NOTES Rigid Transvaginal Cholecystectomy

17

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Abstract

Cholecystectomy is one of the most frequently performed operative procedures in gastrointestinal abdominal surgery. The concept of NOTES moves the reduction in access trauma one step further by using a natural orifice as an access route to the intra-abdominal cavity. NOTES stands for a reduction in access trauma by approaching the abdominal cavity by natural orifices as much as possible for a safe performance of the necessary procedure. Based on their previous experience with colpotomy and surgical procedures, transvaginal hybrid NOTES technique with rigid standard instruments for cholecystectomy was developed. On the contrary to the method with flexible endoscopy, this technique was comprehensible to surgeons. The most common techniques of NOTES cholecystectomy have been the hybrid transvaginal with the aid of rigid laparoscope. The need to convert to laparoscopy was absolutely minimal. The overall incidence of postoperative complication was extremely low and similar between the two most frequently used techniques. First comparative trials have been published demonstrating the only possible advantage of these NOTES Hybrid procedures over classic laparoscopic cholecystectomy regarding the cosmetic result.

Keywords

Cholecystectomy · Transvaginal cholecystectomy · NOTES · Transvaginal surgery

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Introduction

Cholecystectomy is one of the most frequently performed operative procedures in gastrointestinal abdominal surgery, and the introduction of minimal-access surgery was mainly pushed by the success of laparoscopic cholecystectomy among patients [1, 2]. With the advent of the NOTES concept into the endoscopic and surgical world, some anticipated that NOTES cholecystectomy could repeat a similar success story, facilitating the introduction of transgastric cholecystectomy [3–8].

The principle of minimal-access surgery is the reduction in access size and trauma, aiming for a shorter patient recovery, improved postoperative well-being, better cosmesis, fewer postoperative restrictions in order to get the patient quickly back to full physical and psychological abilities, and possibly an improved long-term outcome [9]. The latter could be achieved by a lower wound infection rate and by fewer incisional hernias over time.

The advantage of this concept of minimal-access surgery over conventional open surgery has been clearly shown in the past decades [10, 11]. It must be emphasized that the improvements in patient care 20 years ago with the advent of minimal-access surgery were not only caused by the reduction in abdominal incisions, but also caused by conceptual changes that came along with rethinking perioperative care [12].

The concept of NOTES follows that line of thinking and moves the reduction in access trauma one step further by using a natural orifice as an access route to the intra-abdominal cavity [7, 8, 13]. NOTES represents a reduction in access trauma by approaching the abdominal cavity by natural orifices as much as possible for a safe performance of the necessary procedure. The "hybrid" solution uses a natural orifice and limits access via the abdominal wall by reducing number and size of ports. Further minimizing access trauma at the abdominal wall could possibly lead to less postoperative pain, improved recovery from surgery, fewer postoperative complications, including wound infection and incisional hernia [8, 13].

However, initial experimental and clinical experience quickly revealed the technical difficulties posed by the use of a flexible endoscope for complex intra-abdominal operative procedures, along with the shortcomings in training and experience in flexible endoscopy by most surgeons [8, 13, 14].

The Transvaginal Technique of Laparoscopic Hybrid Cholecystectomy

Facing these difficulties, the transvaginal approach quickly came to the mind of surgeons, as this route has been used for many decades by gynecologists and for more than 10 years by general and GI surgeons for larger specimen retrieval such as spleens and colon segments [15–20].

In the spring 2007, Bessler and Marescaux were the first to remove a gallbladder transvaginally with flexible endoscopes. Both used several additional mini-trocars or instruments to assist the flexible endoscopic instrumentation [21, 22]. The technical difficulties of using insufficient instruments made it very difficult for the average GI surgeon to perform the procedure safely and to get through the learning curve quickly.

In June 2007, based on their previous experience with colpotomy, Zornig et al. [23] developed the transvaginal hybrid NOTES technique with standard, rigid laparoscopic instruments for cholecystectomy. Contrary to the method with flexible endoscopy, this technique was easier for surgeons to understand, and it could more readily be put into practice by surgeons with experience in advanced minimal-access surgery.

