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Feasibility and Technique for Transvaginal Natural Orifice Transluminal Endoscopic Surgery Liver Resection: A Porcine Model

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Introduction: Natural orifice transluminal endoscopic surgery (NOTES) is a challenging minimally invasive procedure. Although laparoscopic techniques for liver resection are gaining acceptance worldwide, few studies have investigated NOTES liver resection. We used a porcine model to assess the feasibility and safety of transvaginal NOTES liver resection (TV NOTES LR).

Materials and Methods: Nine female pigs underwent TV NOTES LR. A nonsurvival acute porcine model with general anesthesia was used in all cases. Using hybrid NOTES technique, we placed only 1 umbilical 12-mm umbilical trocar in the abdominal wall, which was used to create pneumoperitoneum. A laparoscope was then advanced to obtain intra-abdominal visualization. A 15-mm vaginal trocar was inserted under direct laparoscopic vision, and a flexible endoscope was introduced through the vaginal trocar. A long, flexible grasper and endocavity retractor were used to stably retract the liver. The liver edge was partially transected using energy devices inserted through the umbilical trocar. To transect the left lateral lobe, a flexible linear stapler was inserted alongside the vaginal trocar. A specimen extraction bag was deployed and extracted transvaginally. Blood loss, bile leakage, operative time, and specimen size were evaluated. Necropsy studies were performed after the procedures.

Results: Eighteen transvaginal NOTES partial liver resections and 4 transvaginal NOTES left lateral lobectomies were successfully performed on 9 pigs. Mean operative time was 165.8 minutes, and mean estimated blood loss was 76.6 mL. All TV NOTES LRs were performed without complications or deaths. Necropsy showed no bile leakage from remnant liver.

Conclusions: Our porcine model suggests that TV NOTES LR is technically feasible and safe and has the potential for clinical use as a minimally invasive alternative to conventional laparoscopic liver resection.

Key Words: transvaginal, NOTES, liver, hepatectomy, porcine, animal model

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Natural orifice transluminal endoscopic surgery (NOTES) is an emerging minimally invasive procedure that requires no external body incisions. Scarless surgery is appealing to many clinicians, as it is the ultimate goal of minimally invasive surgery. However, development of NOTES has been gradual because technological evolution in surgical instrumentation has been slow to catch up with this innovation.

The first animal study of NOTES was reported by Kallo et al,¹ in 2004. A variety of approaches have been used in animal models of NOTES, including cholecystectomy, splenectomy, gastrojejunostomy, tubal ligation, and oophorectomy.^{2–6} Clinical transvaginal (TV) NOTES cholecystectomy was described in 2007.^{7,8} A recent study found that NOTES resulted in less postoperative pain^{9,10} and excellent cosmetic results.^{11–13} Downsizing of incisions, trocar size, and trocar number can help decrease postoperative pain and increase postoperative quality of life.¹⁴ Data from large case series and case registries suggest that TV hybrid NOTES cholecystectomy is safe when performed by surgeons well trained in minimally invasive techniques.^{15–17} A recent systematic review and meta-analysis of TV hybrid NOTES cholecystectomy¹⁸ supports those findings.

Laparoscopic liver resection (LLR) was initially performed by Reich et al,¹⁹ in 1991. Initially, this procedure was highly specialized due to technical difficulties mainly related to achieving hemostasis during liver parenchymal transection. The development of surgical devices to separate the hepatic parenchyma has enabled bloodless dissection.²⁰ The International Consensus Meeting on Laparoscopic Liver Surgery was held twice, in 2008 and 2014. Their first statement affirmed that laparoscopic liver surgery is safe and effective for management of surgical liver disease when performed by trained surgeons with experience in hepatobiliary and laparoscopic surgery.²¹ Although the evidence is somewhat limited, systematic reviews and meta-analyses of the benefits of LLR suggest that there are significant improvements in intraoperative bleeding, transfusion rate, postoperative complications, and duration of hospital stay.^{22–31} The Second Consensus Meeting evaluated the current status of laparoscopic liver surgery and provided recommendations for future development.³² The feasibility and safety of LLR were confirmed in this

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international consensus meeting. Thus, recognition of LLR has increased, and the procedure is now widely performed.

NOTES liver resection (NOTES LR) has the potential advantages of NOTES and LLR, as it is less invasive than conventional LLR, results in less postoperative pain and better cosmetic outcomes, and avoids incision-related complications. We used a porcine model of TV NOTES LR to evaluate the safety and feasibility of this procedure.

