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Prospective evaluation of transvaginal assisted cholecystectomy

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Abstract
Background Transvaginal video-assisted cholecystectomy (TVC) has so far not been prospectively evaluated using an internationally recognized health-related quality of life (HRQoL) assessment. We report the results of a prospectively studied cohort of patients with clinical and quality of life data.
Methods Prospectively controlled study of 128 patients undergoing TVC and 147 patients with conventional laparoscopic cholecystectomy (CLC). Data reported include patient demography, body mass index, anesthetic risk score (ASA), laboratory data, surgical times, length of hospital stay, pain score, analgesic medication used, complications, and quality of life scores using the combined method of SF-36 and GIQoL.
Results Ninety-five TVC and 96 CLC patients fully completed pre- and postoperative HRQoL questionnaires. Patients with incomplete or missing questionnaires were excluded as well as patients with signs of acute cholecystitis. Differences included cardiovascular comorbidity and previous surgical procedures, but there was no difference in age ($p = 0.4$), body mass index ($p = 0.4$), ASA grade ($p = 0.4$), or preoperative quality of life. No difference was seen in laboratory data, surgical times, or length of hospital stay. Pain score and analgesic medication showed a clear trend and significant differences in favor of TVC. There was no difference in complications. Quality of life and postoperative sexual function did not show any differences between the two groups.
Conclusions This is the first study to report HRQoL outcomes after TVC using a recognized combined HRQoL assessment method. Although differences do exist in patient comorbidity and previous surgical experience, both groups were comparable. Less postoperative pain and no difference in HRQoL in TVC patients underlines this new procedure as a feasible standard approach in female patients. This study also is the first to differentiate between acute cholecystitis and symptomatic cholecystolithiasis in patients undergoing TVC.

Keywords Cholecystectomy · NOTES · Endoscopy · Quality of life · SF-36 · GIQoL

We previously reported our experience with transvaginal video-assisted cholecystectomy (TVC) in clinical practice [1]. So far, only one report has been published assessing health-related quality of life (HRQoL) in TVC using the GastroIntestinal Quality of Life score (GIQoL) according to Eypasch et al. [2, 3]. No report has been published using a standard controlled and recognized combined method of HRQoL assessment in TVC. As an evolutionary step toward true natural orifice translumenal endoscopic surgery (NOTES) procedures, NOTES-assisted procedures need careful evaluation. We prospectively evaluated transvaginal-assisted cholecystectomy as precise as possible in routine clinical practice. For this reason, the data reported

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describe preoperative status and anamnesis in depth. Careful consideration was given not to mix various clinical pictures, such as acute cholecystitis and symptomatic cholecystolithiasis. The combination of the Short Form 36 (SF-36) and GIQoL questionnaires has been used as a standard to evaluate the outcome of gallbladder surgery in several countries worldwide. This was preceded by appropriate validation of this questionnaire combination [4, 5]. The SF-36 represents the most widely used psychometric assessment of general health and was validated for Germany in 1995 [6]. The GIQoL represents a symptom and disease-specific questionnaire used to evaluate the outcome after gallbladder surgery.

Methods

Patients were included into the study as described previously [1]. Data were collected using a standard spread sheet (Excel). Extensive patient history taking was used to elucidate comorbidity and previous surgical procedures. The hospital information system enabled independent calculation of surgical times and length of hospital stay as well as surgical complications. Surgical complications were prospectively documented using the German NOTES register and assessed according to diagnosis, patient charts, and the Clavien-Dindo score [7, 8]. Pain medication is individualized to patients in our hospital. Doses of pain medication were standardized to the equivalent of metamizole and piritramide. The visual analogue score (VAS) is routinely documented in patient charts for pain assessment and, if necessary, repeated according to pain level of individual patients. For analysis, maximum daily pain score was recorded. All patients received the nonacute SF-36 and GIQoL questionnaire in the outpatient clinic preoperatively and on surgical or gynecological follow-up. Patients were asked to return the questionnaires 4 weeks postoperatively. Cases were excluded from statistical analysis if any pre- or postoperative questionnaires were missing or if more than one item per subscale was missing in more than three subscales. No attempt was made to use imputation methods to correct for missing items [9, 10]. Further exclusion of patients followed signs of acute cholecystitis using laboratory data. Statistical analysis followed the report of Quintana et al. and was performed using SPSS version 14.0 (2005). Tests included normal distribution, one-way ANOVA, two-sided t test, Pearson's chi-square test, Fisher's exact test, and logistic regression analyses with adequate forward and backward selection of variables (LRA, results cited in text only). Results were considered significant with $p < 0.05$ [11].

