

Transvaginal Hybrid NOTES Cholecystectomy: Current Techniques and Advantages

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Abstract Laparoscopic cholecystectomy has proven to be a safe and effective procedure, with low rates of complications and mortality since its introduction in the late 1980s. However, surgeons have been working to develop alternatives to this technique to improve clinical outcomes and the level of patient satisfaction. Natural orifice transluminal endoscopic surgery (NOTES) is one such alternative. NOTES has potential benefits compared to conventional laparoscopic and open surgery, including reduced abdominal wall trauma and trocar site complications, lower infection rates, less postoperative pain, decreased hospital stays, and excellent cosmetic results. Transvaginal hybrid NOTES cholecystectomy is the most common NOTES procedure performed. The objective of this article is to review this surgical technique and its clinical outcomes based on the current scientific evidence available in the literature.

Keywords NOTES · Natural orifice · Cholecystectomy · Transvaginal · Hybrid

Introduction

Since its introduction in the late 1980s, laparoscopic cholecystectomy (LC) has been a common surgical procedure worldwide that is relatively straightforward and safe with low rates of complications and mortality [1]. This approach has been widely accepted and adopted by surgeons during

the last decades [2, 3•, 4, 5]. However, with the evolution of minimally invasive surgery (MIS) techniques, surgeons have been working to develop alternatives to this technique to improve clinical outcomes and the level of satisfaction postoperatively [6, 7•, 8, 9, 10•, 11].

One viable option currently being explored is natural orifice transluminal endoscopic surgery (NOTES) [12•, 13–17]. This concept was initially designed to access the abdominal cavity through different natural orifices such as the mouth, vagina, anus, and urethra [9, 18, 19]. In addition, several studies have shown applications in intrathoracic procedures including mediastinoscopy, thoracoscopy, and lymph node dissection [14, 19, 20].

NOTES has potential benefits compared to conventional laparoscopic and open surgery, including reduced abdominal wall trauma and trocar site complications, low infection rates, less postoperative pain, decreased hospital stays, and excellent cosmetic results [3•, 9, 11, 13, 21]. Furthermore, NOTES procedures can be performed using a transabdominal needle or laparoscopic instruments (i.e. “Hybrid NOTES”) or not using any extra instrument (i.e. “Pure NOTES”) [7, 22•, 23–25].

Transvaginal hybrid NOTES cholecystectomy (THNC) is the most common NOTES procedure performed [2, 10•, 23, 24, 26]. In 1993, the first successful THNC was described by Delvaux et al. [27], followed by Marescaux et al. [28], who reported the first successful transvaginal pure NOTES cholecystectomy (TPNC) in humans in 2007.

Despite the increased number of clinical studies confirming the advantages and benefits of THNC [4, 8, 12•, 21, 22•, 29], it is still considered an investigational surgical approach in many aspects, and surgeons still have concerns regarding the safety of this procedure in terms of sexual function and future fertility [30–33, 34•, 35]. The objective of this article is to review this surgical technique and its

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clinical outcomes based on the current scientific evidence available in the literature.

Patient Selection (Preoperative Evaluation)

Several groups have attempted to standardize patient selection criteria for THNC in order to achieve safe and effective clinical outcomes [4, 14, 18, 36, 37]. However, there is not an official consensus defining these criteria. In our institution, candidates for THNC are treated in the same fashion as candidates for standard laparoscopic cholecystectomy. We adhere to the SAGES/NOSCAR standards in preoperative evaluation, and all patients undergo rigorous workup prior to undergoing THNC [38••].

In short, patients are evaluated at the clinic by the attending surgeon. Patients have a complete physical exam and medical history evaluation. Routine radiological evaluation including abdominal ultrasound and computed tomography scan (CT scan) are performed. A pelvic exam is also performed to rule out any anatomic contraindications to the procedure. Laboratory studies are performed as indicated and a human chorionic gonadotropin urine assay must be negative prior to surgery.

Patients with any of the following existing conditions may be excluded for this approach: (1) pregnancy, (2) morbid obesity (BMI \geq 35 kg/m [2]), (3) presence of severe medical comorbidities (ASA of 2 or below), (4) gallbladder masses, or tumor, (5) history of prior open abdominal or transvaginal surgery, (6) prior history of peritoneal or vaginal trauma, (7) history of ectopic pregnancy, pelvic inflammatory disease, or severe endometriosis, (8) known common bile duct stones, (9) patients on anticoagulants, antiplatelet drugs, or with abnormal blood coagulation tests, and (10) immunocompromised patients.

