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Long-Term Outcomes of the Total or Supracervical Hysterectomy (TOSH) Trial

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Abstract

BACKGROUND—Participants in the multi-center, randomized Total or Supracervical Hysterectomy (TOSH) trial showed within-group improvement in pelvic floor symptoms 2 years post-surgery and no differences between supracervical (SCH) versus total hysterectomy (TAH). This study describes longer term outcomes from the largest recruiting site.

STUDY DESIGN—Questionnaires addressing pelvic symptoms, sexual function, and health-related quality of life were administered. Linear models and McNemar’s test were utilized.

RESULTS—Thirty-seven participants (69%) responded (19 TAH, 18 SCH); mean follow up was 9.1±0.7 years. No between-group differences emerged in urinary incontinence, voiding dysfunction, pelvic prolapse symptoms and overall health related quality of life (HRQOL). Within-group analysis showed significant improvement in the ability to have and enjoy sex (P = 0.002) and in the SF-36 physical component summary score (P = 0.03) among women randomized to TAH.

CONCLUSION—9 years after surgery, TOSH participants continue to experience improvement and show no major between-group differences in lower urinary tract or pelvic floor symptoms conferring no major benefit of SCH over TAH.

INTRODUCTION

In the 1990’s supracervical hysterectomy was becoming popular due to concerns over poorer patient outcomes with total hysterectomy. During that time a number of small uncontrolled studies were performed that associated total hysterectomy with higher rates of sexual dysfunction, pelvic organ prolapse, lower urinary tract symptoms and surgical complications(1-4). Learman and colleagues reported results from the Total or Supracervical Hysterectomy (TOSH) trial where patients scheduled for abdominal hysterectomy were randomized to total (TAH) or supracervical (SCH) hysterectomy and followed for two years. No differences were seen between cohorts with respect to urinary incontinence and other

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pelvic floor symptoms or surgical complications at that primary outcome time point (2 years) (5). Sexual function outcomes from the TOSH trial were also analyzed and reported separately, again revealing no differences between the TAH and SCH groups two years after surgery(6).

Several more recent studies have supported the conclusion that there is no advantage to supracervical over total hysterectomy. With regard to urinary incontinence, Robert et al performed a meta-analysis of randomized trials showing no difference in the development of stress or urge incontinence following SCH or TAH at a mean time of 14.2 ± 4.7 months from surgery(7). A randomized controlled trial comparing 32 total (laparoscopic-assisted vaginal) and 31 subtotal (laparoscopic supracervical) hysterectomies revealed no psychosocial adverse effects in either group; 6 to 7 months after surgery the cohorts showed similar improvements in sexual function and no change in overall psychiatric function(8). A 2006 Cochrane Review of total versus subtotal hysterectomy reviewed 3 trials (including the original TOSH trial) with 733 patients and concluded that there was no evidence to confirm the view of improved outcomes for sexual, urinary and bowel function with supracervical hysterectomy(9).

Although study findings have been consistent, follow-up periods have been short (2 years or less), and the question ultimately remains regarding whether leaving or removing the cervix affects patient outcomes in a number of pelvic floor and health-related quality of life (HRQOL) domains over the longer term. To address this issue, we report 9-year outcomes among TOSH participants from the study's largest clinical site, focusing on lower urinary tract symptoms, pelvic organ prolapse, sexual function and overall HRQOL.

METHODS

In the original TOSH trial, participants were administered questionnaires at baseline and every 3 months for 2 years. These questionnaires addressed demographics and gynecologic history (at baseline only), pelvic floor symptoms (vaginal bleeding, pelvic pain and/or pressure, low back pain and urinary incontinence), and several domains of HRQOL including overall HRQOL and sexual function(5, 6).

Institutional Review Board approval was obtained. Participants from the University of Alabama at Birmingham were contacted via mail and/or their last known phone number and re-administered the pelvic and lower urinary tract symptom, treatment and HRQOL questionnaires. These were the same questionnaires utilized in the original trial(5, 6). Although attempted, logistic limitations at the other clinical sites involved in the original TOSH trial precluded their involvement in this follow-up report. On the updated demographics questionnaire, information was obtained regarding any new symptoms of or treatments for vaginal bleeding, urine leakage, pelvic organ prolapse or abnormal pap smears. Any new medical diagnoses and surgical procedures since their 2 year post-operative evaluation were also collected.

