Transvaginal Endoscopic Cholecystectomy in Human Beings: Preliminary Results

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ABSTRACT

Introduction: The exciting concept of performing surgery in the peritoneal cavity without abdominal incisions by means of flexible endoscopes introduced through natural orifices—natural orifice transluminal endoscopic surgery (NOTES) has been widely investigated in recent years in experimental settings. However, experience with this procedure in human beings is still lacking. In this paper, we report the preliminary results of a small consecutive series of transvaginal endoscopic cholecystectomies.

Methods: A standard double-channel gastroscope introduced into the abdominal cavity through a posterior colpotomy was used to perform the cholecystectomy. The introduction of a 5-mm trocar in the left-upper abdominal quadrant was mandatory to create and monitor the pneumoperitoneum and allow the application of the standard laparoscopic clips. This port was also used to introduce a grasper that assisted in the exposure of the gallbladder. The gallbladder was removed through the vagina and was protected in a plastic bag.

Results: Since July 2007, 3 patients were successfully operated on by this approach, including 1 morbidly obese woman with a body mass index (BMI) of 45. The mean operative time was 136 minutes (range, 110–190). No postoperative complications occurred, and the patients did not complain of pain at both access sites. At the 1-month follow-up, none of the patients complained of dyspareunia.

Conclusions: The transvaginal cholecystectomy is feasible, safe, and reproducible in women within a wide range of BMI. NOTES might dramatically change the way surgery will be conceived and performed in the future, as it holds the potential to abolish the historic association of surgery with pain and scars.

INTRODUCTION

“THE FUTURE IS NOT WHAT IT USED TO BE”—Lawrence Peter “Yogi” Berra (USA). Surgery has always been associated with the concept of incisions. The introduction of laparoscopy in the late 1980s started a trend in the surgical field toward minimal parietal invasiveness

and minimal aggression to the patient. At the beginning of the experience with laparoscopic surgery, pioneers in the field were considered with great concern by well-respected surgeons of the leading institutions.¹ Patients, on the contrary, in a very short time, were enthusiastic about those proposing less bodily trauma, less postoperative pain, a faster recovery, and better cosmetic results.

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Videos of this technique can be found online at www.liebertpub.com/lap.

TABLE 1. PATIENT CHARACTERISTICS

Case no.	Age	Weight	BMI	Previous surgery	Menopause	Abdominal ultrasound	Magnetic resonance
Case 1	50	55	25	No	Yes	Cholelithiasis	Cholelithiasis
Case 2	48	57	26	Appendectomy	No	Cholelithiasis	Cholelithiasis
Case 3	46	100	45	No	No	Cholelithiasis	Cholelithiasis

BMI, body mass index.

Currently, laparoscopy is considered the gold standard for the treatment of several diseases, showing favorable results even for malignant conditions.^{2,3}

In 2004, Antony Kallo from John Hopkins University (Baltimore, MD) reported, for the first time, the revolutionary idea of performing surgery through natural orifices, introducing a concept never imagined before: to perform surgery without scars.⁴ This preliminary report stimulated great interest, and soon after, many investigators performed several natural orifices procedures in experimental settings, entering the peritoneal cavity through the stomach, colon, urinary bladder and vagina.^{5,6}

In 2004, N. Reddy, M.D., and P. Rao, M.D., from India presented the first human transgastric appendectomy by using a flexible endoscope.⁷ Although interesting, transgastric natural orifice surgery remained merely anecdotic, mainly because of major concerns regarding the safety of the gastric closure. While entering the peritoneal cavity through the stomach and colon still seems debatable and risky, transvaginal access to the abdominal cavity is not a new concept for surgeons. This access, in fact, has been occasionally used by general surgeons to extract large specimens and by gynecologists to routinely perform diagnostic and therapeutic procedures.^{8,9} In 2007, two independent groups^{10,11} described the feasibility of the transvaginal cholecystectomy in women. To the best of our knowledge, we report in this paper the first preliminary data of a small consecutive clinical series of transvaginal cholecystectomies for symptomatic uncomplicated cholelithiasis.

