CHAPTER

HYBRID TRANSVAGINAL
CHOLECYSTECTOMY,
CLINICAL RESULTS
AND PATIENT REPORTED OUTCOMES
OF 50 CONSECUTIVE CASES

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ABSTRACT

Objective
The aim of this study was to report the clinical and cosmetic results of transvaginal hybrid cholecystectomy (TVC).

Background
Natural orifice transluminal endoscopic surgery (NOTES) has been developed as a minimal invasive alternative for conventional laparoscopic cholecystectomy. Although transvaginal NOTES procedures are becoming increasingly popular, data focusing on body image, cosmesis and sexual recovery are rare.

Methods
Our clinic started to perform the TVC in the beginning of 2011. Female patients with symptomatic gallstone disease that were treated between January 2011 and April 2012 with TVC were entered in a prospective database. All patients received a survey postoperative with questions about recovery, cosmesis and body image.

Results
50 consecutive patients were treated with a TVC. There were no major complications. Mean operative time was 61 minutes. In five patients (10%) a conversion to another type of cholecystectomy was necessary. None of the sexually active women observed dyspareunia postoperative. The results for cosmesis and body image after the transvaginal approach were excellent.

Conclusions
TVC is a safe and feasible procedure when performed on selected patients. The transvaginal route results in excellent cosmetic outcomes without gynaecologic complications after short term follow up. Randomized trials are needed to specify the role of TVC in the treatment of patients with symptomatic gallstone disease.
INTRODUCTION

Laparoscopic cholecystectomy is currently the first choice treatment for patients with symptomatic gallstone disease. In an attempt to further reduce the invasiveness of laparoscopy, natural orifice transluminal endoscopic surgery (NOTES) was introduced in 2004. In this technique, instruments are introduced into the peritoneal cavity via the vagina, the urine bladder, the stomach, or the rectum. The transvaginal approach has gained most popularity as it provides a safe entry, a simple closure and the opportunity to utilize regular laparoscopic instruments.

Theoretically, NOTES reduces the surgical trauma and might improve clinical results with reduced postoperative pain and faster recovery combined with an excellent cosmetic result. However, with the development of natural orifice surgery and transvaginal surgery in particular, recent interest has been focusing on potential complications. Besides the cholecystectomy related complications such as bile duct injury, there is a potential risk of dyspareunia and gynaecological infection, which can strongly influence quality of life.

Our clinic started performing hybrid transvaginal cholecystectomies (TVC) in the beginning of 2011. The aim of this study was to evaluate our initial results after 50 procedures and to evaluate the patients’ experiences and cosmetic outcome with the transvaginal approach after short-term follow up.

METHODS

Patient selection

Patients at our clinic were given the option to undergo either a single port procedure (SPC), a conventional laparoscopic cholecystectomy (CLC) or a hybrid transvaginal cholecystectomy (TVC). For this prospective study, the first 50 consecutive patients who underwent a TVC were selected following institutional review board approval. All patients underwent surgery for symptomatic cholelithiasis. Diagnosis of gallbladder stones was made by ultrasound and all patients were classified ASA grade I or II. No intraoperative cholangiography was performed. Patients with prior surgery in the small pelvis or a history of median laparotomy were excluded. Age, BMI and minor abdominal surgery as an appendectomy or previous laparoscopy were not considered as exclusion criteria. Informed consent was received from all patients. All data were registered prospectively. Patient demographic data as well as body mass index (BMI), ASA score and prior abdominal surgery were recorded.

Surgical technique

All procedures were performed by 2 members of a team consisting of 2 experienced laparoscopic surgeons and 2 senior residents specializing in laparoscopic surgery. During the first 10 procedures a gynaecologist participated to ensure a safe introduction and adequate closure of the fornix posterior.

The TVC was performed as a hybrid technique as described earlier by Zornig. All patients received preoperative antibiotic prophylaxis, 2 gr. of cefacidal and 1 gr. of metronidazole. A 5 mm trocar was inserted through the umbilicus with a 5 mm optic. Under direct vision and with the patient in Trendelenburg position, a vaginal trocar and a forceps are introduced.
through the fornix posterior. The 5 mm optic was then replaced by a dissector, and a 10 mm optic was introduced through the vaginal trocar. With the patient now in anti-Trendelenenburg, the gallbladder was fixated at the ventral abdominal wall with a percutaneous suture through the fundus of the gallbladder. The dissection was conducted with a working instrument through the umbilical port. After critical view of safety was reached, the cystic artery and cystic duct were clipped with hemolock clips\(^{10}\). A removal bag was used to remove the gallbladder through the colpotomy. The defect in the fornix posterior was closed with resorbable sutures (Vicryl, Ethicon, Cincinnati, Ohio, USA). Insertion of an extra abdominal trocar was considered as a conversion. Patients were advised to abstain from sexual intercourse for 4 to 6 weeks.