As part of our analysis of sexual function outcomes, we utilized the Medical Outcomes Study (MOS) Sexual Problems Scale(10) as described by Kuppermann et al (6). This measure utilizes 4 questions regarding lack of sexual interest, inability to relax and enjoy sex, and difficulty in becoming aroused and in having an orgasm. Answers to these 4 items are used to calculate an overall score from 0 to 100, with higher scores representing fewer problems. Overall health-related quality of life was determined using the mental (MCS) and physical (PCS) component summary scores(11) of the SF-36(12).

The TOSH study was a multi-center, randomized controlled trial that was powered to detect changes in health-related quality-of-life outcomes at 2 years of follow-up. For this secondary

analysis, with a sample size of 18 women, testing at a .05 level of significance, and assuming a within-group standard deviation of 14.25, we have 80% power to detect within-group changes in PCS scores of 10 points in each hysterectomy group. Paired t-tests were used to examine change from baseline to 9-year follow-up for each hysterectomy group. Generalized linear models were used to test between-group changes in MCS, PCS, and MOS scores. Differences in baseline characteristics were examined using chi-square tests for categorical variables and t-tests for continuous variables. For analyses of between group differences in pelvic/urinary symptoms at 9 years we calculated risk ratios with 95% confidence intervals; for these analyses categorical responses with multiple levels were dichotomized as follows: never or less than once per week versus more than once per week or daily; never, rarely, or sometimes versus often or always. Using the same simplified coding scheme, within-group change over time was assessed with McNemar's test. All analyses were performed using JMP 5.1 and SAS 9.1 (SAS Institute, Cary, NC).

RESULTS

Thirty-seven of the 54 participants (69%) returned questionnaires; of these, 18 had been randomized to SCH and 19 had been randomized to TAH. Responders were more likely to have private insurance than non-responders ($P = 0.042$), but no other differences in baseline characteristics were observed when comparing the responses of those who did ($N = 37$) versus those who did not ($N = 17$) return questionnaires. Baseline and current characteristics of participants from our site are presented in Table 1. Mean \pm SD follow up, from the date of surgery, was 9.1 ± 0.7 years (range 8.1 to 10.1 years). There was no difference in age, race, education level or preoperative diagnosis between the groups ($P > .05$).

The results of differences in the long-term outcomes of the 2 randomization groups as well as within group changes from baseline to follow up are presented in Table 2. No significant differences were found between the groups with respect to prolapse symptoms, pelvic or bladder pain, urgency, frequency or stress and urge urinary incontinence symptoms 9 years after surgery. Both groups had significant within-group improvements in pelvic/bladder pressure and vaginal bulging, but not in the other measures of pelvic symptomatology. There was an improvement in lower back pain in the TAH group at the time of follow up compared to baseline, and this was statistically significant ($P = 0.014$), but there was no difference in low back pain complaints between groups (RR: 1.81; 95% CI: 0.92, 3.55).

Vaginal bleeding was experienced by two respondents (11%) who had undergone supracervical hysterectomy, compared to none in the TAH group, but this difference was not statistically significant ($P > 0.05$). Two participants from each group (11%) reported having had an abnormal pap smear after surgery, and there was also one patient in the SCH group (5%) who ultimately underwent trachelectomy secondary to recurrent cervical dysplasia. Other gynecologic surgeries undergone by participants in the TAH group included one bilateral oophorectomy and one laser procedure for carcinoma in situ of the vagina.

No significant differences emerged in breast symptoms, hot flashes, weight change, or treatment of urinary incontinence. There was also no difference between or within the two groups in feelings of attractiveness or femininity. Interestingly, within group analysis of the sexual function questions showed a significant improvement in the ability to have and enjoy sex with a partner in the TAH group ($P = 0.002$). The SCH group had fewer sexual problems both at baseline and in the long term, but no significant within or between group changes in the sexual function outcomes (SPS scores) were observed ($P > 0.05$). Overall HRQOL as measured by the SF-36 MCS and PCS showed no statistically significant difference in scores between groups ($P = 0.98$ and 0.7 , respectively) (Table 3). Within group analysis

showed a significant improvement in PCS scores (35.1 to 41.5), again only in the TAH group ($P = 0.03$), consistent with improvements that were seen at 2 years.