Zornig et al. describe their original technique as follows [23, 24]: The patients are placed in the lithotomy position. The vagina is prepped around the introitus and inside with an antiseptic fluid which is appropriate for mucosa. The operation starts with an incision of 5 mm inside the umbilicus for insufflation with a Veress needle, which is subsequently replaced by a 5-mm port through which a 5-mm rigid laparoscope is inserted. Diagnostic laparoscopy is performed,

and the patient is put in a steep Trendelenburg position. The cervix is fixed by a clamp, and a metal bar is inserted into the uterus to lift it up. From the umbilical trocar, a good view can be had of the pouch of Douglas (Fig. 17.1). This allows for the inspection of all important anatomical landmarks and the "triangle of safety" as mentioned by Roberts [25].

A 5-mm extra-long dissector is inserted through the posterior fornix of the vagina, and beside that an extra-long 10-mm port is inserted for the laparoscope (Fig. 17.2). The camera is moved to the transvaginal port, and a 5-mm dissector is inserted through the umbilicus.

The gallbladder is retracted by the transvaginal instrument, and the dissection of the triangle of Calot is performed by the umbilical instrument (Fig. 17.3). The cystic artery and duct are identified and clipped with a multi-fire clip applier placed through the umbilical port. The gallbladder is removed from the liver bed with a monopolar hook. The scope is then moved back to the umbilical port, and the gallbladder is removed through the 10-mm port site in the vagina. If required, the port site can be widened with a blunt clamp. After releasing the pneumoperitoneum, the incisions in the posterior fornix are closed with absorbable suture (Fig. 17.4).

A single dose of prophylactic antibiotics with cefuroxime and metronidazole is administered. Postmenopausal patients receive estrogen suppositories for 5 days for better wound healing. Sexual intercourse should be avoided for 2 weeks, as originally described by Zornig [23].

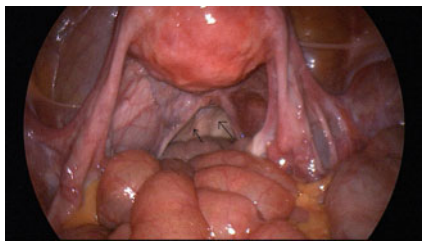

Fig. 17.1 Laparoscopic view in the pelvic region and vaginal area for penetration of the transvaginal trocars and instruments

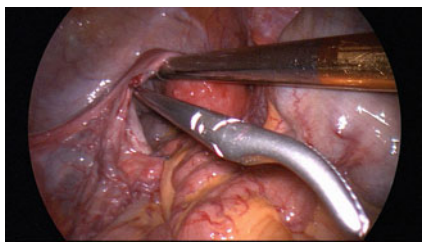

Fig. 17.2 Insertion of the 10-mm camera and one grasper

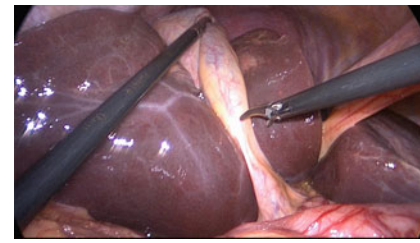

Fig. 17.3 Gallbladder is exposed along with the cystic duct and the hepatoduodenal ligament, to check all necessary anatomical landmarks

Fig. 17.4 Closure of the vagina with a colposcope under direct vision

Results

1. **The Hamburg Results**:

The group in Hamburg, Germany, summarizes their results as follows [24]: All operations (n = 204) could be successfully performed in the described method except one case (0.5%). The latter case was converted to a traditional laparoscopic cholecystectomy due to severe acute

inflammation. In 9 cases (4.5%), an additional abdominal port was used for larger clips, drainage, or a linear stapler.

The average operation time was 50 (23–110) minutes. In 9 cases (4.5%), the transvaginal approach was abandoned and no instruments were inserted through the vagina due to difficulties of the inspection of the pouch of Douglas. The most common reason for this decision was adhesions in the pelvis. These patients were not included in the group of the 204 patients.

