

Case Report

Report on 31 Cases of Laparoscope Assisted Trans-vagina Endoscopic Cholecystectomy

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ABSTRACT **objective:** To investigate the feasibility, safety and superiority of laparoscope assisted trans-vagina endoscopic cholecystectomy used in clinical application. **Methods:** 31 patients with gall-bladder diseases were treated with laparoscope assisted trans-vagina endoscopic cholecystectomy. Through a 5mm incision below the umbilicus, inserted laparoscopic guide endoscope and NOTES manipulator enter abdominal cavity through posterior fornix 15mm incision. After the endoscope can capture stable vision, withdraw the laparoscope and insert normal laparoscopic manipulator. With the endoscope monitoring, cholecystectomy was accomplished. **Result:** All of patients were accepted this new operation. The operation time was 60~150 minutes, and the average time was 85 minutes. No postoperative draining, bleeding and biliary fistula occurred in those patients. There was no obvious scar in belly, and all of patients felt no pains after operation. The average inpatient time was shorten, the medical cost decreased. **Conclusion:** Laparoscope assisted trans-vagina endoscopic cholecystectomy is feasible and safety, which has obviously superiority compared to traditional laparoscopic operation, and should be widely applied at some conditional hospitals.

Key Words: NOTES; Vagina; Endoscope; Cholecystectomy

With the rapid development of minimally invasive technique and the gradually increased desire of patients, traditional laparoscopy has not met higher needs of doctors and patients for minimally invasive surgery. Therefore, a natural orifice trans-luminal endoscopic surgery (NOTES) has emerged today. by means of body's natural orifices (such as mouth, anus, vagina and urethra etc.), soft endoscope can be put into patient's body, then punctures hollow organs (such as stomach, rectum, vagina and bladder etc.) and enters into the abdominal cavity; under the guidance of the endoscope, various operations was completed, and thus to achieve minimally invasive effects such as no abdominal wall scar, lighter postoperative pain, more aesthetic appearance and so on. Due to relatively high technical difficulty of NOTES,

and many other problems such as potential intra-abdominal infection, organ puncture hole fistula and spatial positioning difficulties etc, so the majority of existing studies on NOTES in the world are still at the stages of animal experiment and clinical exploration. After repeated demonstrations and preliminary preparation, successful accomplishment of animal experiment, the design and manufacture of special minimally invasive instruments for NOTES, on May 24, 2009, we successful performed Asia's first trans-vagina endoscopic cholecystectomy. Up to now, we have completed 31 cases of surgery, all patients had no significant postoperative pain and no scar left on the abdominal wall, and thus reached satisfactory cosmetic effect.

CLINICAL DATA AND METHODS

General information

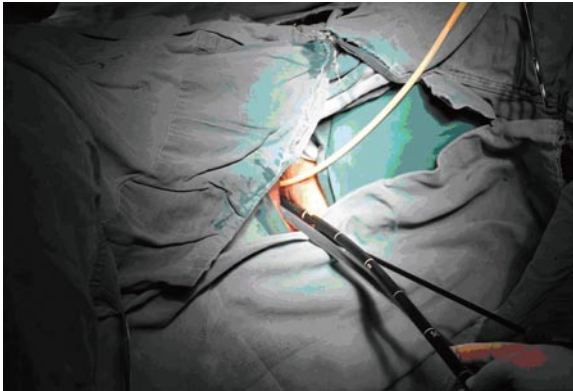
From May to Nov. 2009, we have completed 31 cases of trans-vagina endoscopic cholecystectomy. Patients' age was 32 to 58 years old with average 39. 22 years. In all the cases of gallbladder stone, 5 cases with serious pelvic adhesion had past history of lower abdominal surgery; 1 cases has been treated with radical