Results

Patient demography, comorbidity, and history of surgical procedures

Transvaginal video-assisted cholecystectomy was started in our department with the first patient on October 30, 2007. Quality of life assessment was introduced for all consecutive patients. Data collection for this report ended on November 9, 2009. Thereafter, patients were included into a randomized, controlled trial comparing TVC and conventional laparoscopic cholecystectomy (CLC). Until then, 128 patients undergoing TVC were asked to return a set of HRQoL questionnaires, including the SF-36 and GIQoL, before the operation with a timeframe of 1 week. After recovering from the operation and discharge, patients were seen after 1–4 weeks for surgical and gynecological follow-up. Patients were asked to return a postoperative set of questionnaires in a postage-paid envelope 4 weeks after the operation. This procedure was the same for patients who underwent CLC. Of 128 patients with TVC, 95 patients returned a full set of two preoperative and two postoperative questionnaires, and of 147 CLC patients, 96 returned a full set. Only patients with a full set of questionnaires were included into statistical analysis. Of these further patients were excluded if C-reactive protein (CrP) was more than 10 mg/l and/or white blood cell count (WBC) was more than 12 $x10^9$/l. Accordingly 81 CLC and 84 TVC patients were available for final analysis. There was no difference in patient age for CLC vs. TVC patients (54.7 vs. 52.9 years, $p = 0.4$), body mass index (27.8 vs. 27.1, $p = 0.37$) or ASA grade (American Society of Anesthetists risk score, $p = 0.39$; Table 1). Despite missing difference in ASA grade subtle history taking revealed differences in cardiovascular disease. Comparing CLC versus TVC significantly more women had coronary heart disease (CHD; Table 1). After logistic regression analysis (LRA), neither CHD nor any other comorbidity remained as a significant difference between the two groups. There was no difference in other frequent chronic diseases, such as diabetes mellitus, chronic obstructive pulmonary disease, hyperlipoproteinemia, chronic pain, or chronic pain medication. Regarding social status, more patients undergoing CLC had no partner, but this was not significant ($p = 0.12$). Again LRA did not reveal any differences in social status. There was no difference in history of general surgical procedures. Previous abdominal surgical procedures included splenectomy, large bowel resection, and liver resection. History of previous gynecological procedures revealed clear differences. Overall, the CLC group had less experience with gynecological procedures compared with TVC patients (30 vs. 44, $p = 0.06$), although there was no difference with major gynecological procedures: e.g., hysterectomy (19 vs. 16, $p = 0.48$). CLC

Table 1 Patient demography, comorbidity, and history of previous surgery

	CLC/N	TVC/N	*p* value[a]
N	81	84	
Mean age (yr)	54.7 (20–80)	52.9 (23–79)	0.402
	SD 15.2	SD 12.6	
BMI mean (min-max)	27.8 (18–47)	27.1 (18–42)	0.372
	SD 5.6	SD 4.9	
ASA			0.393
ASA I	7	5	NS[b]
ASA II	55	65	NS[b]
ASA III	19	14	NS[b]
Diabetes mellitus	6	3	0.349
Benign art. hypertension	42	31	0.061
Heart rhythm disturbances	11	5	0.119
Coronary heart disease	10	3	**0.045**[c]
COPD	6	5	0.708
Hyperlipoproteinemia	13	6	0.069
History of breast cancer	7	6	0.721
Steatosis hepatis	13	8	0.209
Gastroesophageal reflux disease	17	15	0.611
Gastritis	15	10	0.236
Hiatus hernia	1	5	0.106
Hypothyreosis	13	8	0.209
Hyperthyreosis	1	3	0.329
Depression	4	4	0.958
Chronic back pain	4	4	0.958
Chronic headache/migraine	3	3	0.964
Chronic pain medication	13	9	0.314
Married/partner	52	66	0.122[b]
Single	22	14	NS
Other	7	4	NS
Mobile within city	78	82	0.593
Mobile within apartment	2	2	NS
Previous surgical procedures	51	55	0.736
Appendectomy	19	21	0.817
Adhesiolysis	0	2	0.162
Splenectomy	0	1	0.325
Large bowel resection	0	1	0.325
Any hernia	3	4	0.736
Liver resection	0	1	0.325
Nephrolithotomy ESWL/open	1	3	0.329
Previous gynecological procedures	30	44	0.06[c]
Hysterectomy ± salpinx	19	16	0.489
Cesarean section	3	5	0.501
Salpingectomy	5	17	**0.011**[c]
Conization/curettage	4	13	**0.038**[c]

