Robotic Retroperitoneal Transvaginal Natural Orifice Translumenal Endoscopic Surgery (NOTES) Nephrectomy: Feasibility Study in a Cadaver Model

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OBJECTIVE To evaluate the feasibility of pure robotic natural orifice translumenal endoscopic surgery (R-NOTES) nephrectomy.

METHODS Two R-NOTES nephrectomy approaches were attempted in 3 female cadavers. A single-port device was inserted through an incision in the posterior vaginal fornix. In the first approach, the peritoneal cavity was accessed in the lithotomy position. In the second approach, the retroperitoneum of 2 cadavers was accessed in the prone jackknife position. The ureter was identified and followed cranially. The hilum was stapled and the kidney was dissected. The specimen was extracted into a bag. The incision was closed with an open approach.

RESULTS The first approach was not possible because of collision of the robotic arms against the legs and limited bowel retraction. After modifying the approach, a right transvaginal R-NOTES retroperitoneal nephrectomy was successfully completed, without adding extra ports. Time for setup was 128 minutes. Time to identify the ureter was 53 minutes. Dissection and control of the renal pedicle was completed in 21 minutes. Time to complete the dissection and extraction of the kidney was 36 minutes. Time to complete the procedure was 238 minutes. There were no injuries to retroperitoneal organs or vessels. In the third cadaver, there was rectal injury during the access. We were unable to complete the procedure because of the cadaver height.

CONCLUSION Transvaginal R-NOTES nephrectomy is technically challenging but feasible in select female cadavers. Retroperitoneal approach in the prone jackknife position was instrumental in facilitating robotic access to the kidney through the vagina. Improvements in the technique and instrumentation are necessary to make this approach safe and reproducible. UROLOGY 81: 1232–1238, 2013.

Over the last 2 decades, surgeons from different specialties have pushed the envelope of minimally invasive surgery with the development of laparoendoscopic single-site surgery (LESS) and natural orifice translumenal endoscopic surgery (NOTES).[1-7]

The concept of surgery with minimal or no scar poses several new challenges to the surgeons. In the urological field alone, more than 1000 LESS procedures have been reported.[8] The feasibility of transvaginal NOTES nephrectomy using laparoscopic instruments has been demonstrated in the clinical setting.[5] However, intrinsic limitations to this approach, including poor ergonomics, nonspecific instrumentation, and technical difficulty, has determined its clinical application to remain anecdotal. Thus, investigators have combined natural orifice access with traditional laparoscopic approaches, the so-called hybrid NOTES or NOTES-assisted techniques.[9,10] Of all the possible sites for NOTES, the transvaginal access is the most largely investigated. One of the advantages of the transvaginal over other routes for NOTES is the possibility to extract large specimens, which is particularly important for nephrectomy. The transvaginal route also has the potential benefit of not creating an intentional enteric opening with the risks of bowel leak or abscess associated.

The incorporation of the robotic technology has allowed us to overcome some of the limitations encountered with standard LESS.[11] Hybrid R-NOTES techniques have been successfully demonstrated in the porcine and cadaver models and they are currently under

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clinical investigation in our institution.[12,13] Attempts of pure R-NOTES have not been successful so far.[14]

The purpose of this study was to evaluate the feasibility of pure transvaginal R-NOTES nephrectomy in the cadaver model.

MATERIAL AND METHODS

Procedure

Two approaches for transvaginal R-NOTES nephrectomy were investigated in 3 female cadavers: lithotomy transperitoneal vs prone jackknife position retroperitoneal.

Instrumentation

The da Vinci Si system (Intuitive Surgical, Sunnyvale, CA) was used in a 3-arm configuration. Different multichannel ports were tested for the transvaginal access. Robotic monopolar curved scissors (Hot Shears) and robotic grasper (ProGrasp Forceps) were used in the right and left hand, respectively. For the kidney extraction, one of the robotic trocars was exchanged with a 15 mm trocar to allow the introduction of specimen retrieval Endo Catch bag (Covidien, Mansfield, MA).

Positioning, Access, Port Placement, and Robot Docking—Lithotomy Position-transperitoneal Approach

The cadaver was placed in the lithotomy position with steep Trendelenburg. Access to the peritoneal cavity was obtained after incision in the posterior vaginal fornix. A single-port device was inserted through the vagina into the abdomen. The robot was brought into the field from behind the head and docked.

