Introduction

NOTES (natural orifice transluminal endoscopic surgery) is an innovative idea developed by Kalloo et al. [1]. A variety of operative procedures in the animal model followed [2–14]. In NOTES, a flexible endoscope enters the abdominal cavity (or thorax) via the transesophageal, transgastric, transcolonic, transvaginal or transvesical route. Almost all organs can be reached by one of these approaches. Operations in humans followed the animal experiments, especially cholecystectomies and appendectomies [15–24]. But the use of flexible endoscopes in the abdominal cavity has proved to be difficult and time-consuming. Only a few patients in different centers have been operated on using this technique, and all the operations were performed with the help of at least one abdominal trocar (with only one exception, a transvaginal appendectomy [24]).

We and others gathered experience with the transvaginal approach from the beginning of the laparoscopic era by removing colon segments and spleens through the posterior fornix of the vagina [25]. Later this technique was abandoned for this purpose, but the approach was continuously used by gynecologists for laparoscopic diagnosis and resection. Hence, we opted for the transvaginal approach when starting NOTES cholecystectomy in June 2007, and instead of a flexible endoscope used rigid instruments as in daily laparoscopic surgery [26, 27]. This technique has all the possible advantages of NOTES, but can be performed routinely, comparable to “conventional” laparoscopic surgery. This is why we want to report our experiences of the first year.

Results: All 68 operations were finished successfully without conversion, with a mean operation time of 51 minutes; in three additional cases severe pelvic adhesions prevented further transvaginal progress. There were no intraoperative or immediately postoperative complications, but one patient presented with a Douglas pouch abscess 3 weeks after surgery. Gynecologic follow-up exams 1 week after surgery were unremarkable. All patients were interviewed 3–10 months after surgery and had no abdominal or gynecological complaints including in relation to sexual intercourse.

Conclusion: Transvaginal NOTES cholecystectomy with rigid instruments can be safely and effectively performed in daily routine.
Patients and methods

Patients presenting for cholecystectomy with classical indications as for laparoscopic cholecystectomy were considered eligible for this new approach. Initially, we started with easy cases, i.e., nonobese patients who had not undergone previous operations and had no signs of acute cholecystitis. With growing experience, this technique was offered to all patients except those with contraindications, such as a body mass index (BMI) above 35, those who had had previous surgery or radiation therapy to the lesser pelvis, in whom severe adhesions could be expected, and those with endometriosis.

All the NOTES procedures were prospectively documented in our database. Age, history, previous operations, indication, degree of inflammation, operative time, intraoperative and postoperative complications, and length of hospital stay were recorded. Discharge was planned for the 2nd postoperative day. One week after the operation the patients were examined by the gynecologists in our team. The cervix and the healing wound in the posterior fornix of the vagina were inspected. Bimanual palpation and transvaginal ultrasonography of the uterus, ovaries, and pouch of Douglas were performed. After no less than 3 months patients were interviewed about any late complications in the abdomen or vagina. They were asked about sexual intercourse and any negative experiences. A structured questionnaire was used, and the interview was carried out on the telephone by one of the authors.

Our operative technique has been approved by the local ethical committee of the Hamburg Chamber of Physicians (Ärztekammer Hamburg), including the quality control described in the present study.

Operative technique

With the patient in the lithotomy position, a 5-mm incision deep in the umbilicus is made and the abdomen is insufflated using a Veress needle. Diagnostic laparoscopy is performed with a 5-mm optic. With the patient in a steep Trendelenburg position, a 5-mm mandrin is inserted in the posterior fornix of the vagina under laparoscopic guidance and replaced by a 5-mm extra-long dissector (Storz, Tuttingen, Germany). Alongside this instrument a 10-mm trocar is inserted. From now on the extra-long 10-mm optic, 45° (Olympus, Hamburg, Germany), is used from there (Fig. 1) and the optic in the umbilicus is replaced by another dissector.

After moving the patient to the anti-Trendelenburg position, the gallbladder is retracted with the instrument coming through the vagina, which is then dissected through the umbilicus (Fig. 2). When the cystic duct and the cystic artery are identified, they are clipped through the umbilicus with a 5-mm clip device (Ethicon, Hamburg, Germany) and divided from there. The gallbladder is then mobilized with an electric hook. For removal the 5-mm optic from the umbilicus is used again. A removal bag can be used through the 10-mm vaginal trocar. The gallbladder is then pulled through the 10-mm colpotomy, which can be enlarged bluntly with a clamp if needed. The defects in the vagina are sutured with resorbable thread. A single shot of antibiotic is given. Postmenopausal patients receive estrogen suppositories for 5 days. Patients are advised not to have sexual intercourse for 2 weeks.

Results

From June 2007 to June 2008, 445 cholecystectomies were performed in our department, 298 in female patients, and in 68 of them (23% of the female patients) the transvaginal technique was used. In the last 6 months it was accepted by 25% of the female patients. In all cases the indication was symptomatic cholecystolithiasis. Eleven patients had acute or chronic inflammation of the gallbladder. The average age of the 68 patients was 50 years (range, 16–76 years); the average BMI was 25.4 (range, 16–35). Twenty-six patients had had previous abdominal operations: 10 of them had had a hysterectomy and/or adnexitomy, while 16 had other previous operations. We operated on the first 8 patients together with one of our gynecologic colleagues. They inserted the vaginal instruments, removed the gallbladder, and closed the defects in the vagina. All further operations were performed by two surgeons. The average operative time overall was 51 minutes (range, 30–100 minutes); for the last 40 cases it was 47 minutes (range, 30–85 minutes). In comparison, our mean operative time for laparoscopic cholecystectomy (n = 430) was 43 minutes in 2006. In the transvaginal group, there were no intraoperative complications. In 3 cases an additional abdominal trocar (2-mm or 5-mm) was required; in one of these cases a drainage tube was placed in this incision.