There was one (0.5%) intraoperative and two postoperative (1.0%) complications. During the insertion of the transvaginal port, the urinary bladder was perforated with a 5-mm dissector in a patient with a previous hysterectomy. A transurethral catheter was placed for 3 days, and the injury healed spontaneously as was shown using contrast radiography. One patient (0.5%) developed a biliary fistula from the liver parenchyma and a laparoscopic closure with a suture on postoperative day 3 was performed. The other (0.5%) postoperative complication was an abscess in the pouch of Douglas 3 weeks after surgery, which was drained laparoscopically. No other complications occurred. The average length of the hospital stay was 2.1 [1–7] days.

Zornig et al. asked their patients to be examined by the associated gynecologists within one week after hospital discharge, and 183 (90%) of the patients underwent this examination. Interestingly, the patient with the abscess in the pouch of Douglas was one of the patients who did not follow this recommendation. They were asked about discomfort or pain in the lower abdomen/pelvis or vagina, and the wounds in the vagina were inspected. A transvaginal ultrasound was performed. None of the examinations presented pathological findings. In another study, Zornig et al. compared the results of matched pairs, investigating transvaginal cholecystectomy with traditional laparoscopic cholecystectomy, and found no differences in all analyzed parameters with the exception of duration of the procedures and cosmesis [26]. The latter was based on subjective patient opinion after transvaginal procedures.

2. **Results of the EuroNOTES Clinical Registry**:

The EuroNOTES Clinical Registry (ECR) was created as a European database to monitor the clinical application of Natural Orifice Translumenal Endoscopic Surgery™ (NOTES®) [27]. The ECR was sponsored by the EuroNOTES Foundation, founded in 2008 as a joint initiative of the European Society for Gastrointestinal Endoscopy (ESGE) and the European Association for Endoscopic Surgery (EAES). The concept of a NOTES clinical registry was announced at several congresses, and all members of ESGE and EAES performing (or intending to perform) NOTES procedures were asked to participate to the ECR.

Data were collected between May 2010 and April 2014, and are visible in an anonymous way online (http://www.euronotes.world.it). Although 62 accounts were created, indicating the number of centers that were interested in participating, only 14 centers participated in data collection. Procedures were included in the ECR retrospectively, so the ECR includes cases performed between April 2007 and April 2014.

At the time of publication in 2014, a total of 571 patients had been entered into the registry [27]. The most frequent procedure in the ECR was cholecystectomy, performed in 442 cases (78.5%). Cholecystectomy was performed in 4 different techniques:

1. A hybrid technique consisting of a transvaginal and transumbilical access, with the aid of a flexible endoscope [14], reported by 9 different centers
2. A hybrid technique consisting of a transvaginal and transumbilical access, with the aid of a rigid laparoscope [15], reported by 2 different centers
3. A hybrid technique consisting of a transgastric and transumbilical access, with the aid of a flexible endoscope [16, 17], reported by 2 different centers
4. A hybrid NOTES transvaginal technique, by means of modified transanal endoscopic

microsurgery (TEM) equipment combined with a transumbilical access, reported by one center.

Table 17.1 demonstrates patient characteristics, showing an average age of 45.3 years and a BMI of 25.3 kg/m. The mean operative time of transvaginal cholecystectomy was 60.5 min (15–270). Age and BMI did not differ significantly among the groups. In all cases, optics were introduced through the transmural access, i.e., transvaginal or transgastric technique.

The transvaginal approach was chosen in 430 of 442 cholecystectomies (97.2%), and only 12 patients underwent a transgastric hybrid approach. Analyzing the transvaginal approach, 145 cases were performed with the support of a flexible endoscope, 279 cases with the aid of a rigid laparoscope, and the remaining 6 cases were conducted with modified TEM equipment. In 406 cases, the transvaginal access was created with a direct surgical opening after a stable pneumoperitoneum was established via transumbilical access. In the remaining 24 cases, the access to the abdominal cavity was obtained by direct insertion of a 12-mm trocar transvaginally, without a previous pneumoperitoneum. The transvaginal access was sutured closed in all cases via a standard colposcope.

In most hybrid NOTES procedures, the transabdominal trocar was used for introducing instruments for dissection, with the exception of the transvaginal approach, which used modified TEM instrumentation with the transabdominal trocar only used to obtain a safe and clear transvaginal access. The TEM instrumentation consists of a 50-cm-long and 33-mm diameter dedicated colposcope through which four dedicated extra-long instruments were used for tissue manipulation, dissection, and suturing.