CLC conventional laparoscopic cholecystectomy, *TVC* transvaginal video-assisted cholecystectomy, *SD* standard deviation, *COPD* chronic obstructive pulmonary disease, *ESWL* external beam lithotripsy, *BMI* body mass index, *NS* not significant

[a] *t* test two-sided and Pearson's chi-square test two-sided were appropriate

[b] Pearson's chi-square test residues for all cells were not <-2 or >2, therefore, no significant differences

[c] Fisher's exact test two-sided

compared with TVC patients rarely had experience with less invasive procedures, such as laparoscopic salpingectomy (5 vs. 17, $p = 0.01$) and conization/curettage (3 vs. 13, $p = 0.03$; Table 1). These less invasive procedures continued to be significantly different in LRA (salpingectomy CLC vs. TVC: 95 % confidence interval (CI) 1.53–14.79, $p = 0.007$, and conization/curettage: 95 % CI 1.1–12.44, $p = 0.034$).

Preoperative laboratory data

Because this prospective study was intended to compare the conventional and transvaginal access to cholecystectomy, we evaluated available laboratory data to confirm the absence of acute inflammation or infection as well as chronic disease of the liver or bile duct system in both groups. Paraclinical assessment is not an automated

Table 2 Preoperative paraclinical results

	CLC/mean	95 % CI	TVC/mean	95 % CI	*p* value[a]
N	47–80		47–83		
ASAT	0.44	0.35–0.52	0.42	0.37–0.48	0.783
ALAT	0.64	0.37–0.9	0.49	0.43–0.55	0.292
AP	2.81	2.50–3.12	2.62	2.32–2.92	0.376
γ-GT	0.89	0.55–1.23	0.84	0.64–1.04	0.812
CrP	3.5	2.67–4.24	3.4	2.66–4.09	0.876
WBC	7.1	6.7–7.5	6.9	6.6–7.3	0.528
PT	97	94–99	99	98–101	0.05

Reference range in brackets: *ASAT* aspartate transaminase (<0.6 µmol/ls), *ALAT* alanine transaminase (<0.6 µmol/ls), *AP* alkaline phosphatase (0.58–1.75 µmol/ls), *γ-GT* γ-glutamyltransferase (<0.65 µmol/ls), *CrP* C-reactive protein (<5.0 mg/l); *WBC* white blood cell count (4.4–11.3 x10^9/l), *PT* prothrombin time (70–120 %), *CLC* conventional laparoscopic cholecystectomy, *CI* confidence interval, *TVC* transvaginal video-assisted cholecystectomy

N is the number of patients with available laboratory data. In CLC, 34 of 81 patients had one or more of seven laboratory parameters missing and 47 patients had complete data. In TVC, 37 patients had one or more laboratory parameter missing and 47 complete data. In each group, one patient had no preoperative laboratory testing before the operation at all. Results are expressed as mean values

[a] One-way Anova test

Table 3 Surgical times and length of hospital stay

	CLC	95 % CI	TVC	95 % CI	*p* value[a]
	Mean		Mean		
Surgical times, min (min-max)	64.2 (29–168)	59.6–69.8	65.1 (22–204)	59.3–70.8	0.832
Hospital stay, days (min-max)	2.81 (1–7)	2.62–3	2.81 (2–7)	2.6–3.02	0.984

[a] One-way Anova test

process but is patient-tailored according to risk profile or previous clinical history. For this reason, it is not expected for every patient to have a full set of laboratory data. The results are given in Table 2 with a detailed legend indicating available and missing data. There was no difference in the liver enzymes (ASAT and ALAT), bile duct parameters (AP and γ-GT), parameters of inflammation and infection (CrP and WBC), or coagulation profile.