MATERIALS AND METHODS

Since July 2007, patients presenting with symptomatic uncomplicated cholelithiasis and no history of major abdominal surgery, gynecologic diseases, major medical contraindications, and who were not wishing for pregnancy were considered eligible for the transvaginal endoscopic cholecystectomy. A preoperative workup included a routine clinical evaluation, gynecologic examination, standard blood tests, abdominal ultrasonography, and magnetic resonance imaging (MRI) with cholangiopancreatographic sequences and multiplanar reconstruction to exclude the presence of common bile duct stones and to clearly assess the anatomy of the biliary tree.

Patient characteristics are reported in Table 1. Informed consent was obtained and patients were informed of the necessity to avoid sexual intercourse for 4 weeks after the operation. Institutional review board approval was also obtained.

Operative technique

On July 25, 2007, a multidisciplinary team, including surgeons experienced both in laparoscopic surgery and interventional endoscopy, together with a gynecologist, performed the first operation at Niguarda Cà Granda Hospital (Milan, Italy). Patients were fasted overnight and received preoperative antithrombotic and antibiotic prophylaxis. Under general anaesthesia, patients were placed in the lithotomy position with the legs parted. The vagina was prepped with povidone-iodine 10% and a urinary catheter was inserted. A nasogastric tube was also routinely used during the operation. Two fully equipped laparoscopic and endoscopic carts were used for the procedure (Karl Storz, Tuttlingen, Germany). Two surgeons were positioned between the legs and one assistant on the left side of the patient (Fig. 1). Owing to an institutional

FIG. 1. Operating room setup.

intranet network, preoperative virtual MRI cholangiograms were available on flat screens during the operation, thereby helping in the identification of the biliary anatomy. The operation started by the induction of the pneumoperitoneum with a Veress needle that was introduced into the left upper quadrant.

The Veress needle was then replaced by a 3-mm minitrocar to allow the introduction of a miniscope (Karl Storz) for the exploration of the abdominal cavity. This port was used for the insufflation and monitoring of the pneumoperitoneum. With the patient in a 30-degree Trendelenburg position, under direct laparoscopic vision, a posterior colpotomy was performed to allow the introduction of a 45-cm-long grasper (Karl Storz) to retract the gallbladder cephalad and, subsequently, the introduction of a standard double-channel gastroscope (Karl Storz) (Figs. 2 and 3).

From this step onward, the endoscopic vision was exclusively provided by the gastroscope with no need for laparoscopic camera support. Dissection of the gallbladder and of the cystic duct and artery were carried out by a total natural orifice transluminal endoscopic surgery (NOTES) technique, using a unipolar round-tipped electrode and a flexible endoscopic grasper (Karl Storz) introduced into the working channels of the endoscope (Fig. 4). The dissection started at the level of the gallbladder neck and proceeded until the complete mobilization and identification of the biliary structures were achieved. With the unipolar round-tipped cautery just a few centimeters out of the working channel, gentle movements of deflection of the tip of the endoscope were used to skeletonize the biliary structures.

A 3-mm minilaparoscopic (Karl Storz) grasper, introduced through the abdominal port, represented the only external assistance during the operation, and helped with the retraction and manipulation of the gallbladder. Once the biliary structures were completely dissected out, the

FIG. 2. Laparoscopic vision of transvaginal gastroscope and grasper.

FIG. 3. Endoscopic view of the gallbladder.

3-mm microlaparoscopic port was switched to a 5-mm trocar (Endopath Ethicon Endosurgery, Cincinnati, OH) to accommodate a standard laparoscopic clip, the LIGA-CLIP Allport (Ethicon Endosurgery). Once clipped, the cystic duct and artery were divided by standard laparoscopic scissors (Fig. 5). Finally, the retrograde cholecystectomy was completed by the endoscopic instruments.

A thorough exploration of the abdominal cavity was carried out at the end of the dissection in order to check the hemostasis of the liver bed and to exclude any inadvertent injury to the surrounding organs. After the retrieval of the gastroscope and under the control of the minilaparoscope that was inserted again into the left upper quadrant, the gallbladder was removed through the vagina and was protected in an Endobag (Ethicon Endosurgery) (Figs. 6 and 7). The colpotomy was closed by

FIG. 4. Gallbladder dissection using unipolar electrode.