MATERIALS AND METHODS

This study was a collaboration between Toho University and University of California, San Diego (UCSD), and all procedures were performed in accordance with the institutional animal care and use committee protocols of Toho University and UCSD. Nine female pigs (5 at Toho University, 4 at UCSD; weight 45 to 50 kg) underwent TV NOTES LR by means of hybrid technique. Before each procedure, general anesthesia was administered in the form of an intramuscular preanesthetic injection of ketamine (33 mg/kg), xylazine (2 mg/kg), and atropine (0.05 mg/kg). Intravenous access was established by way of a large ear vein, after which anesthesia was induced. After intubation and administration of propofol (2.4 mg/kg), general anesthesia was maintained with isoflurane (1% to 2%). The pig was placed in supine position with both hind legs abducted, and a 12-Fr Foley catheter was used to decompress the bladder (Fig. 1). TV NOTES partial liver resection of the edge of the right and left median lobe and left lateral lobectomy were performed.

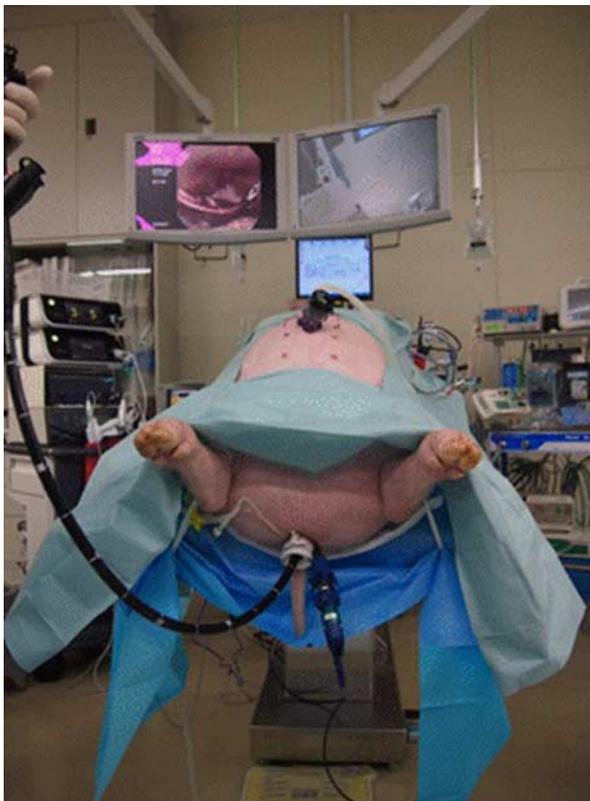


FIGURE 1. Operative position and setting during TV NOTES liver resection. TV NOTES indicates transvaginal natural orifice transluminal endoscopic surgery.



FIGURE 2. The flexible endoscope is inserted through the vaginal trocar.

Duration of TV access, hepatectomy, total operative time, blood loss, and size of the resected specimen were measured. The pigs were then euthanized in accordance with the centers' animal care protocols. Presence of hemorrhage, bile leak, and organ injury was then determined during necropsy.

Operative Procedure

TV Access for Hybrid NOTES

Using standard open technique, first 12-mm trocar was inserted at the side of the umbilicus. Pneumoperitoneum was created at a pressure of 10 mm Hg, and a 10-mm, 30-degree rigid camera (Stryker, Kalamazoo, MI) was inserted into the abdominal cavity. The operating table was tilted to a Trendelenburg position. A 15-mm TV trocar (length, 15 cm) was inserted under direct laparoscopic vision through the umbilical trocar, to avoid organ injury. A dual-channel gastroscope (Olympus GIF 2T240; Tokyo, Japan) was then inserted into the abdominal cavity through



FIGURE 3. The presumptive tumor and resection lines are marked on the liver surface.



FIGURE 4. The liver edge was resected by using laparoscopic coagulating shears inserted through the umbilical port.

the TV trocar (Fig. 2). A long flexible grasper (Novare, Cupertino, CA) was inserted alongside the vaginal trocar. The gastroscope and grasper were positioned in the right upper abdomen by laparoscopic view. The pig was then placed in a reverse Trendelenburg position and observation was changed to a flexible endoscopic view.

Partial Liver Resection in TV NOTES

Electric cautery was used to mark the presumptive tumor and liver resection lines on the liver edge (Fig. 3). The liver edge was then grasped with the long grasper transvaginally. A self-retaining intracorporeal retractor, the Cinch Organ Retractor System (Aesculap, Tuttlingen, Germany), was used to obtain sufficient exposure during the procedure. The liver was transected using laparoscopic coagulating shears (Fig. 4). Because of the presence of intrahepatic vessels, the deep liver layer was transected by using a laparoscopic bipolar sealing device. Bleeding was managed by a forceps electrocautery device inserted through the working channel of the flexible endoscope. A saline-enhanced radiofrequency ablation device (IO-Advance electrode; AMCO Inc., Tokyo Japan) was used for management of persistent bleeding. Specimens were



FIGURE 5. The specimen was easily removed through the vagina.