Conversion to traditional laparoscopy was needed in only 3 cases during any of the transvaginal cholecystectomy procedures, not related to the use of flexible or rigid instruments. The reasons for adding one or more trocarswere for better manipulation in 21 cases, while in 2 cases it was to control bleeding, in 2 additional cases it was due to unclear anatomy, and in 1 case because of a large cystic duct.

Overall, transvaginal procedures were faster than transgastric procedures (58.7 min vs. 125.4 min, $P < 0.001$). Among transvaginal techniques, operative time was significantly shorter in the group with rigid laparoscopes compared to each of the other techniques ($P < 0.001$).

Table 17.2 summarizes complications and hospital stay for the different cholecystectomy techniques. Eight complications (2.5%) were observed post-operatively. Two complications (1.4%) occurred after transvaginal and transumbilical access with a flexible endoscope. One intra-abdominal hematoma was probably due to the dislodgement of the endoscopic clip on the cystic artery. One complication consisted of minimal vaginal bleeding which was controlled by suture. Five complications (1.8%) occurred post-operatively after transvaginal and transumbilical access with a rigid laparoscope. Two required additional surgery due to a bile leak and a pelvic abscess. Another 2 patients needed postoperative ERCP for a bile leak.

Table 17.1 EuroNOTES clinical registry: NOTES cholecystectomies with different access techniques Arezzo et al. [27]

Procedure	*n*	Center	Age	BMI	Add Trocard %	OR time
TV flexible endoscope	145	9	46	27	5.5	76
TV rigid laparoscope	279	2	45	25	4.7	49
TG flexible endoscope	12	2	48	25	25	125
TV with TEM device	6	1	37	–	–	80
Total	442	12	46	25	5.4	61

Table 17.2 EuroNOTES clinical registry: NOTES cholecystectomy with different access techniques: complications Arezzo et al. [27]

Procedure	*n*	Intraop	Postop %	Overall %	Hospital stay
TV flexible endoscope	145	0	1.4	1.4	2.1
TV rigid laparoscope	279	0.7%	1.8	2.5	2.0
TG flexible endoscope	12	0	0	0	2.4
TV with TEM device	6	0	16.7	16.7	2.5
Total	442	0.5%	1.8	2.3	2.1

The mean hospital stay was 2.1 days and ranged from 0 to 11 days. The transvaginal hybrid technique with a rigid laparoscope showed a significantly shorter hospital stay compared to access techniques with a flexible endoscope ($P = 0.02$).

3. **Results of the German DGAV Registry**:

The German Society of General and GI-Surgery (Deutsche Gesellschaft für Allgemein- und Visceralchirurgie, Berlin, Germany) started a NOTES registry in 2007, in which every member was welcome to register their NOTES and hybrid cases. Results were published, and continuous reports were presented in several meetings [28]. Table 17.3 demonstrates the results of the comparative data presented at the D-NOTES meeting in 2014 [24, 27, 28]. In total, 3239 patients were at that time registered, out of which 2708 were transvaginal cholecystectomies. There was a 1.5% conversion rate, with 34 to laparoscopy and 12 to laparotomy. There were 48 intraoperative complications (1.6%) and 116 postoperative complications (3.8%). The complication rate did not differ between low-volume hospitals and high-volume (>100 cases) hospitals.

Discussion

The available data around transvaginal rigid cholecystectomy indicate it is a safe approach in selected patients at centers with adequate training. Similar to the introduction of laparoscopic surgery, cholecystectomy is generally considered the target procedure for developing and testing a novel surgical technique such as NOTES. For this reason, cholecystectomy represents almost 80% of the procedures documented in European registries.

