

# Transvaginal Cholecystectomy

## Effect on Quality of Life and Female Sexual Function

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**Importance:** Transvaginal cholecystectomy (TVC) is the leading natural orifice transluminal endoscopic surgery to date and has the potential to offer improved cosmesis, less pain, and shorter recovery times for female patients.

**Objective:** To investigate quality of life and female sexual function in our patients undergoing TVC.

**Design:** A prospective cohort study from August 14, 2009, to June 12, 2012, of TVCs performed at our institution to date.

**Setting:** Tertiary academic referral center.

**Participants:** The first 47 consecutive female patients (aged 18-65 years) who received a TVC by a single surgeon.

**Interventions:** A hybrid TVC was performed by a 5-mm umbilical trocar and a 12-mm transvaginal trocar with standard laparoscopic instruments.

**Main Outcomes and Measures:** Quality-of-life index (36-Item Short Form Health Survey) and female

sexual function (Female Sexual Function Index) scores.

**Results:** A total of 47 TVCs were performed, with a mean age of 39 years, mean body mass index (calculated as weight in kilograms divided by height in meters squared) of 31, and mean operative time of 65 minutes. No difference was noted in overall female sexual function from preoperatively to 1 and 3 months postoperatively. When comparing quality of life preoperatively vs 1 and 3 months postoperatively, there were significant improvements in physical function ( $P=.02$ ), energy and fatigue ( $P=.001$ ), emotional well-being ( $P=.01$ ), pain ( $P<.001$ ), and general health ( $P=.03$ ). No significant changes were noted in physical limitations ( $P=.18$ ), emotional problems ( $P=.72$ ), and social function ( $P=.12$ ).

**Conclusions and Relevance:** In our experience to date, female sexual function is unchanged and quality of life either is unchanged or improves at 1 and 3 months following TVC. Undergoing TVC does not appear to negatively affect female sexual function or quality of life in the short term.

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**S**INCE THE FIRST DESCRIPTIONS of transvaginal cholecystectomy (TVC) were published in 2007,<sup>1-3</sup> TVC has taken a leading role in the field of natural orifice transluminal endoscopic surgery (NOTES) as the most commonly performed procedure.<sup>4</sup> Both flexible endoscopic and straight laparoscopic instruments have been used successfully, as have

triangulation and dissection. Compared with laparoscopic cholecystectomy (LC), the TVC approach has demonstrated benefits of decreased wound infection, incisional hernias, and postoperative pain and improved recovery.<sup>5-7</sup>

### See Invited Critique at end of article

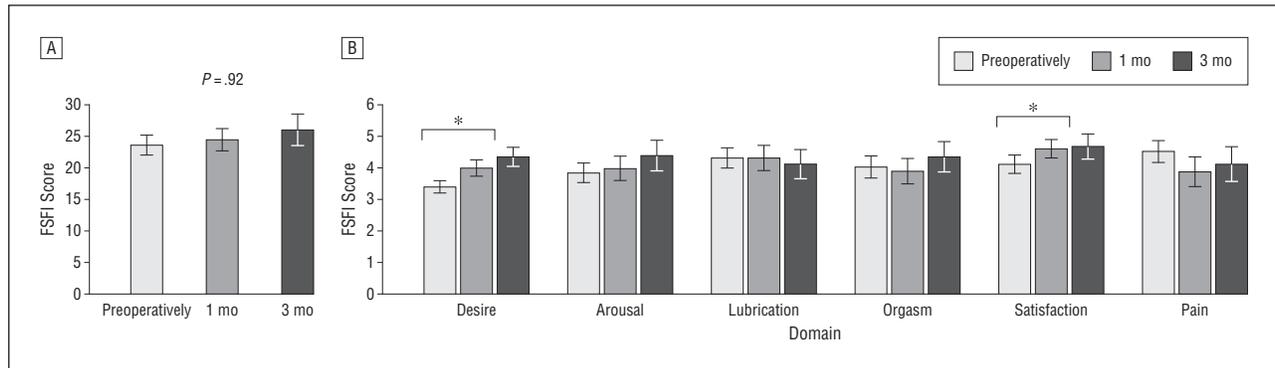
However, studies assessing female patients' opinions regarding TVC have highlighted the perceived potential negative effects on recovery, complications, sexual function, and fertility.<sup>8,9</sup> While these concerns have not been confirmed in the published data thus far, more studies are needed to reassure female patients. To address the paucity of information in relation to TVC, we investigated quality of life