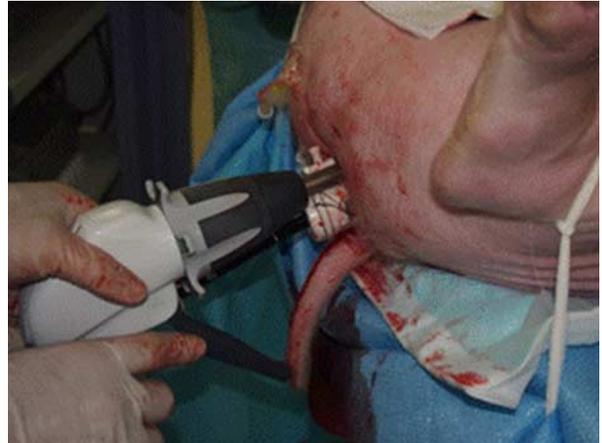


FIGURE 6. The long laparoscopic linear stapler was inserted alongside the vaginal trocar, for transection of the left lateral lobe.

removed transvaginally by using a retrieval pouch (Endo-Catch II; Covidien, Mansfield, MA) (Fig. 5).

Left Lateral Lobectomy in TV NOTES

The operating table was adjusted to the Trendelenburg position, to use gravity for emptying the pelvic cavity. The Echelon LONG60A (Ethicon EndoSurgery, Cincinnati, OH) was inserted carefully alongside the vaginal trocar (Fig. 6). The pig was then placed back in the reverse Trendelenburg position. A Cinch Organ Retractor System inserted through the umbilical trocar was used to lift the left medial lobe, to allow for sufficient exposure of Glisson's pedicles in the left lateral lobe. Liver parenchymal transection with division of intrahepatic vessels was performed by using the Gold cartridge of the Echelon LONG60A (Fig. 7). The stapler was used 2 or 3 times to transect the entire left lateral lobe. The specimen was removed



FIGURE 7. The left lateral lobe is transected with the laparoscopic linear stapler.



FIGURE 8. The specimens were retrieved transvaginally.

transvaginally with an EndoCatch II bag, under transumbilical laparoscopic view.

RESULTS

Eighteen partial liver resections were performed in 9 pigs. Four left lateral lobectomies were performed in 4 pigs. All resections were performed by TV NOTES with no conversion to conventional laparoscopic or open hepatectomy. There were no intraoperative complications or deaths. The average duration of TV access was 31.9 minutes (range, 15 to 50 min). Average duration of resection was 37.6 minutes (range, 23 to 56 min) for partial liver resection and 34.5 minutes (range, 25 to 41 min) for left lateral lobectomy. Overall operative duration was 165.8 minutes

(range, 112 to 230 min). Average estimated blood loss was 76.6 mL (range, 10 to 254 mL).

All specimens were easily removed transvaginally in partial resection cases. However, during the procedure for the first case, specimens could not be removed transvaginally to the pelvic cavity during left lateral lobectomy, due to the large volume of the liver. Therefore, laparoscopic scissors were used for intra-abdominal reduction of specimens to half the original size. For the second and subsequent cases, specimens were removed transvaginally. The average specimen size for partial liver resections was 6.2 × 5.0 cm. The average size for 1 of the 2 specimens retrieved during left lateral lobectomies was 14.6 × 10.6 cm (Fig. 8). No hemorrhage, bile leakage, or other organ injury was noted in necropsy studies.

DISCUSSION

In theory, NOTES LR provides the benefits of NOTES and conventional LLR. However, few studies have evaluated NOTES liver surgery in animals or humans³³⁻⁴⁰ (Table 1). All experimental studies of NOTES LR involved only liver biopsy^{33,34} or a small number of local resections (1 to 2 wedge liver resections³⁵⁻³⁷). Only 3 human clinical case reports described the use of NOTES LR for partial liver resection or left lateral sectionectomy.³⁸⁻⁴⁰ Thus, NOTES LR remains a nascent technique. We believe that the present study is the first to establish a technical model for TV NOTES LR in a porcine model. NOTES LR uses various natural orifices, including the vagina,³³ stomach,³⁴ rectum,^{35,37} and umbilicus, as access routes. Natural orifices are used for far more than specimen extraction by means of natural orifice specimen extraction (NOSE).⁴¹⁻⁴⁵ NOSE is appealing because it maximizes the benefits of laparoscopic surgery while reducing potential abdominal extraction wound complications. In addition, smaller incisions improve cosmetic results and decrease post-operative pain, which is directly associated with incision length.⁴¹⁻⁴⁸ Transvaginal access is the most frequently used route for clinical NOTES⁴⁹ and NOSE procedures,⁴¹⁻⁴⁵ and