Surgical Technique

After all inclusion and exclusion criteria are met, the candidate is brought to the operating room. Each patient receives appropriate pharmacologic deep venous thrombosis prophylaxis and prophylactic antibiotics. As in all operations, preparation of the operating room and patient positioning are critical. 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, and a Foley catheter is placed [29].

The first incision is placed in the umbilicus with a scalpel to permit the entry of a 5-mm port under laparoscopic visualization. Pneumoperitoneum is created to 15 mmHg. A 30-degree 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 could potentially compromise the safety of the operation, standard laparoscopic technique is used and the NOTES technique is aborted [39].

Next, the uterus is elevated by using a uterine manipulator (Fig. 1). A 12-mm port is inserted bluntly through the posterior vaginal wall (Fig. 2). The laparoscopic view is then changed to an endoscopic view. If necessary, an Endograb device (Virtual Ports, Richmond, VA, USA) is inserted through the umbilicus into the peritoneal cavity and positioned to grasp the fundus and secure it to the anterior abdominal wall to expose the target anatomy (Fig. 3). There is liberal use of the umbilical access port in dissection of the gallbladder, as well as to expose the cystic artery and cystic duct (Fig. 4). After obtaining a definitive critical view, and confirming this view with a standard 30-degree laparoscope placed through the umbilicus, the cystic artery and then the duct are triply clipped and divided. The gallbladder is taken off the hepatic bed using electrocautery or ultrasonic dissection. Complete hemostasis is ensured. A 30-degree laparoscope is again inserted through the umbilicus and the endoscope in the vagina is exchanged for a retrieval bag [22•].

The gallbladder is placed in the bag and removed from the vagina (Fig. 5). Laparoscopic instruments are removed, and the abdomen is desufflated. Before closing the vaginotomy, the umbilical port is infiltrated using 0.5 % bupivacaine. Finally, the vaginotomy is closed under direct vision using absorbable suture.

Postoperative Care and Follow up

Post-operatively, patients are treated under the same standard of care as a laparoscopic cholecystectomy.