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pure and hybrid techniques. Most TVCs are performed as a hybrid transvaginal approach in which a transabdominal (umbilical) port is placed, with an advantage of visualizing the transvaginal access as well as providing better ergonomics/

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**Figure.** Analysis of female sexual function using Female Sexual Function Index (FSFI) scores of patients undergoing transvaginal cholecystectomy. A, Overall sexual function scores. B, Sexual function domain scores. \* $P = .02$ . Error bars indicate standard error of the mean.

(QOL) and female sexual function in our patients undergoing TVC to date.

## METHODS

### SUBJECT RECRUITMENT

This is a prospective cohort study of consecutive TVCs performed at a single tertiary academic referral center from August 14, 2009, to June 12, 2012. Female patients aged 18 to 65 years who received an elective TVC by a single surgeon (K.E.R.) were included. All patients were enrolled in an institutional review board–approved protocol. The exclusion criteria were defined as follows: pregnancy; body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) greater than 45; undergoing peritoneal dialysis; receiving immunosuppressive medication or immunocompromised; receiving therapeutic anticoagulation or antiplatelet therapies or having abnormal results on preoperative coagulation studies; prior transvaginal surgery; history of pelvic inflammatory disease or suspected severe endometriosis; or inability to understand English. Informed consent was obtained for all patients prior to TVC by the operating surgeon in the clinic setting.

Questionnaires on QOL (36-Item Short Form Health Survey [SF-36]) and female sexual function (Female Sexual Function Index) were completed at the preoperative visit and during follow-up at 1 and 3 months by telephone interview by a research assistant. Data were entered in a prospective database (Excel; Microsoft Corp) and deidentified prior to analysis. The SF-36 is a validated questionnaire of 36 queries assessing 8 domains of QOL: physical function, physical limitations, emotional problems, energy and fatigue, emotional well-being, social function, pain, and general health.<sup>10,11</sup> The Female Sexual Function Index is a validated, reliable questionnaire involving 19 questions and assessments of 6 domains of sexual function: desire, arousal, lubrication, orgasm, satisfaction, and pain with intercourse.<sup>12-14</sup> Each domain is scored on a scale of 1 to 6, with higher scores indicating better function. The overall sexual function score is the determined sum of all 6 domains (maximum score of 36).

### SURGICAL TECHNIQUE

All patients brought to the operating room were placed supine on the operating room table. After application of sequential compression devices and administration of preoperative intravenous antibiotics, general anesthesia was induced. Following intubation, patients were placed in lithotomy position, and shoulder holders were placed to avoid the sliding of the pa-

tient during steep Trendelenburg positioning. The abdomen was prepared with 3M DuraPrep solution and the vagina was prepared with povidone-iodine, after which the areas were draped.

All operations were hybrid TVC. Access to the peritoneal cavity was initially obtained through a transumbilical 5-mm incision. Pneumoperitoneum was established with a Veress needle to achieve an intra-abdominal pressure of 15 mm Hg. A 5-mm trocar was subsequently placed through the umbilical incision and the patient was placed in steep Trendelenburg position. Transvaginal access was obtained by colpotomy through the posterior vaginal fornix and a 12-mm port was introduced under direct laparoscopic visualization. We used only standard straight laparoscopic instruments for dissection and specimen retrieval (video, <http://www.jamasurg.com>).

