbilicus with a scalpel to permit the entry of a 5-mm port under direct vision. Pneumoperitoneum is created to 15 mmHg. A 30° laparoscope is inserted to visualize the abdominal cavity and assess the gallbladder. If there is any evidence of dense inflammatory response in the pelvis or right upper quadrant, or any intra-abdominal pathology that can potentially compromise the safety of the operation, standard laparoscopic technique is used and the NOTES technique is aborted.

Next, the uterus is elevated by using a uterine manipulator. A 12-mm port is inserted bluntly through the posterior vaginal wall. The laparoscopic view is then changed to an endoscopic view. A 2-mm grasping instrument is inserted through the right upper quadrant in the mid-clavicular line in the subcostal region. An Endograb device (Virtual Ports, Inc., Richmond, VA) is inserted through the umbilicus into the peritoneal cavity. This is positioned to grasp the fundus and secure it to the anterior abdominal wall to expose the triangle of Calot. The 2-mm grasping instrument is used to grasp the infundibulum, and a dissecting instrument through the umbilicus is used to expose the cystic artery and cystic duct. The cystic artery and then the duct are triply clipped and divided. The gallbladder is taken off the hepatic bed using electrocautery. Complete hemostasis is ensured. A 30° laparoscope is again inserted through the umbilicus and the endoscope in the vagina is exchanged for an Endocatch retrieval bag (Ethicon Endosurgery, Cincinnati, OH). The gallbladder is placed in the bag and removed from the vagina. Irrigation is performed until the return is clear. Laparoscopic instruments are removed, and the abdomen is desufflated. The vaginotomy is closed under direct vision using absorbable suture.

Postoperative care and follow-up

Standard guidelines for postoperative care were adhered to in the NOTES cohort. Patients were followed for pain and any temperature changes for 7 days postoperatively. Patients were given a log book to record these events. Pain following the surgery was assessed by using a pain score scale from 1 to 10, where 0 was defined as no pain at all, and 10 was defined as the worst pain. Telephone follow-up was done by the research nurse after discharge. Patients were followed at 1 week in the clinic as standard protocol. They also were followed up at 6 months and 1 year by telephone calls to assess their status.

Results

A total of 33 women with diagnosis of gallbladder disease were enrolled in the study. Six patients were excluded from the study at the time of placement of the laparoscope. These were converted to traditional laparoscopy due to dense adhesions in the gallbladder fossa. Twenty-seven patients underwent hybrid transvaginal NOTES cholecystectomy during 43-month period, from September 2007 to April 2011. The indications were cholelithiasis without acute cholecystitis. The median age was 40.1 (range 23–63) years. The mean body mass index (BMI) was 25.2 (range 16.4–34.1). All patients had an ASA I–II classification.

The mean operative time was 92 (range 38–165) min. Initial operations were associated with longer times due to the learning curve. The NOTES hybrid technique was successfully completed in all the patients enrolled without conversion to conventional laparoscopy or open surgery. There were no intraoperative complications.

None of the patients required admission to an intensive care unit (Table 1). Of the 27 patients evaluated in this study, 25 (92 %) were discharged on postoperative day 1. This is the standard of care at the UCSD. Two patients (8 %) were discharged on postoperative day 2; both patients complained of incisional pain and preferred to stay in the hospital until resolution. The mean hospital stay was 1.07 (range 1–2) days.

Pain was at a mean of 4.57 on day 1, and this decreased to a mean of 1.21 by day 7 (Table 2). This pain was very well controlled by standard oral narcotic pain medications. The etiology of the postoperative abdominal pain included moderate pain at the 5-mm abdominal incision, right upper quadrant tenderness, and dull pain from partially evacuated pneumoperitoneum.

Patients were followed for a mean of 3.32 (range 0.06–12.2) months. There were no postoperative complications, including but not limited to, bile duct injuries,

Table 1 Patient characteristics

N	27
Age (years)*	40.1 (23–63)
BMI*	25.2 (16.4–34.1)
ASA (%)	I–II (100)
Gallbladder disease (%)	27 (100)
Operation time (min)*	91.9 (38–165)
Hospital stay (days)*	1.07 (1–2)
Complications (intra and post)	0
Reoperations	0
Deaths	0

* Data are means with ranges in parentheses

Table 2 Patient pain log

Postoperative day	Pain measure
1	4.57 (4–8)
2	4 (4–7)
3	3.48 (3–7)
4	2.6 (2–6)
5	1.81 (2–5)
6	1.56 (1–5)
7	1.21 (1–4)

Data are means with ranges in parentheses

intra-abdominal abscesses, surgical wound infections, or dyspareunia. The overall morbidity and mortality rate were zero. No scars were visible on the abdominal wall.

Discussion

This study is the largest series of hybrid transvaginal cholecystectomy published in the United States. With our experience, we demonstrated that this technique is safe and clinically viable.

Transvaginal approach is usually approached with trepidation by general and laparoscopic surgeons. There are doubts of possible association with dyspareunia and female sexual dysfunction. We would like to emphasize that transvaginal hysterectomy and oophorectomy have been the standard approach in gynecology for several years. The transvaginal approach is singularly used for treatment of fertility and for assessment of pelvic pain [13, 14].

There are mixed opinions on the viewpoint of women toward the transvaginal approach [6, 15, 16]. This may be because physicians are unable to provide a scientific answer to the postoperative effect on fertility and sexuality [16]. We have a prospective, randomized study in place to answer this question definitively. However, in our experience and our extensive patient follow-up, we have not had any reports of dyspareunia or infertility following this procedure. In fact, three of our patients in the reproductive age became pregnant. This also has been seen by Hensel et al. [10].

Although the risk of incisional hernia is low after laparoscopic surgery, it is not insignificant [17–20]. Jones et al. [21] published a case report that demonstrated gangrenous small bowel in a trocar site hernia at a 12-mm site. Trocar site herniation at 5-mm sites have been demonstrated [22]. Necrotizing fasciitis at the trocar sites also has been demonstrated [23]. NOTES operative procedures are a more attractive option.

Furthermore, the NOTES approach may be associated with potential advantages, including low rate of complications,

such as adhesions, wound infection, and postoperative pain associated with abdominal incisions. There also is a potential advantage of better cosmesis and improved recovery and hospital stay periods [8, 24, 25].

This technique potentially may be extended to males as the transrectal approach, which has been demonstrated for nephrectomy in a porcine model [26] and for appendectomy in a cadaveric model [27], among others. Transgastric approaches also have been utilized for appendectomy and cholecystectomy [6, 28], which may be used in men. Novel methods to close the gastric defect are being studied [29–31].

We anticipate that this technique can be converted to a pure NOTES technique in the future with the advent of longer and flexible instruments and multiple channel ports. At UCSD, we believe that this is the first step to a pure natural orifice safe cholecystectomy.

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