The surgical data included operative time, conversion rate and peroperative complications. Operative time was measured as time between first incision and time of completion of closure. Postoperative assessment was focussed on duration of hospital stay, pain scores and recovery. All patients received a patient controlled analgesia (PCA) pump with 1.5 mg morfine per dose. PCA use and pain scores were measured 24 hours postoperative by an independent physician, using the numeric rating scale.

**Postoperative survey**

All patients were contacted by telephone at least 10 weeks after surgery and asked to complete a survey (appendix 1). After patient consent, they received a code to complete the web-based survey. Upon request the survey was also sent by post to some patients. The survey incorporated a body image questionnaire (BIQ) and a series of questions regarding recovery and sexual activity following surgery. The BIQ is an eight item questionnaire incorporating body image and cosmetic subscales, each with a high internal consistency (Cronbach \( \alpha \) of 0.80 and 0.83 respectively)\(^{11}\). The body image scale investigates patients’ perception and satisfaction with their body after surgery, the cosmetic scale measures the satisfaction with the surgical scars.

**RESULTS**

50 consecutive women were treated with a TVC for symptomatic gallstone disease between January 2011 and April 2012. Baseline characteristics are shown in table 1. The mean age of the patients was 38 years (range 18-62). The mean BMI was 25 (range 18-37) and 15 patients had a history of previous abdominal surgery.

The peroperative results are listed in table 2. Mean operative time was 61 min (range 44-87). Five patients (10%) were converted. One patient was converted to a single port cholecystectomy, because a safe introduction of the vaginal trocar was not possible as a result of previously unknown endometriosis in the small pelvis. In four other patients the transvaginal procedure was converted to a regular laparoscopy, as critical view of safety was difficult to obtain. One of these patients eventually needed an open procedure due to severe adhesions and fibrosis of the gallbladder. There were no peroperative complications such as bleeding or bile duct lesions. We didn’t observe peroperative complications with special regard to the transvaginal access.
There were two minor postoperative complications as one patient developed a wound infection of the abdominal wound after conversion to an open procedure. Another patient developed a vaginal fungal infection, which resolved after adequate antifungal therapy. All patients were discharged on the first postoperative day, except the patient who was converted to an open cholecystectomy. The median pain score on the first postoperative day was 2 according to the numeric rating scale. The median score for PCA pump usage was 5 during the first 24 hours postoperative.

**Table 1. Patient demographics**

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (range)</td>
<td>38 (18-62)</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>-</td>
</tr>
<tr>
<td>Female</td>
<td>50 (100%)</td>
</tr>
<tr>
<td>Male</td>
<td>-</td>
</tr>
<tr>
<td>BMI (kg/m2), mean (range)</td>
<td>25 (18-37)</td>
</tr>
<tr>
<td>ASA I/II</td>
<td>40/10</td>
</tr>
<tr>
<td>ERCP, n (%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Previous abdominal surgery, n (%)</td>
<td>15 (30%)</td>
</tr>
</tbody>
</table>

*BMI: body mass index, ASA: American society of Anesthesiologists, ERCP: endoscopic retrograde cholangiopancreatography*

**Table 2. Perioperative outcomes**

<table>
<thead>
<tr>
<th>Operative time (min), mean (range)</th>
<th>61 (44-87)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion rate, total (%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Open procedure</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Single port cholecystectomy</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Conventional laparoscopic surgery</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Bile duct injury, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>Bile spillage (intraoperative), n (%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Wound infections, n (%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Hernia cicatricalis, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>Postoperative hospital stay, median (range)</td>
<td>1 (1-5)</td>
</tr>
</tbody>
</table>

**Survey results**

45 patients (90%) returned the questionnaire with a median follow up time between surgery and questionnaire of 12 weeks. The cosmetic subscale scores were excellent among the study group. The average score of their scars was 9.7 (range 4-10) on a 1 to 10 scale. The body image subscale scores were also high with an average of 43 points (range 27-44) on a 8 to 44 points scale. 84% of the respondents were sexually active after surgery. 44% of this group had sexual intercourse within 4 weeks postoperative, 56% waited longer than 4 weeks as advised pre-operatively. None of the
transvaginal cholecystectomy, patient reported outcomes

16% of the women were not sexually active, but no one referred to surgery as the reason. 70% of the sexually active women didn’t notice a change in the frequency of sexual intercourse, 24% reported a small decrease whereas 6% reported a large decrease in frequency.