Prone Jackknife Position-retroperitoneal Approach

To obtain the prone jackknife position, also known as the Kraske position, the cadaver was first placed prone on the surgical table. Then, rolls were longitudinally placed under the abdomen in the targeted side. The inferior part of the table was flexed and the cadaver legs were placed downward and in abduction, tied to Bierhoff leg holders. Finally, a steep Trendelenburg was applied to the table (Fig. 1A,B). An incision was made in the posterior vaginal fornix, pulling the cervix inferiorly with a forceps. By alternating sharp and blunt dissection, a space was developed posterior to the peritoneum and anterior to the rectum. Digital dissection of the retroperitoneal space was obtained by simultaneously placing a finger into the rectum to identify the correct plane (Fig. 1C). The dissection was carried out until enough space was obtained to allow the insertion of a single-port device. During the procedure, the commercially available QuadPort+ (Advanced Surgical Concepts, Wicklow, Ireland) and GelPoint (Applied Medical, Rancho Santa Margarita, CA) were used, as well as a homemade device with a surgical glove attached to a small Alexis wound retractor (Applied Medical) and trocars inserted through the glove's fingers (Fig. 1D,E), as first described by Park et al.[15] The placement of the single-port device follows the same principles of LESS. The internal ring is introduced into the cavity while the external ring is left exposed. The port's cap is then attached to the outer ring and trocars for instrument insertion are placed directly through the cap. A sleeve connects both rings. The robot was brought into the field behind the head and docked with the camera oriented approximately in line with the target organ. We used a 30° down scope.

Lithotomy-transperitoneal Approach

Transvaginal access to the peritoneal cavity was obtained. However, further progression was not possible with this approach. Details are provided in the "Results" and "Discussion" sections.

Prone Jackknife Position-retroperitoneal Approach

The retroperitoneal dissection progressed cranial and slightly lateral, toward the target organ. The iliac vessels, which represent the first main anatomic landmark of this approach, were identified. Through this perspective, they look like an arch, with the ureter passing anterior and attached to the peritoneum (Fig. 1F). The ureter was then followed in the cranial direction until the identification of the kidney lower pole. In this position, the kidney appears hanging from the posterolateral wall, which is located at the top of the surgical field, while the peritoneum (anterior) appears at the bottom (Fig. 2A,B). Figure 2C shows an external view of the robotic instruments in action. Figure 3 schematically represents the retroperitoneal dissection through a sagittal view.

The dissection continued until the identification and exposure of both renal artery and vein, which were clamped and divided en bloc by the bedside assistant with a laparoscopic stapler introduced from a 12 mm trocar placed through the vaginal port device (Fig. 4A). The assistant placed metallic clips on the ureter, which was then sectioned by the surgeon with robotic scissors. The kidney was dissected out from all its attachments and the specimen was extracted intact through the vagina in a laparoscopic Endo Catch bag, which was introduced from the vagina by the assistant (Fig. 4B,C). At the completion of the procedure, the port was removed and the robot was undocked. The vaginal incision was closed using a 2-0 polyglactin running suture with an open approach (Fig. 4D). The cadaver was then placed in supine position and a laparotomy was performed to examine surgical site for any visceral injuries that may be unnoticed during the robotic approach.

RESULTS

Lithotomy-transperitoneal Approach

The first cadaver was 5 feet 3 inches tall and weighed 155 pounds, with a body mass index (BMI) of 27.5 Kg/m^2. We were able to obtain access to the peritoneal cavity. However, it was not possible to progress further with the procedure with this approach because of 2 main limitations. The first was the clashing of the robotic arms against the upward-positioned legs, which significantly restricted the range of movements of the robotic instruments. The second issue was the impossibility of adequate bowel retraction, which precluded the progression toward the kidney.