In three further patients the transvaginal approach was planned, but we found severe adhesions in the lesser pelvis during the di-
agnostic laparoscopy. In these cases we proceeded to the conventional laparoscopic technique. Thus, on an intention-to-treat basis, transvaginal cholecystectomy was feasible in 96% of all attempted cases.

The postoperative course in hospital was uneventful in all cases. Patients only complained about the well-known consequences of pneumoperitoneum; none reported on pain caused by the vaginal manipulation. Sixty-four patients were discharged on the 2nd postoperative day, three on the 3rd, and an older woman (72 years of age) went home on the 5th postoperative day. Fifty-nine patients presented for the 1-week gynecologic follow-up. The patients had no complaints, and the physical examination including vaginal endosonography revealed no pathological findings. One patient, who did not undergo the 1-week follow-up exam, presented 3 weeks after surgery with an abscess in the pouch of Douglas. It was drained laparoscopically and healed well.

All 68 patients were interviewed 3–10 months after surgery (mean, 5 months). There were no complaints concerning the cholecystectomy or the transvaginal approach. Forty-eight of the patients had had sexual intercourse after the operation. None of them noticed any changes.

Discussion

At present, this technique of transvaginal cholecystectomy appears to be the only NOTES technique that can be reliably used in humans in daily routine. Since the first description by us in this journal in 2007 [26], only a few papers have been published about NOTES cholecystectomy, mostly case reports or small series with low patient numbers [15–24], and only one has a meaningful follow-up period [28]. Ramos et al. use the same technique as described by us, except that they use two abdominal trocars. The German Society of General and Visceral Surgery (Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie) has registered more than 300 NOTES operations by now, almost all transvaginal cholecystectomies using this technique. The present report shows that transvaginal cholecystectomy is feasible in adult women of any age, even those who are obese, who have had previous abdominal operations, and those with gallbladder inflammation. However, in our experience the transvaginal approach is somewhat more demanding than the conventional laparoscopic technique, resulting in a longer time requirement for both patient positioning and performance of the procedure. Although operative time is currently decreasing for the transvaginal approach, we must point out that this group is positively selected with regard to degree of inflammation. Furthermore, all these operations were performed by the four most experienced surgeons of the department. In the first eight cases we needed the help of our gynecologic colleagues. But the vaginal part of the operation is easy for a surgeon to learn, and is always under visual monitoring via the umbilical laparoscope. This is why we were able to perform all the remaining operations with just two surgeons, as we do in conventional laparoscopic cholecystectomy.

It is difficult to judge whether this technique is laparoscopically assisted transvaginal surgery or transvaginally assisted laparoscopic surgery: on the one hand, the decisive dissection steps are performed through the umbilical port, but on the other hand two instruments are inserted through the vagina and only one through the umbilicus. The defects made by a 5-mm and a 10-mm instrument in the vagina are five times as large as the one in the umbilicus, and the removal is performed transvaginally. For this reason, we understand this operation as a laparoscopically assisted transvaginal cholecystectomy.

Twenty-three percent of our female patients accepted the offer of transvaginal cholecystectomy, mostly for cosmetic reasons as this operation leaves no visible scar. This percentage has only slightly increased to date, but it may increase further when the transvaginal approach becomes more accustomed to laparoscopic surgery. Nevertheless, in our opinion it will always be an additional tool, while the conventional laparoscopic technique will continue to be the basis for minimal invasive operations in the abdominal cavity.

All operations in which we decided to proceed transvaginally were successfully finished using this technique without intraoperative complications. When severe adhesions were detected during diagnostic laparoscopy (n = 3), the intervention was switched to the conventional laparoscopic technique. The postoperative course was uneventful in all cases, and the length of hospital stay was similar to that after laparoscopic cholecystectomy in our country. The gynecologic follow-up after 1 week revealed no negative findings, and in the interview after a minimum of 3 months no patient had any complaints with relation to either the cholecystectomy or the transvaginal access, including any relating to impairment of sexual intercourse. There was only one complication, namely in the patient with a pouch of Douglas abscess.

Why should we perform NOTES? Potential arguments for NOTES are a better cosmetic result, fewer wound infections, fewer trocar hernias, less pain, a shorter hospital stay, and less time off work. Arguments against could be that it is a more difficult operation which may take longer, have more complications, and, finally, it is more expensive. Only one of these potentially controversial issues can be answered today: The cosmetic result of an operation that leaves no visible scars is ipso facto superior to any kind of transabdominal approach. All other issues need large comparative studies to be answered. Expected advantages for NOTES in relation to infection, hernia, pain, hospital stay, and time off work are still only theoretical, and these possible advantages will have to be compared to the possible disadvantages mentioned above.

Assuming that there are good reasons to perform NOTES in the long run, which approach should be chosen and what instruments used? Today, there is only sufficient experience with the transvaginal approach; in gynecology it has proved to cause even fewer complications than the abdominal access [29]. All other possibilities of inserting instruments, whether somewhere through the gastrointestinal wall or the bladder, are experimental. The problem of the insertion of sterile instruments into the abdominal cavity has not been solved, and nor has the problem of closure. Finally, the flexible instruments that are on the market today are much more difficult to use for abdominal surgery.

In summary, this medium-size series shows that there is a NOTES technique that can be used in daily routine in humans. However, only when it is in more widespread use, with larger case numbers and longer follow-up, will the true value of transvaginal cholecystectomy be elucidated. Finally, the question as to whether it is really superior to conventional laparoscopic surgery, and, if so, in what respects, can only be answered in large comparative studies.

Competing interests: None
References