Surgical times and length of hospital stay

Surgical times were recorded from the digital hospital information system. As previously reported, surgical procedures were performed by general surgery consultants and residents in advanced stages of training. There was no difference in surgical times for CLC compared with TVC (64.2 vs. 65.1 min, $p = 0.83$). Length of hospital stay was retrieved from the hospital information system as well. There was no difference in hospital stay between the two groups. CLC and TVC patients stayed an average of 2.8 days (range, 1–7 and 2–7 days, respectively; $p = 0.984$; Table 3).

Pain score and analgesic medication

Visual Analogue Score and analgesic medication were prospectively collected into the database, analyzed, and reported according to Mantha et al. [12]. Analgesic medication was given toward the end of the surgical procedure as a standard with 1 g of metamizole and 15 mg of piritramide. When on the ward, patients were assessed by nursing staff for their needs of further analgesia. VAS scores are documented routinely once in the morning. These values were recorded into the database. If any pain, then patients were started on regular pain medication, which was prescribed tailored to patients VAS score and wishes thereafter. Metamizole (NSAID) and piritramide (opioid) were used for regular pain medication. If metamizole was not tolerated, other NSAIDS, such as paracetamol or ibuprofen, were used. This was similar with piritramide. Rarely other opioids, such as oxycodon or tilidine, were used. Efficacy of other analgesic medication was expressed in the database as relative equivalent to metamizole or piritramide. For example, metamizole was recorded in 250 mg steps and 1 g of paracetamol would be judged as equivalent to 750 mg of metamizole. Chronic pain medication was not taken into account, because there was no difference between the two groups in terms of chronic pain (Table 1). Four patients in the CLC group and two patients in the TVC group received paracetamol instead of metamizole. In the CLC group, five patients received opioids other than piritramide and in the TVC group one patient received opioids other than piritramide.

Table 4 Postoperative pain score and analgesia

	CLC		TVC		
	N	Mean ± SD	*N*	Mean ± SD	*p* value[a]
VAS 1	80	2.03 ± 1.7	79	1.81 ± 1.9	0.456
VAS 2	78	1.56 ± 1.9	74	1.08 ± 1.7	0.097
VAS 3	51	0.69 ± 0.9	77	0.34 ± 0.8	0.026
NSAID 1	80	2256 ± 1075	81	2037 ± 1187	0.221
NSAID 2	80	2056 ± 1231	79	1765 ± 1267	0.145
NSAID 3	46	1788 ± 1248	77	734 ± 1128	<0.001
Opioids 1	80	3.56 ± 11.8	81	2.41 ± 7.3	0.454
Opioids 2	80	1.31 ± 7.6	79	1.52 ± 6.6	0.856
Opioids 3	46	0.98 ± 4.9	77	0 ± 0	0.082

CLC conventional laparoscopic cholecystectomy, *TVC* transvaginal video-assisted cholecystectomy, *VAS* visual analogue score, *NSAID* non-steroidal anti-inflammatory drugs days 1–3 in milligram per day; opioids days 1–3 in milligram per day

[a] Parametric *t* test two-sided

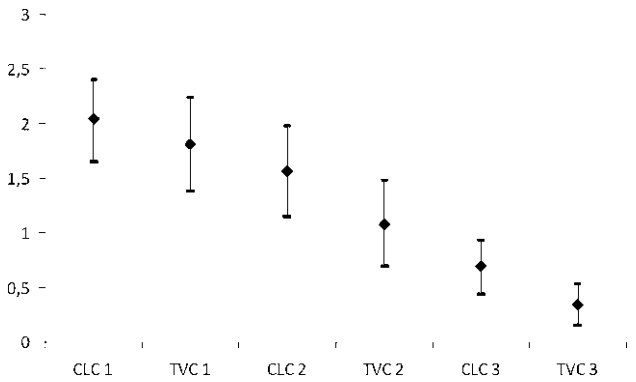

Fig. 1 Visual analogue score, days 1–3 with mean and 95 % CI. *CLC* conventional laparoscopic cholecystectomy, *TVC* transvaginal cholecystectomy, *filled diamond* mean, *filled rectangle upper* and *lower* limits 95 % confidence interval