DISCUSSION

This long-term follow up report of the TOSH study participants showed no difference between patients undergoing supracervical and total hysterectomy with respect to lower urinary tract symptoms, pelvic organ prolapse, sexual functioning and overall health-related quality of life. Within group analysis did show a difference in improved sexual functioning in the TAH group. However, in the original study group, women who were randomized to TAH had lower baseline sexual function scores than those reported by women in the SCH group. The improvement in sexual function reported by Kuppermann et al after 2 years was sustained in the current study (6). The TAH group also had a significant 6.4-point improvement in the Physical Component Summary scores compared with supracervical hysterectomy. For comparison, patients with mild asthma had PCS scores 0.86 points below the average US adult score of 49.7 (13), and intermittent treatment for duodenal ulcers has been associated with a 3.2-point improvement on the PCS (14). A possible explanation for these improvements in the TAH group may be that among responders, more participants in the SCH group underwent bilateral oophorectomy at the time of surgery (50% v. 26%). Furthermore, of the 6 patients on hormone replacement therapy at the time of follow-up, 5 were in the TAH group.

Another interesting finding in this study was that of persistent vaginal bleeding in 2 of the 18 (11%) supracervical hysterectomy respondents. These participants were 40 and 47 years of age at the time of this follow up, and neither had undergone treatment for their vaginal bleeding. In comparison, the original TOSH trial reported vaginal bleeding in 4, 3 and 3 (5%) patients from the SCH cohort at 3, 12 and 24 months postoperatively, respectively. One participant underwent trachelectomy 15 months after surgery due to persistent cyclic bleeding (6). The incidence of post-supracervical hysterectomy bleeding is reported to be anywhere from 1 to 25% in the literature (15, 16), including both abdominal and laparoscopic techniques. This is an important point to discuss with patients considering supracervical hysterectomy, as there is a risk of cervical stump complications, and rates of subsequent trachelectomy as high as 22% in one retrospective series (17). While several techniques exist for destruction of the endocervical canal at the time of subtotal hysterectomy, no comparative studies exist to help guide surgeons as to which is most effective. This is an area in need of further study.

The primary strength of this study is the follow-up time of greater than 9 years on participants from a robust randomized clinical trial. To date, no other randomized trial has reported follow up of greater than 2 years comparing outcomes of total and supracervical hysterectomy. The majority of studies have endpoints at 1 year (7 - 9). Additionally, the response rate of nearly 70% from our site with equal numbers of participants in the two groups strengthens our findings and lowers the probability of differential loss to follow-up in one group versus the other.

Another study strength is the inclusion of the SF-36 as a measure of health-related quality-of-life. Being the most widely used generic HRQOL measure, population norms have been established in the United States for major chronic medical conditions, and it has been used to assess the impact of several non-cancerous uterine conditions(18), as well as to evaluate the effect of treatments for these conditions(19). The SF-36 scales also have good internal reliability and validity, and are responsive to changes due to medical or surgical treatment for menorrhagia (20, 21).

In a cross-sectional study of women with pelvic pain, heavy uterine bleeding, and/or fibroids with pressure, mean SF-12 PCS scores ranged from 43 (pain and bleeding) to 44 (bleeding with or without fibroids and fibroids with pressure), and mean SF-12 MCS scores ranged from 41 (pain and bleeding) to 49 (fibroids with pressure) (18), lower than population norms for non-institutionalized women (49.7, PCS and 49.5, MCS) (19). Patients with bleeding conditions have been shown in several studies to have lower HRQOL than healthy controls (22, 23). Although there is no universal agreement on the minimally important difference in HRQOL scales (24, 25), a change of 6 points on a 0-to-100 point scale has been utilized as a threshold on the MCS (26) and a difference of 3 to 5 points on the MOS Sexual Problems Scale has been suggested to be clinically meaningful based on comparisons between patient populations(27).

The main limitations of this study include the small number of participants available for long-term follow-up. The original study was powered to detect differences in the MOS Sexual Problems Scale with only two years of planned study attrition. Had longer term follow-up been planned at the outset, the original target sample size would have been much larger. Considerable attempts were made to involve participants from the other original TOSH sites, but the numerous logistical issues encountered prevented their inclusion in this follow-up study. With its limited numbers, our follow-up study had sufficient statistical power to detect only larger magnitude differences. With one exception, the modest risk ratios we found make it unlikely that clinically meaningful differences escaped detection due to limited statistical power. Participants were over three times more likely to report pelvic pain at least weekly after SCH than TAH, but the difference was not statistically significant and the confidence interval was wide. There is biological plausibility for this finding in that SCH does not include interruption or removal of the paracervical Frankenhauser's plexus, while TAH does. Although being somewhat limited in drawing definitive conclusions of differences between the cohorts, this data could be utilized in subsequent meta-analyses.