Prone Jackknife Position-retroperitoneal Approach

For the first retroperitoneal procedure, the cadaver was approximately 5 feet tall, 110 pounds of weight, and BMI 21.5 Kg/m^2. The time necessary for setup, including positioning, incision, creation of the retroperitoneal space for insertion of the single-port device, robot docking, and insertion of instruments was 128 minutes. No significant gas leak was noticed during the whole time of the procedure with all ports, except the GelPoint. This occurred because of its large internal ring, which could

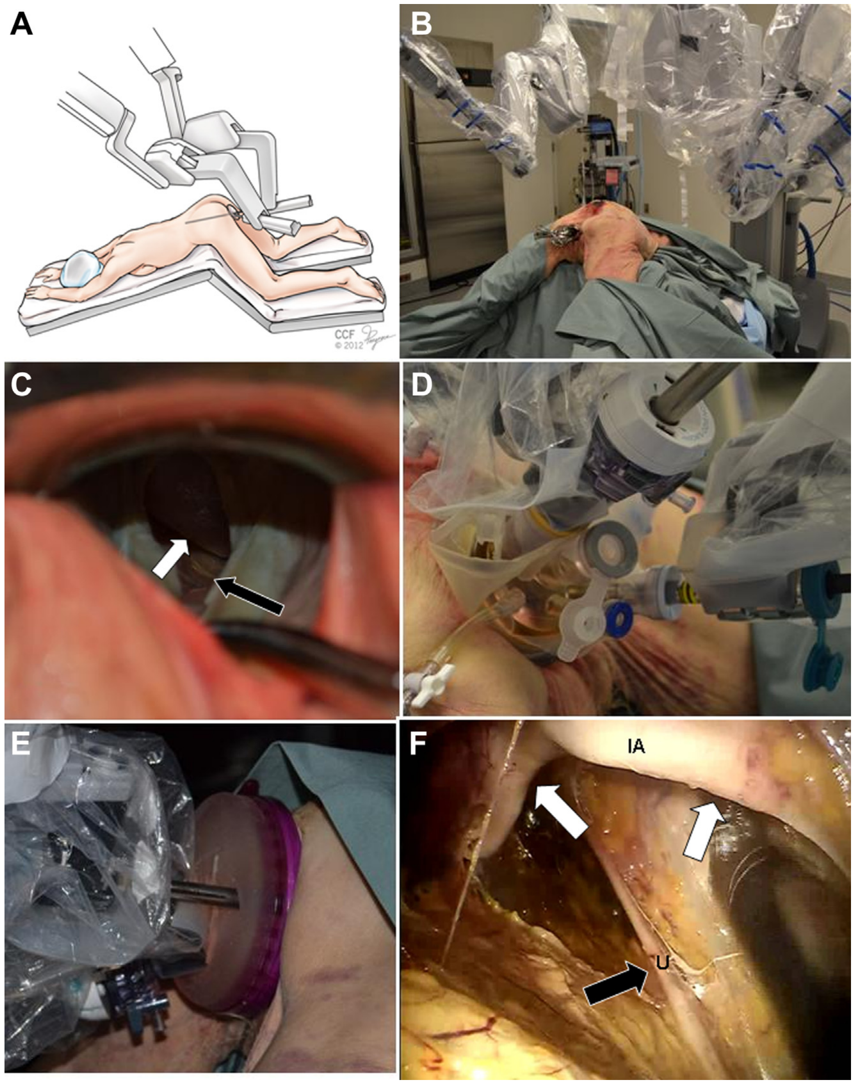

Figure 1. (A and B) Prone jackknife position; **(C)** retroperitoneal access through the vaginal posterior fornix (black arrow) and rectum (white arrow); **(D)** QuadPort+; **(E)** GelPoint; and **(F)** identification of the right ureter (black arrow) anterior to the iliac artery (white arrows). (Color version available online.)

not be completely inserted into the small retroperitoneal space created. Despite the CO_2 leakage from the transvaginal access site, the visualization was not impaired during the procedure.

A right side nephrectomy was successfully completed without the addition of extra ports. Time to identify the ureter was 53 minutes. Dissection and control of the renal pedicle was completed in 21 minutes. Time to dissect the kidney out from all its attachments and extract the specimen was 36 minutes. Total time to complete the nephrectomy, including setup, was 238 minutes. No injuries to intra-abdominal organs or vessels occurred.

Left side nephrectomy was attempted in another cadaver, 5 feet 6 inches tall, 170 pounds of weight, and BMI 27.4 Kg/m^2. In this second retroperitoneal procedure, the time for setup decreased to 45 minutes. During the access, it was noticed a blind-ending vaginal sac. At this point, the dissection was difficult, likely because of fibrosis from prior transvaginal hysterectomy, and rectal injury occurred. The defect was closed with a 2-0 polyglactin running suture through an open approach. Time to identify the left ureter was 170 minutes. Dissection was feasible up to the identification of the left kidney lower pole and took 15 minutes. It was not possible to progress beyond this level. Because of the higher position of the kidney in this cadaver, likely related to the cadavers' height, we were unable to reach further cranially with the robotic instruments.