There was no difference in pain level on postoperative days 1 and 2 between CLC and TVC patients (Table 4). The number of patients given for each day indicate that patients had no pain, did not receive any analgesia, were discharged, or values have not been entered into the database. Overall, surgical and analgesic therapy achieved patients being in the analgesic success zone at any given time (VAS < 4). On day 3, there was a significant difference in pain level for CLC vs. TVC patients in those indicating pain at all and not being discharged (mean VAS 0.69 vs. 0.34, 95 % CI 0.44–0.93 vs. 0.15–0.53, $p = 0.026$; Fig. 1). This was matched by analgesic medication. There was no difference in medication on days 1 and 2. On day 3, CLC patients needed significantly more NSAID (mean 1788 vs. 734 mg, 95 % CI 1417–2159 mg vs. 478–990 mg, $p < 0.001$). No significant difference was detected for opioids on day 3 (0.98 vs. 0 mg, $p = 0.082$). Moreover analyses of item 21 of the SF-36, which asks patients about bodily pain, indicated that there was no difference in pain between both groups 4 weeks postoperatively ($p = 0.187$, Pearson's chi-square, two-sided). Similar analyses of item 1 of the GIQoL, which asks patients about episodes of abdominal pain within the last 2 weeks, indicated that there was no difference in pain episodes between CLC and TVC patients postoperatively ($p = 0.215$, Pearson's chi-square, two-sided).

Table 5 Surgical complications according to Clavien-Dindo classification

	CLC/N	TVC/N	*p* value[a]
No complications	89	93	0.162
Grade I	3	1	
Grade II	2	0	
Grade III	2	1	

[a] One-way Anova test

Complications

Surgical complications were analyzed, including patients with acute cholecystitis and rated according to the Clavien-Dindo classification system of surgical complications. In the CLC group 89 patients and in the TVC group 93 patients had no complications. There was no significant difference ($p = 0.162$). In the CLC group, three patients had grade I, two patients grade II, and two patients grade III complications. In the TVC group, there was one grade I, no grade II, and one grade III complication. The grade I complication was an urinary catheter inserted intraoperatively for laceration of the urinary bladder on transvaginal trocar insertion, and the grade III complication was an endoscopic bile duct stenting for bile duct leakage. The patient mentioned in our previous report who required

Table 6 HRQoL results comparing CLC ($N = 81$) versus TVC ($N = 84$) patients using the combined method of GIQoL and SF-36 questionnaires

Domain	Preintervention			Postintervention		
	CLC	TVC	p value	CLC	TVC	p value
GIQoL questionnaire						
Symptomatology	2.84 (0.69)	2.8 (0.6)	0.65	3.27 (0.5)	3.36 (0.46)	0.22
Emotion	2.4 (0.95)	2.34 (0.84)	0.69	3.21 (0.73)	3.23 (0.68)	0.88
Physical functioning	2.39 (0.75)	2.32 (0.77)	0.57	2.88 (0.72)	3.03 (0.59)	0.13
Social functioning	2.9 (0.96)	3 (0.85)	0.48	3.06 (0.91)	3.27 (0.73)	0.11
Global score	2.68 (0.69)	2.65 (0.62)	0.77	3.14 (0.55)	3.27 (0.47)	0.12
SF-36 questionnaire						
Physical functioning	71.8 (25.9)	77 (24.4)	0.17	77.8 (23.4)	82.9 (19.5)	0.13
Physical role	56.2 (43.7)	61.4 (41.6)	0.44	59.8 (42.6)	69.6 (38.5)	0.13
Bodily pain	54.9 (30.5)	51 (29.2)	0.41	70.3 (25.5)	75.1 (22.9)	0.21
General health	58.8 (19.4)	58.2 (19.9)	0.86	64.5 (18.8)	64.5 (20.9)	0.99
Vitality	51.2 (22)	47.2 (20.1)	0.23	62 (19.8)	61.3 (18.6)	0.81
Social functioning	75 (25.9)	75.9 (26.3)	0.83	84.9 (23.2)	86.8 (19.3)	0.57
Emotional role	64.5 (44.4)	64.9 (42)	0.3	79 (38.5)	84.7 (31.8)	0.3
Mental health	66 (19.8)	63.8 (22.2)	0.52	78.1 (17.6)	76.3 (17.6)	0.51
Physical summary scale	42.8 (10.8)	43.6 (10.3)	0.66	44.7 (10.6)	47 (9.18)	0.15
Mental summary scale	46.5 (11.1)	44.8 (12.1)	0.41	52.3 (11.1)	51.9 (9.43)	0.79