The 2 most common techniques of NOTES cholecystectomy, i.e., hybrid transvaginal with the aid of either a flexible endoscope or a rigid laparoscope, both required a further transabdominal trocar in about 5% each. The need to convert to laparoscopy was minimal. The overall

Table 17.3 Overview on transvaginal cholecystectomy series

	DGAV registry	EuroNOTES registry	Zornig et al.
TV CE n	2411	442	100
Age years	48	45	49
BMI	27	25	26
OR time min	57	60 (15–270)	52 (23–100)
Intraoperative complications	1.4%	1.8%	0
Postoperative complications (%)	2.6	1.8	1–2

incidence of postoperative complications was extremely low and similar between the two most frequently used techniques. The shorter operative time in the hybrid transvaginal techniques with a rigid laparoscope might reflect the similarity to the standard multiport laparoscopic technique, as well as the standardization of a consistent series of only two centers compared to the fragmentation of data reported by many different centers. This has probably increased confidence and reduced the duration of the learning curve.

Rigid transvaginal cholecystectomies were well established in Europe by 2010. There is an experience of several thousand cases. The safety record of the published series is remarkable, with less than 3% complications. Comparative trials have been published demonstrating a possible cosmetic advantage of NOTES hybrid procedures over classic laparoscopic cholecystectomy [26].

The concept of hybrid transvaginal cholecystectomy is comprehensible to surgeons and can be quickly introduced in clinical practice with a steep (rapid) learning curve [16–24]. As with many hybrid techniques, primary abdominal access is performed via a safe standard laparoscopic approach, with establishment of a capnoperitoneum and a transumbilical camera port, preferably 5 mm in size. This allows for a safe introduction of a larger access via the vagina with several ports and/or instruments. Technical maneuvers to dissect and remove the gallbladder are similar to established laparoscopy.

In addition to cholecystectomy, transvaginal appendectomy and colon resections were introduced into clinical practice with a remarkable safety record [29–33].

Although concern remains about possible side effects of postoperative dyspareunia after transvaginal procedures, the transvaginal technique has a good safety record and is well established [25, 26, 28, 33]. Several working groups recommended that transvaginal NOTES procedures should be performed initially in cooperation with gynecologists until surgeons have gained enough experience to perform this technique safely [18, 23, 26].

Contraindications for transvaginal access are recto-vaginal endometriosis, pregnancy, and malignant tumors of the cervix and vagina. Previous gynecologic operations can cause severe adhesions. Therefore, it is advisable to use extra caution in these cases, such as a preliminary capnoperitoneum and intraperitoneal visual control, when penetrating the vagina. It is advised to perform a suture closure of the access route of the posterior vaginal wall. Also, a gynecologic postoperative check is advised.

In the USA, NOSCAR has finished a randomized trial comparing various methods of cholecystectomy, one of which is the transvaginal procedure. Schwaitzberg [34] presented the data at the 2015 NOTES annual summit, showing a low complication rate.

Despite the above-mentioned results, the attractiveness of this technique has not persisted, since the frequency of applications, especially in Germany, has decreased after the initial hype. Table 17.4 shows the number of registered patients and the number of actively participating centers in the German DGAV-NOTES Registry has substantially decreased after 2010. The proposed and anticipated benefits of transvaginal surgery are less postoperative pain, fewer wound-related complications (including wound infections and hernias), shorter length of hospital stay, shorter convalescence, and superior cosmesis. Several series in the literature have supported these benefits. However, these benefits have not yet been confirmed in prospective, randomized trials.

The overall penetrance of transvaginal cholecystectomy as a mainstream operation is limited.

Table 17.4 Overview on case development in German DGAV-NOTES registry D Bulian & K Lehmann (May 2014) (3239 patients, 58 hospitals)

Year	2008	2009	2010	2011	2012	2013
Cases	318	584	662	707	488	391
Active centers	22	36	31	22	17	11

A survey of 409 women revealed that only 41% would consider the transvaginal approach for cholecystectomy [25]. Patients expressed concern over pain, infection, recovery time, and technical aspects of the technique. These concerns do not seem to be supported by the data published to date.

Nobody can predict what the future will bring regarding transvaginal procedures in gastrointestinal surgery, but it is not imaginable that many cholecystectomies will be performed by NOTES techniques. Without any doubt, this is even more valid for the more complex procedures such as colectomies. Traditional standard laparoscopic procedures, and especially laparoscopic cholecystectomy, are excellent and safe operative techniques which will be difficult to be surpassed by other approaches. As of now, better cosmesis will be the main driver for NOTES. Whether surgeons will ultimately accept longer operative times and more difficult techniques just to achieve better cosmesis remains an open question.

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