DISCUSSION

We were able to successfully complete a right side transvaginal R-NOTES retroperitoneal nephrectomy in a cadaver model. To the best of our knowledge, this is the first time that the feasibility of a pure transvaginal R-NOTES was demonstrated. The novel prone jackknife retroperitoneal approach described herein contributed significantly to achieve this goal.

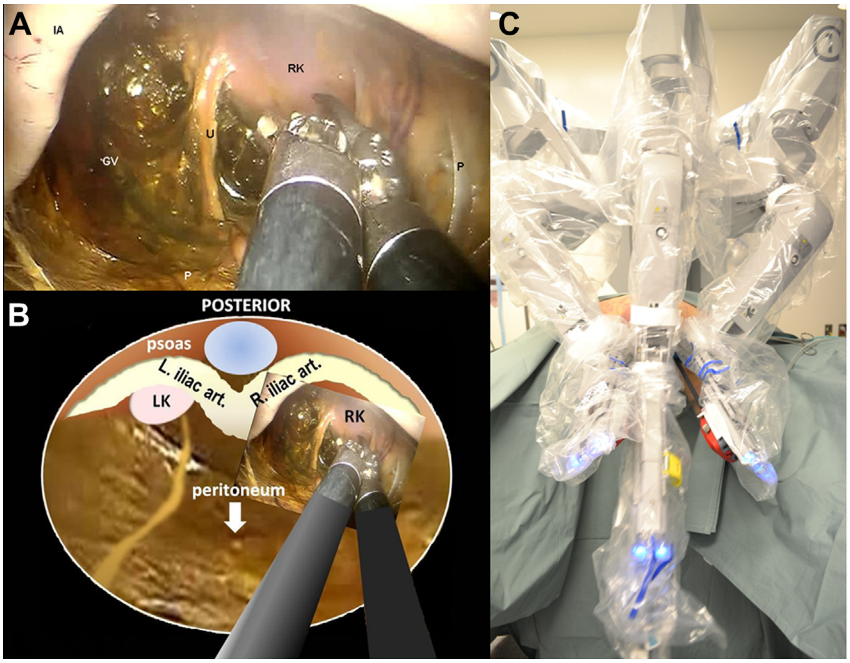

Figure 2. **(A)** Intraoperative view: iliac artery (IA); right kidney (RK); ureter (U); gonadal vein (GV); peritoneum (P). **(B)** Panel A inserted into the context of a schematic representation of the whole retroperitoneal cavity; left kidney (LK). **(C)** External view. (Color version available online.)

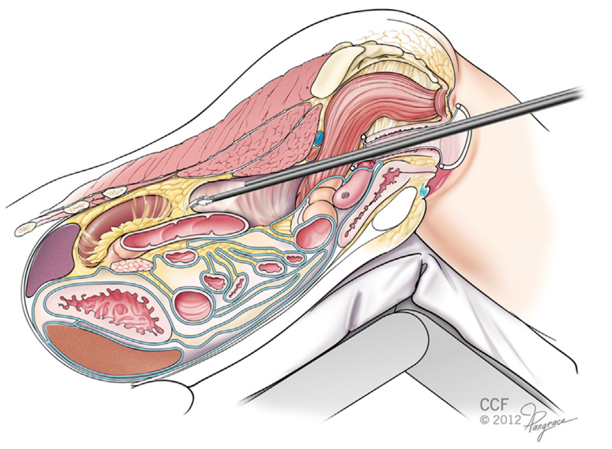

Figure 3. Schematic representation of the retroperitoneal dissection through a sagittal view. (Color version available online.)

Previously, Hagen et al[14] had tried to perform robotic abdominal surgery with intersecting robotic instruments through the vagina of a cadaver in the lithotomy position. They concluded that robotic transvaginal surgery was not feasible with this setup for reasons similar to what we found in the first cadaver of our study.