Mean relative subscale scores (±SD)

Relative subscale scores are added absolute values of items in subscale divided by the number of items

Parametric t test two-sided after testing for normal distribution; differences significant with $p < 0.05$; results of logistic regression analysis cited in text

relaparoscopy due to bleeding from the fossa vesica fellea was not included in this study, because the complete set of postoperative questionnaires was not sent back to our department. We report any complications to the German NOTES register, and recent data analysis of this register indicated an overall low level of complications for hybrid NOTES procedures (Table 5) [7].

Quality of life after transvaginal cholecystectomy

Quality of life was evaluated by using the combined questionnaire system of the SF-36 and GIQoL. Data were collected prospectively, entered into the database, and analyzed through a statistician not related to our hospital. After exclusion of patients with incomplete pre- and postoperative sets of questionnaires, 98.2 % of SF-36 and 98.9% of GIQoL data were available for analysis. Data were analyzed according to Quintana et al. [11] to enable comparison with historical data. Preoperative statistical analyses did not reveal differences in any of the four GIQoL or eight SF-36 domains between the two groups (Table 6). No preoperative differences were detected for the global GIQoL score and the physical and mental health summary scales of the SF-36. Postoperatively again there was no difference in any of the four domains for the GIQoL or eight SF-36 domains. After adjusting for independent variables (CHD, salpingectomy, and conization/curettage; Table 1), LRA approved the absence of any differences in quality of life after conventional laparoscopic compared with transvaginal cholecystectomy.

Postoperative sexual function

The GIQoL allows for assessment of postoperative sexual function (item 26 of GIQoL). There were no differences in preoperative sexual functioning and experience between the two groups (mean CLC vs. TVC ± SD: 3.06 ± 1.12 vs. 2.95 ± 1.15, $p = 0.574$). After 4 weeks of convalescence, pre- and postoperative experience of illness and surgery did not impact sexual function. Instead sexual function improved as expected without significant difference between the two groups (mean CLC vs. TVC ± SD: 3.28 ± 1.11 vs. 3.19 ± 1.16, $p = 0.603$). For comparison, Linke et al. [2] reported a preoperative score of this item, including patients with symptomatic cholecystolithiasis and acute cholecystitis in TVC patients with a mean ± standard deviation of 3.1 ± 1.3 and postoperative with a mean of 3.6 ± 0.7.