TABLE 1. Review and Our Case of NOTES Procedures

References	Subject for Study	Type of NOTES Liver Surgery	No. Specimen	Transection Size	Location	Complication	Access Route
Claus et al ³³	6 pigs	Liver biopsy	6	2 liver fragments	NA	One access bleeding	Pure TV
Tagaya and Kubota ³⁴	1 pig, 4 dogs	Liver biopsy	5	NA	NA	No complication	Pure TG
Ohdaira et al ³⁵	1 pig	Partial liver resection	1	60 mm	NA	Laceration of incision	Hybrid TR
Phee et al ³⁶	2 pigs	Partial liver resection	2	14 × 8 × 5 mm, 21 × 10 × 7.6 mm	NA	No complication	Pure TG
Shi et al ³⁷	3 pigs	Partial liver resection	2	50 × 25 × 0.5 mm in TR, 45 × 30 × 7 mm in TV	NA	No complication	Pure TA, Pure TV, and TU
Castro-Pérez et al ³⁸	1 woman	Enucleation for benign tumor	1	NA	Left lobe	No complication	Hybrid TV
Truong et al ³⁹	1 woman	Left lateral liver resection	1	140 × 80 × 35 mm	Left lateral lobe	No complication	Hybrid TV
Noguera et al ⁴⁰	1 woman	Partial resection	1	40-50 mm	Segment 5	No complication	Hybrid TV
Present study			18 PA, 4 LLL	Ave 62 × 50 mm in PA, Half size Ave 146 × 106 mm in LLL	Median lobe left lateral lobe	No complication	Hybrid TV

LLL indicates left lateral lobectomy; NA, not applicable; PA, partial resection; TA, transanal; TV, transvaginal; TG, transgastric; TU, transumbilicus.

the TV approach provides safe entry, easy access, and lower risk of contamination of the abdominal cavity, as compared with gut access.^{50–52} The vaginal wall can be easily closed using standard suturing methods under direct vision. Moreover, direction for the manipulation toward the liver can be straight angle by the TV approach, similar to conventional LLR. Therefore, all previous clinical studies of NOTES LR used a TV approach.^{38–40} The primary technical issue in NOTES LR is overcoming difficulties in the operative field and procedure, which are related to the limited maneuverability afforded by the natural orifice. Exposure of the hepatic parenchymal transection plane is a key achievement in successful liver resection and is best accomplished by hybrid NOTES, which uses laparoscopic trocars for assistance. Almost all clinical studies of NOTES used hybrid technique with the assistance of 2 or more abdominal trocars.^{38–40} The present study used only 1 trocar—a 12-mm umbilical trocar—which was minimal but extremely helpful. In addition, the long articulating grasper and self-retaining retractor helped obtain optimal exposure of the operative field, by retracting the liver during the procedure.

Transection of liver parenchyma with adequate control of bleeding is essential during liver surgery. Appropriate selection and use of energy devices are indispensable, especially in endoscopic procedures, during which management of unexpected bleeding is more difficult than in open surgery.⁵³ The energy devices used in liver transection each have important roles: ultrasonic shears are used for tissue transection of the superficial layer, the bipolar tissue sealing device for the deep layer, and the saline-enhanced monopolar device for tissue coagulation and hemostasis. A long stapling device that traverses the distance from the vagina to the liver is available for liver parenchymal transection in hybrid TV NOTES procedures and is described in our previous study of clinical liver resection.⁵⁴

In our series, transected specimens could be easily removed from the vagina in all partial liver resection cases. In contrast, it was not possible to remove the entire left lateral lobe through the porcine vagina. Of course, there are anatomic differences between the porcine and human pelvic cavity and vagina. Truong et al³⁹ reported that they were able to remove a 14-cm left lateral liver section through the vagina. However, intracorporeal downsizing with scrupulous attention to avoid exposure of malignancies may be necessary to retrieve large specimens through a natural orifice. In addition, future studies should evaluate vaginal trauma after specimen removal.

CONCLUSIONS

TV NOTES LR is technically feasible and safely reproducible for liver resections of the lower edge and left lateral section of the liver. Our experience indicates that this procedure is indicated for selected cases when performed by surgeons with appropriate training and knowledge of conventional LLR.

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