The detailed operative techniques have been previously reported.<sup>15</sup>

### STATISTICAL ANALYSIS

The statistical analyses were performed using SPSS for Mac version 19.0 statistical software (SPSS Inc). Descriptive statistics included frequency tables, means, standard deviations, and standard errors of means. As QOL and female sexual function variables did not conform to a normal distribution, nonparametric tests were applied. Friedman test was used to determine overall differences in variables over time. Wilcoxon signed rank test was used for comparisons between specific times.  $P < .05$  was considered statistically significant.

## RESULTS

A total of 47 TVCs were performed between August 14, 2009, and June 12, 2012. The mean (SD) age was 39 (12.5) years, the mean (SD) BMI was 31 (6.4), and the mean (SD) operative time was 65 (17.5) minutes. The mean (SD) time until return to normal activity was 6 (4.8) days, and the mean (SD) time until return to work was 8 (5.2) days. Of the 47 patients who were administered questionnaires preoperatively, 32 and 25 patients completed both the Female Sexual Function Index and the SF-36 at 1 and 3 months postoperatively, respectively.

Female sexual function results are shown in the **Figure**. Among the patients, 41 of 47 (87%) were sexually active preoperatively, followed by 28 of 32 (88%) at 1 month and 21 of 25 (84%) at 3 months. No significant difference was noted in overall female sexual function from preopera-

**Table. Quality-of-Life Scores of Patients Undergoing Transvaginal Cholecystectomy Using the 36-Item Short Form Health Survey**

Variable	Score, Mean (SD) <sup>a</sup>			P Value <sup>b</sup>
	Preoperatively (n = 47)	1 mo (n = 32)	3 mo (n = 25)	
Physical function	85 (18.4)	91 (15.4)	98 (4.2)	.02
Physical limitations	60 (43.2)	89 (23.7)	91 (26.4)	.18
Emotional limitations	79 (37.8)	88 (33.6)	96 (20.9)	.72
Energy and fatigue	53 (22.3)	67 (21.5)	73 (20.6)	.001
Emotional well-being	70 (18.9)	77 (22.7)	85 (14.2)	.01
Social function	69 (25.9)	87 (20.0)	88 (19.1)	.12
Pain	56 (24.6)	91 (14.2)	94 (13.0)	<.001
General health	65 (19.3)	76 (19.8)	77 (20.1)	.03

<sup>a</sup>A higher score implies that the domain function is better (or pain is less).

<sup>b</sup>Nonparametric Friedman test used after testing for normal distribution; differences statistically significant at  $P < .05$ .

tively to 1 and 3 months postoperatively. Within the sexual function domains, only desire and satisfaction significantly improved from preoperatively to 1 month postoperatively. There were no statistically significant differences detected for the remaining sexual function domains, including arousal, lubrication, orgasm, and pain.

The results of the QOL questionnaire (SF-36) are shown in the **Table**. There was significant improvement in physical function, energy and fatigue, emotional well-being, pain, and general health. There were no significant changes in physical limitations, emotional problems, and social function from preoperatively to 1 and 3 months postoperatively.

## DISCUSSION

### SEXUAL FUNCTION

Our study demonstrated that there was no significant change in overall female sexual function after a TVC. The improvement in desire and satisfaction noted postoperatively is not surprising given the patients' preoperative morbid state of gallbladder dysfunction. These results support our previously published findings comparing female sexual function in patients undergoing transvaginal appendectomy vs laparoscopic appendectomy<sup>16</sup> as well as another recent study comparing TVC vs LC.<sup>17</sup> A series of hybrid transvaginal–low anterior resections for diverticulitis also did not demonstrate a change in female sexual function postoperatively.<sup>18</sup> Finally, within the gynecology literature, several studies have found no significant difference in sexual function after transvaginal hysterectomy compared with laparoscopic hysterectomy.<sup>19–21</sup> It has been argued that the vaginal anatomy, with minimal sensory innervation of the upper vagina, may explain why female sexual function is not affected by a transvaginal procedure.<sup>16</sup> This fact as well as the relative ease of peritoneal access through the posterior fornix and the ability to heal quickly make transvaginal access an attractive alternative for intraperitoneal procedures.