Discussion

This is the first prospective study of transvaginal-assisted cholecystectomy using a combined and procedure targeted set of HRQoL questionnaires. The study was designed to fulfill a further step in an accepted model of research. We first published small and larger case series and presented our experience at several conferences [1, 13, 14]. We then collected the data for this prospective study. We are now reporting these prospective data while a randomized, controlled trial comparing TVC and CLC is nearing the end in our department. Investigating and introducing new surgical procedures will almost always be accompanied by several forms of bias. This bias may arise at patient level, within the research team, from statistical analysis, within a peer group, or even at the level of the reader. New surgical procedures would rather not be used for patients predictive for an unfavorable outcome. For these reasons, extended description of patient demography and presentation enables detection of possible bias in patient selection. We tried to take into account reviews on NOTES procedures criticizing the lack of detailed patient data [15]. Our study revealed subtle differences between both groups for cardiovascular disease. It also revealed that patients who chose TVC had more experience with gynecological procedures and were single less often and were married or had a stable partnership more often. Despite these differences, there were no differences in the preoperative HRQoL. There also were no differences between accepted measures to compare patient groups, such as age, body mass index, and ASA grade. The evaluation of preoperative laboratory results indicates that only elective cases were included in this study as intended, although no routine, immediate, preoperative, ultrasound assessment and analysis of specimen histology was performed to further ascertain true elective status. From a clinical viewpoint, strictly elective cases with symptomatic cholecystolithiasis are reported in this study. Previous research on surgical outcomes after cholecystectomy has been criticized for missing adjustment between acute and elective cases [16]. Great care was taken in this study to avoid a similar situation. Several other studies that investigated the transvaginal approach included patients with acute cholecystitis [2, 17, 18]. Rarely authors reported acute cholecystitis as exclusion criteria selecting patients for TVC [19]. To enable HRQoL assessment, we restricted our study to patients with a history of symptomatic cholecystolithiasis. The postoperative results revealed no differences in surgical times or length of hospital stay. The surgical times and length of hospital stay are comparable to previous studies. Interestingly, Zornig et al. reported significantly longer surgical times for TVC vs. CLC (52 vs. 35 min, $p < 0.001$), whereas Hensel et al. reported shorter surgical times compared with CLC (45 vs. 60 min, $p < 0.002$) [18, 20]. Hensel et al. attributed this difference to the experience of the operating surgeons. Similar to laparoscopic surgery, individual cases with transvaginal approach can become very difficult and time consuming. Our range of surgical times for TVC vs. CLC (22–204 vs. 29–168 min, $p = 0.717$) indicates that cases admitted for simple cholecystectomy can easily use up operating room time otherwise reserved for major abdominal surgery. Pain scores and need for analgesia showed an advantage of TVC compared with CLC. Although no immediate postoperative benefit for pain relief and reduction of analgesic medication could be demonstrated for TVC using the visual analogue score as pain scoring method. Two recent studies reported less pain after TVC [18, 19]. Whereas Kilian et al. measured abdominal pain twice daily on coughing on a numeric analogue scale, Hensel et al. reported pain on a numeric rating scale and analgesic medication. In both reports, TVC patients had significantly less pain during the immediate postoperative situation (recovery room) and thereafter. Hensel et al. also reported significantly lower doses of analgesic medication needed for TVC patients. Our data show a similar decrease in pain and need for analgesia, although not on a similarly significant level. Pain level and analgesia reported in this study are well within published international experience [21]. We reported complications in our TVC patients in a previous case series with no difference between TVC and CLC [1]. The complications documented in this prospective study exclude several patients from analysis due to missing questionnaires. However, similar to our previous report, the type and rate of complications as classified according to Clavien and Dindo did not reveal any statistical differences [1]. Complications were well within what has been reported already from several other studies in TVC. Only one study so far reported the use of a HRQoL questionnaire to assess differences in patients pre- and postoperative health status [2]. The study by Linke et al. reports the absolute global score of the GIQoL questionnaire in 102 female patients with TVC. As expected, HRQoL improved for patients (preoperative absolute global score 98.9 ± 22.8, postoperative global score 119.1 ± 18). The subscale scores for symptomatology, emotion, physical, and social functioning are not reported. Our data result in similar absolute global scores for TVC patients (preoperative absolute global score 95.5 ± 22.2, postoperative absolute global score 117.7 ± 16.9). In our study, the results of the SF-36 and GIQoL were compared between CLC and TVC. No pre- or postoperative differences were detected. In a recent study, Solomon et al. investigated sexual function after TVC using a specific female sexual function index [22]. They concluded that neither CLC nor TVC influences sexual function. The QoL data of this study support the finding of Solomon et al.

Overall our results indicate that both surgical approaches are comparable in terms of HRQoL outcome. Our data are in line with reported studies that evaluated surgical techniques in laparoscopic cholecystectomy. Downsizing incision and trocar size as well as reducing trocar number decreases postoperative pain and increases postoperative quality of life [23]. Limitations of this study include missing analyses of preoperative ultrasound examinations and postoperative histology assessment to further ascertain absence of acute inflammation. Nevertheless, no previous studies on TVC reported any data to prove the absence of acute cholecystitis. Future research on TVC should assess time for convalescence, incidence of trocar hernias, and quality of life at 6-month to account for possible response shift in HRQoL after TVC [24]. Moreover, explicit data collection on female patients with acute cholecystitis undergoing TVC should be started.

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