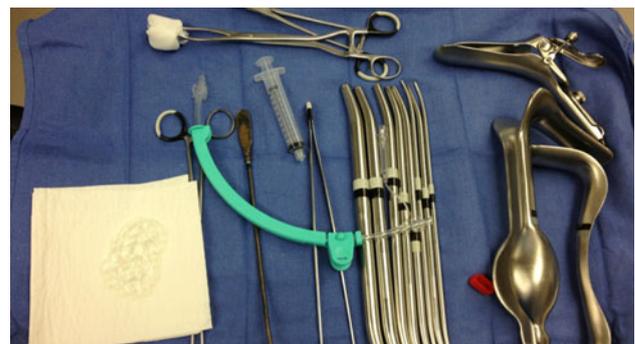


Fig. 1 Transvaginal trocar placement instruments set

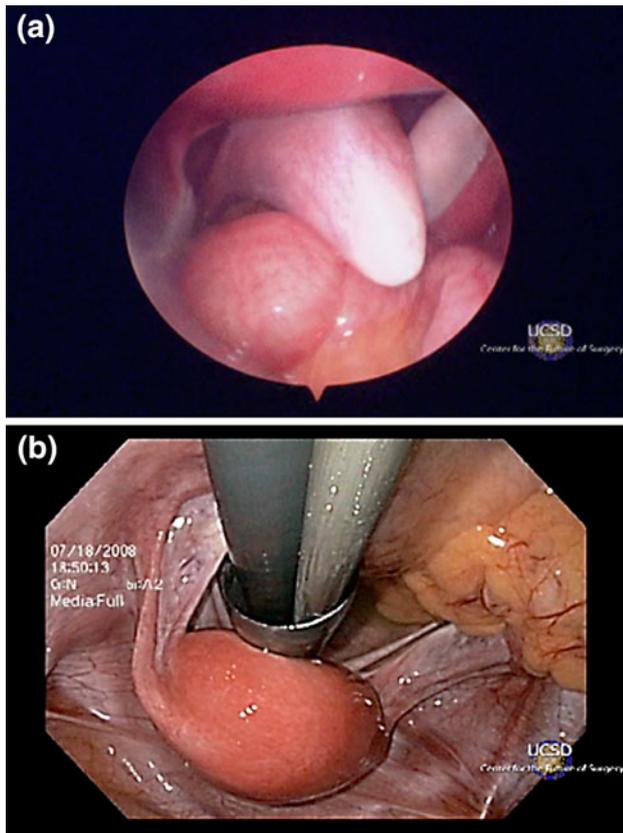


Fig. 2 Transvaginal entrance

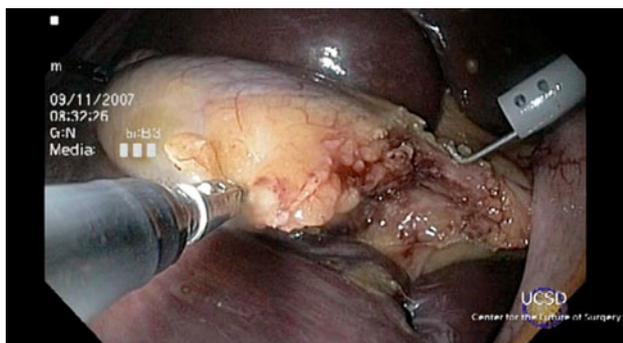


Fig. 3 Cystic duct exposed

Patients are discharged from the hospital when they can tolerate a liquid diet, are adequately mobile, and their pain is well controlled. Upon discharge, patients are instructed to recognize potential postoperative complications and/or alarms (signs and symptoms) related to this procedure. Patients are recommended to avoid sexual intercourse during the first month after surgery. Furthermore, patients are evaluated in clinic at 1 week postoperatively, and by phone at 6 months and 1 year postoperatively (Fig. 6).



Fig. 4 Cystic artery and duct clipped and divided



Fig. 5 Dissected gallbladder during its removal



Fig. 6 Trocar incision 7 days postoperatively

Literature Search

A medical literature search was conducted using PubMed, attempting to find publications available describing human NOTES cholecystectomies in clinical studies from January 1, 1993 to April 15, 2013. In this search, keywords included “Natural orifice transluminal endoscopic surgery”, “Minimally invasive surgery”, “Cholecystectomy”, “Transvaginal approach”, “Surgical procedure”, “Review” and “Clinical trials”. Non-English language

Table 1 Selected large clinical studies of THNC from 2008 to 2013

Study	Year [Ref. no.]	Journal	Location	Patients (n)	Type	Age (years)	BMI	Operative time (min)	ICU admissions (%)	Conversions (%)	Complications (%)		Hospital stay (days)	Mortality (%)	Follow-up (months)
											Intraoperative	Postoperative			
Van den Boezem et al.	2013 [21]	J Gastrointest Surg	Netherlands	50	Hybrid	38 ^a	25 ^a	61 ^a	0	10	0	4	1 ^a	0	NA
Nijhawan et al.	2013 [22•]	Surg Endosc	USA	27	Hybrid	40 ^a	25 ^a	91.9 ^a	0	0	0	0	1 ^a	0	3.3 ^a
Brescia et al.	2013 [7•]	The Surgeon	Italy	21	Hybrid	52 ^b	27 ^b	58 ^b	0	0	0	0	1 ^b	0	NA
Arezzo et al.	2013 [40]	Surg Endosc	Italy	423	Hybrid	45.3 ^a	25.5 ^a	60.5 ^a	0	1	0.8	1.8	2.1 ^a	0	NA
Mofid et al.	2012 [41]	Surg Endosc	Germany	220	Hybrid	46 ^b	24	46 ^b	0	1	0.7	0.5	2 ^b	0	6.5 ^b
Santos et al.	2012 [18]	Surg Endosc	USA	7	Hybrid	38 ^a	29 ^a	162 ^a	0	0	0	14	1 ^a	0	NA
Noguera et al.	2012 [42]	Surg Endosc	Spain	20	Hybrid	40.6 ^a	27.5 ^a	64.8 ^a	0	0	0	0	1 ^a	0	12 ^a
Borchert et al.	2012 [35]	Surg Endosc	Germany	50	Hybrid	46.3 ^a	26.7 ^a	77.8 ^a	0	0	2	4	2.7 ^a	0	NA
Niu et al.	2011 [14]	Surg Endosc	China	43	Hybrid	47.2 ^a	21.5 ^a	87.1 ^a	0	0	0	0	2.7 ^a	0	5.5 ^a
Hensel et al.	2011 [37]	J Laparoendosc Adv Surg Tech A	Germany	80	Hybrid	52 [*]	29 [*]	47 ^a	0	0	1.25	0	3 ^a	0	3 ^a
Cuadrado-Garcia et al.	2011 [19]	Surg Endosc	Spain	25	Hybrid	39.7	NA	89.5 ^a	0	0	0	0	1 ^a	0	4.6 ^a
Zorron et al.	2010 [12••]	Surgical Innovation	Brazil	240	Pure/ Hybrid	NA	NA	96.1 ^a	0	0	5	2	2 ^a	0	NA
Federlein et al.	2010 [8]	Surg Endosc	Germany	128	Hybrid	52.4 ^a	27.8 ^a	60.6 ^a	0	11	3	0.7	2.8 ^a	0	NA
Linke et al.	2010 [2]	Endoscopy	Switzerland	102	Hybrid	52.3 ^a	27.3 ^a	62.3 ^a	0	2	0	2	3.3 ^a	0	NA
Lehmann et al.	2010 [9]	Annals of Surgery	Germany	488	Hybrid	48.9 ^a	27 ^a	61.9 ^a	0	4.7	1.4	4.8	3.2 ^a	0	NA
Zomig et al.	2009 [16]	Endoscopy	Germany	68	Hybrid	50 ^b	25.4 ^a	51 ^a	0	0	0	0	2 ^a	0	10 ^a
Ramos et al.	2008 [17]	Endoscopy	Brazil	32	Hybrid	33 ^a	29 ^a	38 ^a	0	3	0	0	1 ^a	0	5 ^a