To assure data comparability between baseline and follow-up, we decided to use the same measures used in the original study and not more recently published measures such as the Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire (23, 24). The sexual function measure utilized was recently validated as the Sexual Health Outcomes in Women Questionnaire (SHOW-Q) (28).

Our finding of no long-term significant differences in pelvic floor symptoms, sexual function and overall health-related quality of life between participants randomized to total versus supracervical abdominal hysterectomy begs the question of whether these findings are relevant to laparoscopic procedures that are currently being performed. One study with 66-month follow-up comparing laparoscopic supracervical and laparoscopic-assisted vaginal hysterectomies reported fewer complications (2.4 versus 3.7%) and better sexual function in the supracervical group, but this was a retrospective analysis (29). Two randomized trials of laparoscopic supracervical versus either total laparoscopic (30) or laparoscopic-assisted vaginal (8) hysterectomy found no differences in surgical complications, clinical or psychosocial outcomes with follow-up ranging from 6 to 24 months. Given the scarcity of long-term data, it is unclear how outcomes of laparoscopic total and subtotal hysterectomy might compare, and randomized trials with extended follow-up should be performed.

Our 9-year findings confirm and extend those of other randomized trials with 1-2 year follow-up indicating that there are no clinically important long-term differences in outcomes that would favor one method of hysterectomy over the other. However, persistent vaginal bleeding occurs in an important minority of patients after SCH and the optimal way to prevent this complication merits further investigation. Our results add to the existing data

available to physicians and patients considering hysterectomy and provide reassurance that decision-making on cervical removal or retention following well-balanced informed consent, based on patient preferences and skill of the surgeon, will result in highly comparable outcomes.

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ABBREVIATIONS

TOSH	Total or Supracervical Hysterectomy
TAH	Total Abdominal Hysterectomy
SCH	Supracervical Hysterectomy
HRQOL	Health-Related Quality of Life
MOS	Medical Outcomes Study
MCS	Mental Component Summary
PCS	Physical Component Summary
SHOW-Q	Sexual Health Outcomes in Women Questionnaire

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Table 1

Baseline and current characteristics by treatment group

	SCH (n = 27)	TAH (n = 27)	P
BASELINE			
Demographics			
Age (y)	41.8 ± 5.7	40.8 ± 6.1	0.56
African American	17 (63)	20 (74)	0.38
Education > high school	15 (55)	9 (33)	0.10
Insurance, private or HMO	12 (44)	12 (44)	> 0.99
Preoperative Diagnosis			
Abnormal uterine bleeding	21 (78)	18 (67)	0.36
Uterine fibroids	21 (78)	18 (67)	0.36
Pelvic pain or pressure	10 (37)	8 (30)	0.56
Endometriosis	2 (7.4)	1 (3.7)	0.55
Urinary incontinence	1 (3.7)	3 (11)	0.30
Pelvic mass	1 (3.7)	0 (0)	0.31
CURRENT	(N = 18)	(N = 19)	
Demographics			
Age (y)	52.5 ± 5.6	50.1 ± 6.6	0.25
African American	12 (67)	14 (74)	0.64
Education > high school	9 (50)	5 (26)	0.14
Interim new diagnoses			
Hypertension	9 (50)	7 (37)	0.42
Diabetes	3 (17)	2 (11)	0.59
Heart disease	1 (5.6)	2 (10.5)	0.58
Lung disease	2 (11)	1 (5.3)	0.51

SCH = supracervical hysterectomy; TAH = total abdominal hysterectomy; HMO = health maintenance organization.

Data presented as mean ± standard deviation or *n* (%).

Table 2
Pelvic/Urinary Symptoms Following Supracervical or Total Abdominal Hysterectomy