In order to avoid the clashing of the robotic arms against the legs, we decided to put the cadaver in a prone position, placing the hips at the distal edge of the table and the legs down. A favorable feature of this position for R-NOTES is that it allows the robotic arms to reach the operative field with an adequate angle. The prone jackknife position is commonly used for anorectal surgery.[16] Potential hazards for this position have been reported in the literature, including reduced airway accessibility, increased blood pressure, decreased chest movement impairing pulmonary compliance, and possible face and airway venous congestion.[17] Moreover, the prone position obligates the surgeon to readapt to the retroperitoneal anatomy through an unusual perspective.

Bowel retraction is usually a challenging task with procedures that use a limited working space, such as LESS and NOTES. To address this issue, we decided to access the kidney through the retroperitoneal space. Dr. Marescaux's group in Strasbourg, France, described the retroperitoneal access using standard laparoscopic and endoscopic instruments in the lithotomy position. They reported porcine acute and survival studies, as well as cadaver studies, demonstrating the feasibility of the access for lymphadenectomy, nephrectomy, partial nephrectomy, adrenalectomy, and distal pancreatectomy.[18-20] Zorron et al[21] reported the first clinical case using endoscope and laparoscopic instruments through a transvaginal retroperitoneal access for decortication of a left lower pole renal cyst, with the patient in the supine position. Because of significant leakage of gas to the peritoneal cavity, they needed to add 2 5-mm laparoscopic trocars in the flank. Another option to tackle gas leakage is to insert a Verres needle into the peritoneum to drain the accumulated CO_2.[22]

The retroperitoneal approach bears the potential for injuries to major structures. The rectum must be gently displaced posterior to allow obtaining space to progress dissection into the retroperitoneum. It is important to constantly remember to stay parallel to the longitudinal

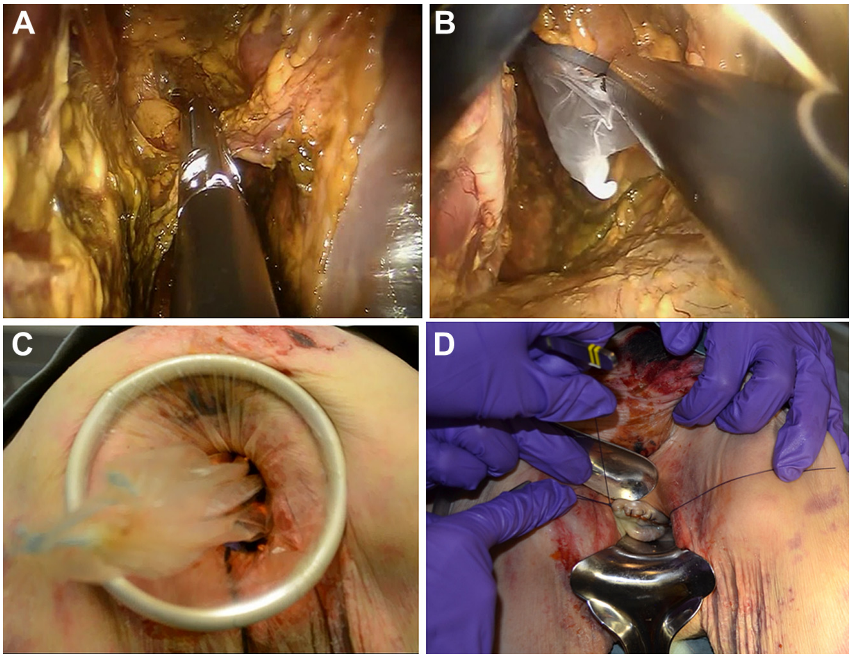

Figure 4. **(A)** Renal hilar control with laparoscopic stapler; **(B)** placement of the kidney into a laparoscopic bag; **(C)** extraction of the specimen through the vagina; and **(D)** closure of the vaginal incision. (Color version available online.)

orientation of the table, avoiding dissecting parallel to the floor. This will help prevent rectal injury or entering the posterior wall muscles, which would lead to missing the correct plane of dissection. The rectal injury during the open access in the third cadaver was probably related to this mistake, along with a distorted anatomy caused by scarred tissue from a previous vaginal hysterectomy. Care must also be taken to avoid injury to sacral nerves. The next major structures that deserve attention are the iliac artery and vein, which must be carefully dissected to identify the ureter located anterior to the vessels. Once the ureter is identified, the dissection is relatively safe up to the kidney. If the ureter is followed cranially, avoiding medial dissection, the infrarenal aorta or inferior vena cava should not impose additional risk. The dissection of the renal hilum represents another challenging step.