^a Values are expressed as mean

^b Values are expressed as median

manuscripts were excluded from this search to expedite the review process. There was no limitation to the level of evidence of these studies that were evaluated. A total of 150 articles were found in PubMed using the search terms listed above. Of this 150, 77 were considered relevant to review by authors and 33 were selected for detailed further review.

Clinical Outcomes

Arezzo et al. published a 2-year activity report from the EURO-NOTES clinical registry describing 423 THNC cases. The mean age was 45.3 years (range 16–76) and the average body mass index (BMI) was 25.3 (range 16–50). All patients had an American Society of Anesthesiology (ASA) classification of 2 or below [40].

Horgan et al. reported 48 THNC cases with a mean operative time of 89.8 min (range 38–165). Conversions to an open or laparoscopic operation and intraoperative complications were not found, and all the procedures were successfully completed. No patients required admission to an intensive care unit in this study. In the follow-up period, there were three pregnancies and an equal number of successful vaginal deliveries [39].

Mofid et al. published 220 THNC cases with a median hospital stay of 2 days. Patients were followed for a median of 6.5 months. The only intraoperative complication was a puncture of the urine bladder. Two postoperative complications were observed: one biliary fistula 3 days after THNC, and one abscess in the Douglas pouch 3 weeks after THNC. There were no trocar site complications and the mortality rate in this study was 0 % [41].

Noguera et al. evaluated postoperative pain in 20 THNC cases. Using a visual analog scale (VAS), postoperative pain was assessed after surgery on postoperative evaluations on days 1, 7, and 30, and months 6 and 12. The median pain scores were 3.94, 2.52, 0.73, 0.36, and 0.10, respectively. This pain was very well controlled by the standard oral narcotic pain medications [42].

Linke et al. published a prospective single-center cohort study investigating sexual function, patient satisfaction, and quality of life in sexually active women 1 year after THNC. A total of 106 patients participated in this study. Patient satisfaction was assessed 1 year after surgery with the validated version of the female sexual function index (FSFI-D). Sexual life impairment and quality of life were assessed by the gastrointestinal quality of life index (GIQLI) prior and 1 year after surgery. FSFI-D total scores showed that 84 out of 88 patients (95 %) were satisfied with THNC. Sexual life significantly improved (GIQLI scores 3.2 ± 1.0 pre surgery vs. 3.7 ± 0.7 1 year postoperatively, $P < 0.001$) and painful sexual intercourse

(3.3 ± 1.0 vs. 3.6 ± 0.7 , $P = 0.008$) decreased post-surgery [34]. Preoperative parameters and postoperative outcomes of selected large published clinical studies from 2008 to 2013 are summarized on (Table 1).

Conclusions

THNC is a safe and feasible surgical approach that suggests superior clinical outcomes compared with the standard laparoscopic cholecystectomy in terms of improved cosmetic results, decreased rates of trocar site complications, shorter hospital stay, less postoperative pain, and reduced use of pain medications. Current clinical evidence has not found relevant impacts on sexual function and future fertility. Given this promising data, this surgical approach may prove to be a superior mode of gallbladder removal in female patients. Further randomized studies and long-term follow-up are needed to determine if this procedure will play a major role in the daily clinical practice.

Compliance with Ethics Guidelines

Conflict of Interest Garth R. Jacobsen has received honoraria for serving as a consultant and has received payment for development of educational presentations including service on speakers' bureaus) from Ethicon Endo Surgery. Juan S. Barajas-Gamboa declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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