FIG. 5. Division of biliary structures.

resorbable (Vicryl; Johnson and Johnson Gateway LLC, Piscataway, NJ) interrupted sutures, whereas the 5-mm skin incision was approximated either by intradermic stitches or by glue (Fig. 8). To exclude any inadvertent rectal injury, a proctoscopy was performed at the end of the procedure. Finally, the urinary catheter and nasogastric tube were removed.

RESULTS

Since our first case on 2007, 25, July a total of 3 patients have been successfully operated on by this approach. No mortality, conversions, or complications occurred. The complete dissection and isolation of the biliary structures were successfully performed in all cases by the total NOTES technique. We elected to use a 5-mm trocar to pass standard MRI-compatible laparoscopic clips to secure the cystic duct and artery. The currently available endoscopic clips, in our opinion, may carry the risk of dislodgment and migration in the common bile duct.

In the morbidly obese patient, for safety reasons, we decided to use an optical 5-mm trocar (OptiView port; Ethicon Endosurgery) since the beginning of the procedure, and although the colpotomy was more challenging because of the thicker preperitoneal fat layer and slightly hypertrophic uterus, no major differences were encountered during the procedure in this patient. The dissection of the gallbladder from the liver bed was possible by a total NOTES technique in all patients.

The mean operative time—from the introduction of the transvaginal gastroscope to the closure of the colpotomy—was 136 minutes (range, 110–190), requiring more than 3 hours in the first case and less than 2 hours in the

last 2 cases. None of the patients complained of abdominal and vaginal pain or discomfort with no analgesic medication required in the immediate postoperative period.

All the patients were allowed to eat on the evening of the operation and were discharged within 48 hours. A histologic examination confirmed the presence of gallbladder stones in all cases, showing signs of chronic cholecystitis in 1 patient. The 2 patients with a follow-up longer than 1 month did not complain of any vaginal discomfort or dyspareunia.

DISCUSSION

To the best of our knowledge, this small consecutive case series of transvaginal endoscopic cholecystectomies represents the first such series ever reported in the literature. In our group of patients, 1 case was performed in a morbidly obese woman with a BMI of 45 (100 kg/1.49 m²), representing the first ever reported in the literature in such patients.

After many years of debate and experimental works in laboratory settings, the NOTES technique does not represent any longer a topic of discussion among experts or an experimental model for enthusiastic investigators, but a new, feasible, and safe approach to access and operate in the abdominal cavity with great potential for a further reduction of surgical trauma owing to abdominal incisions.

The transvaginal route to the abdominal cavity, at this stage, seems to be particularly suitable for NOTES applications in humans because of the well-demonstrated safety of this approach in the gynecologic field and for the advantages offered by the frontal view of the upper abdomen given by the endoscope coming from the vagina. Common concerns about accessing the abdomi-

FIG. 6. Gallbladder extraction in an endobag.

FIG. 7. Transvaginal extraction of the gallbladder.

nal cavity through the vagina are represented by the risk of bowel perforation, pelvic infection, herniation, fertility, and chronic dyspareunia.

As reported by other researchers,^{10,11} we performed the colpotomy under direct laparoscopic vision to prevent lesions to the surrounding organs and in addition we routinely check the rectum by a proctoscopy at the end of the procedure. In a survey of 3667 transvaginal pelvic endoscopies for the diagnosis of gynecologic diseases, in the absence of any laparoscopic control, the reported incidence of bowel perforation was 0.65%, which decreased after initial experience to 0.25%. No delayed diagnosis and sepsis were reported, and all but 1 case were managed conservatively with antibiotics.⁹ To further reduce complications, in addition to a routine vaginal examination, a vaginal ultrasound should be performed to exclude pathologies of the Douglas' pouch.

Pelvic infections and herniation are rarely reported after the transvaginal extraction of abdominal masses¹² and pelvic surgery, even when the colpotomy is not routinely closed.¹³ Fertility may also represent a major concern; hence, in the lack of clear current evidence, it is our policy to limit the indication for a transvaginal cholecystectomy to women in menopause or those who are not wishing for a pregnancy. The exact incidence and nature of dyspareunia after gynecologic surgery is still a matter of debate, and data are inconclusive about this problem, which seems to be strongly related to nonorganic mechanisms.¹⁴

In our initial experience, the 2 patients with a follow-up longer than 1 month did not complain of any pain or discomfort during sexual intercourse. However, we believe that this issue should be clearly discussed preoperatively. The present limitations of standard endoscopic devices still call for some transparietal assistance.