Another theoretical limitation, although we did not observe it in any of our experiments, could be caused by the angle from the vaginal fornix to the sacral promontory, which could potentially limit the access to the kidney or cause compression of the iliac vessels by the rigid shaft of the robotic instruments. Preoperative assessment of the pelvic anatomy by thorough physical examination and imaging studies would be extremely important in the clinical setting in order to identify patients that would be unsuitable for this approach.

The reason for testing different ports was simply to help achieve our main goal, which was to demonstrate the feasibility of R-NOTES. Because of the inexistence of a port specifically designed for R-NOTES, we used trial and error to identify which of them would work better. A detailed comparison of the ports was not our focus on this experiment. For the first cadaver (lithotomy position), we used the GelPoint. Although we were not able to complete that procedure, we did not observe limitations from the port itself. We started the second procedure (first cadaver in prone jackknife position) using a QuadPort+, but the trocars built in its cap impose some additional restriction for configuration of instruments in an already limited space. During that procedure, we switched to a GelPoint and we were then able to complete the right nephrectomy. The main disadvantage of the GelPoint for this approach is the large size of its internal ring, which was not adequate for the limited space created in the retroperitoneum. This caused continuous gas leakage with this port, although it did not limit the completion of the procedure with enough working space. In the third cadaver, we used a homemade port. The port worked properly and we did not perceive it to be related with the failure to complete the procedure. Of the ports we tested, the GelPoint and the homemade port provided the best flexibility for configuration of the trocars.

The length of the current robotic instruments is not ideal for R-NOTES nephrectomy. The first cadaver of the retroperitoneal approach was approximately 5 feet tall. Despite limiting the workspace, the small cadaver size was considered an advantage to reach the kidney upper pole and successfully complete the dissection. Moreover, the right kidney is located in a lower position than the left, which was also favorable. In the second cadaver, we were not able to complete the procedure in the left kidney. However, we speculate that this difficulty was likely because of a combination of the cadaver's height and weight, rather than the nephrectomy side. As the dissection progresses in the cranial direction, at some point, the robotic instruments start crossing, increasing the clashing against the scope. We were able to use 2 robotic instruments simultaneously up to the kidney lower pole level. Beyond this point, we often needed to dissect with 1 instrument only. After stapling and sectioning the hilar vessels from the vagina by the assistant, the kidney was pulled down and rotated with the grasper, allowing the completion of lateral and upper pole dissection with scissors.

Further experimentation will likely make us improve some aspects of the technique; however, longer robotic instruments would be likely necessary to overcome all the issues. Potential initial clinical applications of this technique would probably be the treatment of benign ureteral and kidney lower pole conditions, such as ureterolysis for retroperitoneal fibrosis or decortication of a lower pole renal cyst. However, this should be further evaluated in the laboratory and all the safety issues should be addressed before any attempts in the clinical scenario. Improvements in the technique and the development of new robotic instrumentation are still needed, especially for procedures that include dissection further cranial to the lower pole. If current limitations are surpassed, this technique could, in theory, be used for the surgical treatment of any retroperitoneal structure within the reach of the robotic instruments. This approach may provide a reasonable exposure of the ureter in its entire length, kidney, adrenal, retroperitoneal lymph nodes, psoas muscle, and iliac vessels.

Beside the technical restrictions of this approach, we must also acknowledge several limitations of our study. This was an experimental cadaver study with a short number of procedures attempted and was conducted by experienced robotic surgeons. Although the cadaver model provides us with an ideal assessment of anatomic aspects, the absence of bleeding limits our ability to fully evaluate the safety of this approach. Nevertheless, the present study is essentially a proof of concept. Its main merit is to propose a different positioning and access approach for transvaginal R-NOTES, which allowed its feasibility. Because of the limitations mentioned, reproducibility of this technique was not achieved and still needs to be proven with further experiments.

CONCLUSIONS

Transvaginal R-NOTES nephrectomy is technically challenging, but feasible in select female cadavers. The prone jackknife position and the retroperitoneal approach were instrumental to accomplish this goal. Further refinements of the technique, as well as development of the available platforms and instrumentation, are awaited in order to make this approach safe and reproducible.