The question remains: why have many studies found significant skepticism among potential female patients of NOTES or TVC? Women generally prefer LC or laparo-

scopic single-incision surgery to transvaginal NOTES.<sup>9,22</sup> Most worrisome to patients is the transvaginal access, with specific concerns for postoperative dyspareunia, decreased sensation during intercourse, the postoperative abstinence, and infertility.<sup>9</sup> Concern for such procedures is higher among physicians, nulliparous women, and younger women (aged <45 years),<sup>8,23</sup> perhaps owing to the uncertainty of a relatively new procedure. Conversely, among women who would prefer a transvaginal procedure in the future, the promise of decreased risk of hernia and pain as well as improved cosmesis have been cited.<sup>8</sup>

Indeed, minimal data are available on the effect of transvaginal NOTES on infertility, with only 1 report of a patient becoming pregnant 3 weeks after a TVC.<sup>24</sup> Just as transvaginal procedures are more common within the gynecology literature, so too are reports of postoperative fertility. A study on hybrid laparoscopic-transvaginal rectosigmoid resection for endometriosis reported that 4 of 13 patients who tried to conceive were successful, with a median follow-up of 13 months. Of note, 15 of 33 patients in the study (45.5%) had a history of preoperative infertility. Another study on transvaginal myomectomies for symptomatic uterine leiomyomas noted that all 8 patients who tried to conceive in the follow-up period were successful, with 14 full-term pregnancies among a total of 16 patients who received the treatment.<sup>25</sup>

### QUALITY OF LIFE

A QOL assessment, measured by the SF-36, was used in this study to broaden our understanding of the patients' perspective of their health and wellness over time. A significant improvement was noted postoperatively in the majority of QOL measures (5 of 8), including general health. In the remaining QOL measures, no significant change was noted. These findings affirm our belief that TVC has no detrimental effect on postoperative QOL. The positive effect seen in several domains of QOL may be representative, again, of the relative preoperative biliary morbidity rather than the TVC procedure itself. Although our results were not compared with LC, a recent article by Borchert et al<sup>17</sup> demonstrated no significant dif-

ference in QOL between TVC and LC, which supports our findings.

## LIMITATIONS

Our study is limited by the high loss to follow-up during the course of the study, with a 32% loss at 1 month and a further 22% loss at 3 months, which can underpower our ability to detect differences (type II error). Beyond the initial 2-week postoperative clinic visit, patients were less likely to respond to a telephone call. We postulate that the elective nature of the procedure, whereby a patient is typically discharged the same day of surgery, may yield less incentive to participate in follow-up. Other limitations are the short-term nature of the study and the lack of a study control (or comparison with LC). Potential long-term effects on female sexual function and QOL will be assessed as more data become available. We cannot conclude that female sexual function and QOL in patients undergoing TVC are the same as or different from those in patients undergoing LC based on our data. However, there is no published evidence to date to suggest TVC to be inferior to LC in these regards.<sup>17</sup>

In conclusion, this prospective cohort study found no overall change in sexual function and QOL after TVC for female patients. However, the discrepancy between skeptical public opinion and current data highlights the uncertainty that still exists in the paradigm of transvaginal NOTES and will continue to act as a barrier to its acceptance and future application. Future randomized trials of TVC and LC are needed to confirm our findings.

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**Author Contributions:** Dr Roberts had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. *Study concept and design:* Wood, Solomon, Bell, Duffy, and Roberts. *Acquisition of data:* Solomon and Panait. *Analysis and interpretation of data:* Wood, Bell, Duffy, and Roberts. *Drafting of the manuscript:* Wood, Bell, and Duffy. *Critical revision of the manuscript for important intellectual content:* Solomon, Panait, Bell, Duffy, and Roberts. *Statistical analysis:* Wood and Solomon. *Administrative, technical, and material support:* Solomon, Panait, and Bell. *Study supervision:* Bell, Duffy, and Roberts.

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**Online-Only Material:** The video is available at <http://www.jamasurg.com>.

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