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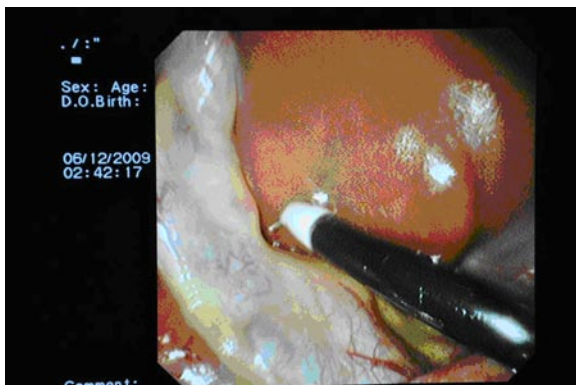
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rectal cancer surgery before (Dixon surgery); 3 cases with pelvic structural abnormalities have accepted total hysterectomy; 10 cases of multiple gallbladder stone accompanied by sub-acute cholecystitis and severe gallbladder edema; 3 cases of multiple gallbladder stone with anatomically structural abnormalities; 9 cases of gallbladder polypoid lesion.



Fiber electronic gastroscope into the abdominal cavity through the natural orifice—vagina



Cholecystectomy under the guide of Fiber electronic gastroscope

Surgical methods

Cut the skin and fascia and made a 5mm incision at the lower edge of belly button, then placed a 5 mm laparoscope into abdominal cavity for exploration. Under a laparoscopic monitoring, made a 1.5cm incision at the posterior fornix and put a 8mm Olympus electronic gastroscope (GIF TYPE Q180) and a 7mm silicon tube in which special surgical devices for NOTES (Tonglu Youshi Co.) can be placed into abdominal cavity respectively. Pulled out 5 mm laparoscope at the lower part of belly button after obtaining stable endoscopic images,

then put general laparoscopic instruments into a trocar. Under an endoscopic monitoring, accomplished cholecystectomy and took out specimens from the incision at the posterior fornix. Sutured the incisions at the umbilical region and the posterior fornix respectively, and then packed vagina with sterile gauze. In the course of surgery, gentle operations, strict hemostasis and the prevention of biliary fistula were necessary. Drainage device was not needed by any postoperative patient.

RESULTS

Thirty-one patients were treated successfully with surgery without additional intraoperative laparotomy. Operative time was 60 to 150 minutes, and average 85 minutes. Surgical procedure was precise and meticulous without postoperative drainage, bleeding, biliary fistula and other complications. The sterile gauze packed in the vagina was removed at 24 hours after operation. After sutured the 5mm incision, owing to umbilical region itself has relatively more folds, so there was almost no visible scar could be found. In addition, owing to the short incision, all patients had no significant postoperative pain. Moreover, the patients could get out of bed for movements at 6 hours after surgery, some of them who recovered most quickly could discharge from hospital at 24 hours after surgery, and average hospitalization time was 2 days. A 1-6 month follow-up indicated treatment effects were quite satisfactory without any complications.

DISCUSSION

The concept of natural orifice trans-luminal endoscopic surgery (NOTES) was first proposed by Wilk in 1994[1]. In 2004, American doctor Kalloo first reported animal experiments on trans-stomach intra-abdominal exploration and liver biopsy [2] which confirmed the feasibility and security of NOTES. Since then, many doctors have carried out corpse studies or animal experiments on NOTES respectively [3-7].

The surgical approach adopted by natural orifice trans-luminal endoscopic surgery in foreign countries was commonly “trans-stomach approach”, that is, making use of electrocoagulation to make an ostiole at the anterior wall of stomach, and then using a balloon to dilate it so as to ensure an endoscope can be passed the ostiole smoothly. In the current technical conditions, this approach will bring about not only unreliable close of puncture hole at the gastric wall and potential intra-abdominal infections, but also easily lead to flipped endoscopic images and reverse operation. Since 2007, our research group began to study natural orifice trans-luminal endoscopic surgery. By means of animal experiments, we selectively compared the advantages

and disadvantages of various surgical approaches for NOTES (Trans-stomach, trans-colon, trans-vagina), and confirmed that endoscope-assisted trans-vagina approach was more easy for the completeness of surgical operation than other approaches. Moreover, its puncture hole could be closed more easily compared to that of stomach and colon walls, in addition, intra-abdominal infection could be effectively controlled by preoperative vaginal preparation. By means of the advantages above, a safe and reliable access for trans-vagina surgical approach for NOTES was eventually established.