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EDITORIAL COMMENT

The authors present a creative and impressive technical feat of performing a prone cadaveric robotic natural orifice transluminal endoscopic surgery (NOTES) retroperitoneal transvaginal nephrectomy. This is certainly a pioneering effort. I could not help but think that their experience must have been similar to the first percutaneous nephrolithotomy, in that the anatomy is being presented from such a novel vantage point that new landmarks have to be conceived because few precedents exist. Just the thought of approaching the kidney in this "outside the box" approach is fascinating. Overall, the approach was born out of necessity. First, a prone patient leaves room for the bulky robotic arms, potentially limiting clashing with the patient's legs. Second, staying in the retroperitoneum obviates bowel retraction.

So many aspects of this unfamiliar anatomic approach are potentially disorienting, and it is, therefore, no surprise that they were only able to complete 1 of 3 attempted cases. Furthermore, the assistant performed some key maneuvers rather than the console surgeon (hilar control and clipping the ureter). Normally one would hope for another group to duplicate the experience, but here we might first just be satisfied with the authors' repeating their own success. Caveats aside, many unanswered questions remain before clinical cases can be accomplished: can the upper pole be consistently accessed from this approach? Is the left or right kidney easier? What morphometric characteristics of the patient's bony pelvis are permissive? Is there a body mass index cutoff? A height cutoff?

As this and other pioneering groups forge ahead in pursuit of "scarless" surgery, we have to keep in mind that female patient willingness or desire to undergo NOTES surgery is not a foregone conclusion. In fact, in a recent study of perceptions of NOTES and laparoendoscopic single site surgery cholecystectomy, the perception of NOTES was not favorable.[1] We should keep asking ourselves if this is real progress, or progress for the sake of progress? Ultimately, patients will determine the answer.

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REPLY

We would like to thank the reviewer for his valuable and encouraging comments. Indeed, the whole experience of conceiving, planning, and executing this project was exciting. As you highlighted, the initial attempt done with the cadaver in the lithotomy position resulted to be unsuccessful. This represented a key moment in this learning process, challenging us to think about the causes for the failure and what we could do differently to overcome them. After a few days reflecting, drawing sketches, and reviewing many sagittal section images of the abdomen and pelvis, we finally had a potential solution: move the legs down and obtain a retroperitoneal access. Because of the unconventional nature of the approach, even among us there was a bit of skepticism. The successful first experience with the new approach encouraged us to continue. In the next attempt, we did not repeat the same success. Many new questions arose, pertinently pointed above by the reviewer. Further work is needed to answer each of them.

One might argue that we are reaching the limit of what is achievable for robotic natural orifice translumenal endoscopic surgery (R-NOTES) with the current robotic platform and instruments. For example, a robotic stapler has become recently available (Vessel Sealer, Intuitive Surgical Inc.), which might give more control to the console surgeon in such a procedure. However, again, this was not designed for this application and it is unlikely it will be the solution.

Another important question raised by the reviewer is to whether there will be a well defined role for NOTES in the future, and the perception and view of patients represent determining factors. In the population survey cited, 300 women from different age groups and educational backgrounds received anonymous questionnaires about a hypothetical cholecystectomy through transvaginal NOTES, umbilical single-port, or conventional laparoscopic approaches. Regarding the transvaginal route, the greatest concern among the responders was related to dyspareunia.[1] However, this is not the only study reported in the field. In a recent comprehensive literature search, a total of 18 studies were found, with conflicting findings.[2] Overall, safety and efficacy remain the key factors in the decision-making process of patients. In 1 of these studies, Peterson et al[3] assessed the perception of 100 women to transvaginal NOTES and found that 70% would consider a transvaginal procedure and 68% indicated that they would prefer NOTES if there was equivalency between laparoscopic and transvaginal approaches.

However, even more important than the subjective perception of hypothetical situations is investigating the actual incidence of such potential complications after NOTES procedures. In a prospective randomized trial by Noguera et al,[4] dyspareunia did not occur in any of the 20 patients randomized to transvaginal NOTES cholecystectomy at 1, 6, and 12 months after surgery.

The best way to address all these open questions is to further investigate carefully and objectively. This is our responsibility as researchers and it represents the best way to find the correct answers and to ultimately enable our patients to make better informed decisions.

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