Number (%) of participants with symptoms	Supracervical Hysterectomy (n=27) [†]		Total Abdominal Hysterectomy (n=27) [‡]		Within group change p-value	Between group RR (95% CI)
	Baseline	Long-term	Baseline	Long-term		
Data available, n (%)	27 (100)	18 (67)	27 (100)	19 (70)		
Vaginal bleeding, n (%)	12 (44)	2 (11)*	14 (52)	0 (0)*	<0.01	NA
Pelvic pain, n (%)	5 (19)	14 (78)	1 (4)	16 (84)	<0.01	3.17 (0.36, 27.72)
Never	3 (11)	1 (5)	6 (22)	2 (11)		
< once a week	11 (41)	2 (11)	12 (44)	1 (5)		
Daily	8 (30)	1 (5)	8 (30)	0 (0)		
Pelvic/bladder pressure, n (%)	4 (15)	12 (67)	4 (15)	11 (61)	<0.01	2.11 (0.44, 10.15)
Never	6 (22)	2 (11)	7 (26)	6 (32)		
< once a week	7 (26)	2 (11)	8 (30)	2 (11)		
Daily	10 (37)	2 (11)	8 (30)	0 (0)		
Vagina bulging out, n (%)	10 (37)	18 (100)	10 (37)	18 (95)	<0.01	NA
Never	2 (7)	0 (0)	2 (7)	1 (5)		
< once a week	9 (33)	0 (0)	9 (33)	0 (0)		
Daily	6 (22)	0 (0)	6 (22)	0 (0)		
Back pain, n (%)	3 (11)	3 (17)	2 (7)	6 (33)	0.18	1.81 (0.92, 3.55)
Never	4 (15)	3 (17)	5 (19)	6 (33)		
< once a week	14 (52)	8 (44)	15 (56)	4 (22)		
Daily	6 (22)	4 (22)	5 (19)	3 (16)		
Urinary urgency, n (%)						

Number (%) of participants with symptoms	Supracervical Hysterectomy (n=27) [†]		Total Abdominal Hysterectomy (n=27) [‡]		Within group change p-value		Between group RR (95% CI)
	Baseline	Long-term	Baseline	Long-term	SCH	TAH	
	Never	6 (22)	3 (17)	9 (33)	7 (37)	0.41	
Rarely	2 (7)	3 (17)	5 (19)	3 (16)			
Sometimes	12 (44)	8 (44)	5 (19)	4 (21)			
Often	6 (22)	2 (11)	6 (22)	4 (21)			
Always	1 (4)	2 (11)	2 (7)	1 (5)			
Incomplete emptying, n (%)							2.64 (0.58, 11.92)
Never	9 (35)	7 (39)	13 (48)	10 (53)	0.65	0.41	
Rarely	4 (15)	3 (17)	4 (15)	3 (16)			
Sometimes	8 (31)	3 (17)	6 (22)	4 (21)			
Often	4 (15)	4 (22)	3 (11)	2 (11)			
Always	1 (4)	1 (5)	1 (4)	0 (0)			
Frequent urination, n (%)							0.70 (0.24, 2.09)
Never	5 (19)	4 (22)	4 (15)	5 (26)	0.06	0.65	
Rarely	1 (4)	4 (22)	9 (33)	5 (26)			
Sometimes	9 (33)	6 (33)	4 (15)	3 (16)			
Often	7 (26)	4 (22)	4 (15)	5 (26)			
Always	5 (19)	0 (0)	6 (22)	1 (5)			
Stress incontinence, n (%)							0.95 (0.21, 4.35)
Never	3 (11)	2 (11)	2 (7)	2 (11)	0.10	0.08	
1-2 times/month	5 (19)	6 (33)	5 (19)	3 (16)			
1-2 times/week	6 (22)	1 (5)	2 (7)	2 (11)			
Daily	3 (11)	2 (11)	5 (19)	0 (0)			
Urge incontinence, n (%)							0.73 (0.26, 2.07)
Never	6 (22)	3 (17)	1 (4)	2 (11)	0.16	0.32	
1-2 times/month	6 (22)	4 (22)	9 (33)	2 (11)			
1-2 times/week	3 (11)	3 (17)	2 (7)	3 (16)			
Daily	2 (7)	1 (5)	2 (7)	1 (5)			

* Long-term percentages are based on N of 18 and 19 responders for SCH and TAH, respectively.

† Original site cohort total N

Table 3

Health related quality of life and sexual function outcomes

	Baseline	Long term	Change	Within group p	Between group p
MCS:					
SCH	43.9 (± 11.2)	44.7 (± 14.0)	+ 0.8	0.82	0.98
TAH	40.9 (± 10.5)	41.5 (± 11.0)	+ 0.6	0.79	
PCS:					
SCH	32.1 (± 6.9)	36.8 (± 12.5)	+ 4.7	0.17	0.70
TAH	35.1 (± 9.5)	41.5 (± 9.4)	+ 6.4	0.03	
MOS SPS:					
SCH	69.4 (± 33.5)	76.2 (± 30.3)	+ 6.8	0.57	1.00
TAH	50.9 (± 36.3)	57.8 (± 32.0)	+ 6.9	0.52	

All scores are mean±standard deviation