54% of the respondents returned to work or study within 10 days, in 31% it took longer than 10 days and the remaining 15% did not work or study.

96% would recommend this procedure to other persons. If our patients had the option to choose again, only 2 patients would opt for another technique. One patient preferred the SILS technique and another patient preferred a normal four-port laparoscopy.

DISCUSSION

In an attempt to further reduce surgical trauma NOTES was developed. We present the results of our first 50 consecutive patients that were treated with a hybrid NOTES cholecystectomy. Our results show that TVC is a feasible procedure and can be performed within reasonable operative times in a selected population. A mean operative time of 61 minutes is comparable with other reports of TVC\textsuperscript{12-14}. In our series of 50 patients, no major complications were observed, especially no bile duct lesions. One patient developed a minor complication with a vaginal fungal infection and is now free of symptoms after treatment. The patient that was converted to an open procedure developed a wound infection.

Although NOTES is a new technique, we observed that the learning curve for this procedure is short. After 10 procedures, operating time decreased from 90 minutes to approximately 55 minutes. The learning curve is mainly determined by the introduction and closure of the incision in the fornix posterior, as the dissection of the gallbladder is very similar with a normal laparoscopic cholecystectomy. Later on in our study, operative times increased somewhat to a mean of 61 minutes. This is because senior residents specializing in laparoscopy were also starting to perform this procedure under strict supervision of one of the experienced laparoscopic surgeons (C.S.).

We considered all extra abdominal trocars besides the 5mm umbilical port as a conversion to normal laparoscopy. In all procedures the safety rules of Strasberg were followed\textsuperscript{10}. In our series of 50 patients, 45 procedures were successfully performed as a hybrid NOTES procedure. In order to reach critical view of safety four conversions to conventional laparoscopy were necessary and one patient eventually needed an open cholecystectomy. A 10% conversion rate is comparable with other publications of initial results\textsuperscript{12-14}. However, several other studies report a lower conversion rate\textsuperscript{15,16}. This can be due to an increased experience with the transvaginal technique. Another reason could be our strict definition of conversion as in some other reports insertion of an extra abdominal trocar was not considered as a conversion to normal laparoscopy\textsuperscript{17}. Finally, stricter patient selection could contribute to a lower number of conversions.

The advantages and disadvantages of a TVC are not clearly known, and the debate is mostly based on theoretical grounds and assumptions. With only a small incision in the abdominal wall at the umbilicus, TVC could be associated with less pain. Additionally, TVC should be
associated with less hernias at the trocar site, as trocar hernias following 5 mm trocar insertion are rare and after a conventional laparoscopic cholecystectomy a trocar hernia rate of up to 1% is documented. Another advantage could be the superior cosmetic result, as reported in this study. Recent studies however suggest that the absence of abdominal scars might not be such an important factor for patients.

With the introduction of transvaginal NOTES concerns were raised about postoperative sexual complaints because of scar formation from the vaginal wall incision. The potential risk of an infectious complication with the risk of infertility is also subject to discussion. It can be advocated that the risk of infection is low after a transvaginal approach according to data in gynaecologic literature.

There is also the question as to how transvaginal surgery influences postoperative sexual function and frequency. None of the women observed postoperative problems like dyspareunia or changed sensibility during sexual intercourse. Our data is supported by Zornig et al, where no sexual complaints were recorded after TVC in a large case matched study with short follow up. A majority of 70% of the women in our series didn’t notice a change in sexual activity, whereas 30% did observe changes with a decrease of sexual activity with short term follow up. As TVC is a new technique and not yet widely used, long term follow up on sexual complaints and sexual behaviour is lacking. Future research should address this topic with long-term follow up.

Results of the BIQ were good with high scores on body image and cosmetic subscales. It is probably not surprising that body image scores were high as our study group is a selected group of ASA I/II patients with a relatively young average age of 38 years. Next to that, a cholecystectomy can be seen as a relatively easy surgical procedure without many complications. After a TVC there are no visible scars and that is reflected in the high scores of self-assessment of scars. A majority of the respondents awarded their scars with the maximum score of 10 points. Only one patient was not satisfied and gave her scar only 4 points as her procedure was converted to an open procedure.