The existing NOTES commonly adopted a common soft-digestive endoscope such as electronic gastroscope and colonoscopy etc. It is composed of a more than 1 meter long flexible shaft and a bendable head with joints. The bendable head is about 10 cm long, it can horizontally and vertically move under the control of a navigation gear; moreover, a built-in mini-camera in the head can get stable images. Early animal experiments confirmed that it was difficult to complete some complex surgical operations by using such endoscope alone [8]. The reasons can be described as follows: 1) relatively less traditional endoscopic operating approaches lead to sufficient surgical instruments can not be placed; 2) low degrees of freedom (DOF) of endoscope causes unsatisfactory surgical area; 3) the lack of multi-mission platform will make surgeon to be hard to independently complete a number of operations; 4) as regard to a dual-approach endoscope, There is also a lack of sufficient operational angle between different surgical instruments in the two surgical approaches. To solve these problems, some foreign research institutions have in succession launched a series of new-type endoscopic operating systems, such as "ViaCath" endoscope (Hansen Medical Inc, USA), "Cobra" endoscope (USGI Medical Inc, USA), "R" endoscope (Olympus Co, Japan) and "HVSPS" endoscope (Munich University of Technology) [9-12]. Although these new endoscopes can resolve the issues above to a certain extent, however, all of them have some defects such as complex structure, difficult maintenance and high cost etc.

Based on the premises of ensuring a safe, reliable operation and on domestic clinical practices, we replaced "simple" NOTES which solely relies on endoscopic equipment with "combined" NOTES which combines endoscopic and laparoscopic techniques. By means of a 5mm concealed incision at the umbilical region, an ordinary laparoscope or conventional endoscopic instrument can be placed into patient's abdominal cavity, which will safely guide the endoscope to enter into abdominal cavity through the posterior fornix and compensate for the defects caused by insufficient operation equipment of conventional digestive endoscope. As relatively more folds at the umbilical region, so a 5mm concealed incision will not lead to visible scar on the abdominal

wall; In addition, owing to scarce distribution of sensory nerve within a 1.5cm region around the umbilicus and at the vaginal fornix, therefore, based on the existing technological conditions, "laparoscope assisted trans-vagina endoscopic cholecystectomy" has farthest realized the original intention of NOTES--" pain-free and scar-free".

Marescaux, a French doctor, has completed the world's first laparoscope assisted trans-vagina endoscopic cholecystectomy[13]. In this surgery, a right-upper abdominal incision was necessary for percutaneously implanting a 3mm surgical grasping forceps which was used to lift and pull gallbladder so as to complete surgery. Due to damaged integrity of peritoneum at the incision, so such surgery will not only lead to small scars on the abdominal wall, but also result in patients' postoperative pains. Based on the characteristics of trans-vagina endoscopic surgery, we designed and invented some special operating equipment. After putting these equipments into abdominal cavity through the incisions at umbilical region and vagina, all surgical operations can be completed in the absence of surgical grasping forceps above; at the same time, surgical trauma can be further reduced and postoperative abdominal pain can also be significantly reduced, which further shortened average hospitalization time and thus significantly reduced medical costs.

While natural orifice trans-luminal endoscopic surgery is still in its exploratory stage of clinical application, the lacks of endoscope with high cost performance and appropriate specialized instruments, and there is also some distance to go before this new surgical method is widely applied, but we think that, under the conditions of existing technologies, "laparoscope assisted trans-vagina endoscopic cholecystectomy" is worthwhile to be applied at some conditional hospitals. With the continued progresses of technology and gradual improvements of related equipments and appliances, there is no doubt that NOTES will become more mature and thus step into clinical application in the near future.

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