In previously reported experience in humans,^{10,11} one or more parietal access have been used, both for inducing and monitoring the pneumoperitoneum, owing to the current lack of an endoscopic system that can reliably control abdominal pressure and for the retraction of the gallbladder. Owing to a 45-cm-long grasper introduced through the vagina, we were able to effectively retract cephalad and manipulate the gallbladder. This transvaginal grasper also allowed a favorable triangulation that greatly facilitated the dissection and clipping.

Developments in the field of magnetics technology,¹⁵ specifically designed endoscopic platforms,¹⁶ and the new generation of "in vivo" robots¹⁷ should overcome the limitations of the NOTES procedure in the near future, thus allowing completely nonscar operations. To the best of our knowledge, flexible endoscopic clips specifically developed to be used intraperitoneally are not yet available on the market, and so we electively decided to start the operation by using a 3-mm minitrocar to test the feasibility of the procedure with minimal transparietal assistance, and then to switch the miniport to a 5-mm one in order to accommodate and safely apply standard laparoscopic clips that were compatible with MRI.

Looking back on the initial experience with minimal access surgery, we learned that the early phase of the learning curve of laparoscopic cholecistectomies was associated with a significantly higher rate of common bile duct injuries.¹⁸ This was probably due to the misinterpretation of the anatomy because of the unusual approach and technologic limitations. Moreover, because of several drawbacks of current endoscopes, the dissection is performed in close contact with the biliary structures and with a lack of panoramic view, which can further increase the risk of anatomic misinterpretation.

In our study, we decided to routinely perform preoperative MRI with cholangiopancreatographic sequences and multiplanar reconstruction to exclude anatomic abnormalities and common bile duct stones and for intraoperative guidance during the dissection of biliary structures, thanks to an institutional intranet network that

FIG. 8. Final view of the abdomen with the single 5-mm skin incision.

allowed us to visualize virtual MRI cholangiograms in the operative room.

Intraoperative cholangiography, even if feasible, would have limited the advantages of the NOTES approach and required additional abdominal incisions. Ideally, in the future, augmented reality systems by superimposing preoperative MRI images with real operative ones associated to real-time tracking and registration of the devices in the reference images will strongly facilitate transluminal natural orifice surgery.¹⁹ Also, reducing number and size of the abdominal port will be particularly advantageous for obese patients, who present a higher risk for incisional hernias and postoperative limitations owing to bodily pain.

New endoluminal and transluminal techniques can offer the opportunity to perform less morbid procedures for the growing number of obese patients worldwide, thereby potentially offering treatment options on an outpatient basis.²⁰ Many challenging issues must be addressed before the widespread application of NOTES.

Whereas the acceptance of passing through the vagina to enter the abdominal cavity seems quite acceptable, owing to the large experience in the gynecologic field, the transgastric, transcolonic, and transvesical approaches are still considered with skepticism and will require further extensive investigations and technologic developments before patients and doctors will be convinced that these routes are safe and advantageous for performing abdominal surgery. The diffusion of NOTES will require changes at the educational, organizational, and institutional levels. Presently, the safest way to perform transluminal surgery seems to be that of creating a multidisciplinary team of interventional gastroenterologists and surgeons with laparoscopic experience. In the future, we will probably see the birth of a new brand of "flexible interventional physicians" who are trained to operate both inside and outside the digestive lumen, possibly working in newly designed operative suites with patients alternatively under conscious sedation or general anesthesia.

CONCLUSIONS

There is much more to the imagination than can currently be said about natural orifice surgery. Our preliminary experience shows that transvaginal endoscopic cholecystectomy is feasible, safe, and reproducible in human beings within a wide range of BMIs. It is always hard to predict the future because "it is not what it used to be," but we see the potential of the NOTES technique to dramatically change the way surgery will be conceived and performed, introducing the basis for a new paradigm shift as it was for laparoscopic surgery in the late 1980s. The continuous effort to improve patient care, the creativity of pioneers in the field, and the collaboration

offered by instrument manufacturers will bring the NOTES technique to a wide range of clinical applications, with the promise to abolish the historic concept associated with surgery of pain and scars.

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