Several publications have shown conflicting results regarding the preference of women for transvaginal cholecystectomy. These studies were all conducted as questionnaires among a healthy female population, in contrast with our study. Procedure-related risks, pain, recovery time and concerns about postoperative sexual complaints were rated more important than cosmesis in these surveys. A recent survey among a female population has shown a strong preference for SPC when compared to TVC for symptomatic gallstone disease. The authors concluded that TVC was strongly related to fears regarding postoperative sexuality and fertility. Short-term sexual abstinence was also a main issue for the female respondents. Our study shows that these fears might be overrated. 96% of the women who underwent a TVC would opt for the same treatment if they were asked to choose again and the same percentage of the women would recommend a TVC to other women. Two patients expressed a preference for another technique instead of a TVC. These two patients were both treated with an uncomplicated transvaginal procedure. In
our opinion this is another example, besides the high BIQ scores, of the overall satisfaction with this procedure among our patients.

With a 90% response rate of our questionnaire we introduce a potential bias. It is likely that patients who are satisfied after their treatment are more willing to cooperate with our questionnaire. However, among the respondents were two patients who had a conversion to normal laparoscopy and one patient who underwent an open cholecystectomy. Therefore, we think that our results on body image and cosmesis are a good reflection of our total study group of 50 consecutive patients.

This study has several other limitations. A validated survey for scar assessment and body image is not available\textsuperscript{23}. However, the BIQ is used in multiple publications discussing abdominal surgery for assessment of body image and cosmesis and has a high internal consistency\textsuperscript{11,24,25}. Second, self-assessment of scars is a subjective outcome. Moreover, the women who were treated in this study with a TVC were motivated for this procedure because they had chosen a TVC as their first choice. This introduces a bias and could influence results of the questionnaires with relatively high scores. Finally, follow up is short. Future research should focus on possible mid- and long-term complications of the transvaginal route.

**CONCLUSION**

A TVC is a safe and feasible procedure with acceptable operating times. In a motivated group of patients TVC results in excellent cosmetic results. Much feared complications as dyspareunia and bile duct lesions were not seen. Long-term follow up is needed to confirm the safety of the transvaginal access.
REFERENCES


APPENDIX 1

Body image questionnaire (BIQ) consisting of a body image score (items 1 to 5) and a cosmetic score (items 6 to 8)

1. Are you less satisfied with your body since the operation?
   1. no, not at all
   2. a little bit
   3. quite a bit
   4. yes, extremely

2. Do you think the operation has damaged your body?
   1. no, not at all
   2. a little bit
   3. quite a bit
   4. yes, extremely

3. Do you feel less attractive as a result of your operation?
   1. no, not at all
   2. a little bit
   3. quite a bit
   4. yes, extremely

4. Do you feel less feminine as a result of your operation?
   1. no, not at all
   2. a little bit
   3. quite a bit
   4. yes, extremely

5. Is it difficult to look at yourself naked?
   1. no, not at all
   2. a little bit
   3. quite a bit
   4. yes, extremely

6. On a scale from 1 to 7, how satisfied are you with your scar?
   1. very unsatisfied
   2. quite unsatisfied
   3. a bit unsatisfied
   4. not unsatisfied/not satisfied
   5. a bit satisfied
   6. quite satisfied
   7. very satisfied

7. On a scale from 1 to 7, how would you describe your scar?
   1. revolting
   2. quite revolting
   3. a bit revolting
   4. not revolting/not beautiful
   5. a bit beautiful
   6. quite beautiful
   7. very beautiful

8. Could you score your own incisional scar(s) on a scale from 1 to 10?
Recovery questionnaire

1. Do you feel reserved in establishing/maintaining (a) sexual relationship(s) since the operation?
   1. no, not at all
   2. a little bit
   3. quite a bit
   4. yes, extremely
   5. not applicable

2. Has there been a change in sexual activity since the operation?
   1. yes, much less active
   2. yes, a little less active
   3. no
   4. yes, a little more active
   5. yes, much more active
   6. not applicable

3. Did you have sexual intercourse since the operation?
   1. yes, within 2 weeks
   2. yes, between 2 and 4 weeks
   3. yes, after 4 or more weeks
   4. no, as a result of the operation (discomfort/pain)
   5. not applicable

4. If ‘yes’ to question 3, did anything change compared to before the operation? (For instance: pain, embarrassment, etc.)
   1. no
   2. yes
   3. yes, other reasons than pain

5. On a scale from 1 to 10, how would you score your self-confidence?

6. How long was the period of your sick leave? How many days did you remain off work?
   1. not applicable (no work/study)
   2. 1 to 5 days
   3. 5 to 10 days
   4. more than 10 days, i.e. […] days

7. Do you feel generally healthy?
   1. yes, extremely
   2. quite a bit
   3. a little bit
   4. no, not at all

8. Would you recommend the operation you had?
   1. yes
   2. no

9. If you needed the same surgery again, which technique would you prefer most and which technique would you prefer last?

(English translation was performed for this publication only and has not been validated clinically.)