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Two-Year Outcomes After Sacrocolpopexy With and Without Burch to Prevent Stress Urinary Incontinence

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Abstract

OBJECTIVES—To report anatomic and functional outcomes 2 years after sacrocolpopexy in stress-continent women with or without prophylactic Burch colposuspension.

METHODS—In the Colpopexy and Urinary Reduction Efforts (CARE) trial, stress-continent women undergoing sacrocolpopexy were randomized to receive or not receive a Burch colposuspension. Outcomes included urinary symptoms, other pelvic symptoms, and pelvic support. Standardized pelvic organ prolapse quantification examinations and validated outcome measures including the Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire were completed before surgery and at several postoperative intervals, including at 2 years.

RESULTS—This analysis is based on 302 of 322 randomized participants. Most were Caucasian (94%), with a mean age of 62±10 years (mean±standard deviation). Two years after surgery, 32.0% and 45.2% of women in the Burch and control groups, respectively, met the stress incontinence endpoint (presence of symptoms or positive cough stress test or interval treatment for stress incontinence, P=.026). The apex was well supported (point C within 2 cm of total vaginal length) in 95% of women, and this was not affected by concomitant Burch (P=.18). There was a trend toward fewer urgency symptoms in the Burch group (32.0% versus 44.5% no Burch, P=.085). Twenty participants experienced mesh or suture erosions.

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*For members of the Pelvic Floor Disorders Network, see the Appendix online at www.greenjournal.org/cgi/content/full/112/1/49/DC1.

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CONCLUSION—The early advantage of prophylactic Burch colposuspension for stress incontinence that was seen at 3 months remains at 2 years. Apical anatomic success rates are high and not affected by concomitant Burch.

The Colpopexy and Urinary Reduction Efforts (CARE) study wasconductedto estimatethe utility of Burch colposuspension at the time of sacrocolpopexy in stress-continent women. The short-term protective benefit of concomitant Burch colposuspension on bladder symptoms up to 1 year has been described.[1,2] Recent evidence suggests that the Burch colposuspension is less effective than a rectus fascial sling to treat stress incontinence symptoms in women with and without prolapse[3] and that the efficacy of both studied procedures decreases over the initial 2 years after surgery. To provide longer term information about the optimal strategy for minimizing bothersome bladder symptoms at the time of prolapse surgery, the CARE trial included a 2-year assessment. In addition, concomitant colposuspension can affect vaginal support, an effect best appreciated over time.

The aims of this report are to compare, between women who did and did not undergo Burch colposuspension at the time of sacrocolpopexy, bladder, functional, sexual, and anatomical outcomes 2 years after the index surgery and to report complications related to surgery over the 2-year period.

MATERIALS AND METHODS

We previously reported the CARE trial methods[4] and 3-month[1] and 1-year outcomes of bladder symptoms.[2] This trial was registered and received institutional review board approval at all participating sites before enrollment of women planning sacrocolpopexy for stage II–IV prolapse without symptoms of stress incontinence between March 7, 2002 and February 7, 2005. To be eligible, participants had to be categorized as stress continent based on their responses of “never” or “rarely” to the six questions of the Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire, which focus on stress incontinence symptoms.[5]

Participants were assigned with equal probability to sacrocolpopexy with or without prophylactic Burch colposuspension using computer-generated random numbers in blocks of varying sizes and stratified by surgeon and intent to perform paravaginal repair (done at the surgeon’s discretion and disclosed before randomization). Surgical materials and techniques for the Burch colposuspension were standardized; other surgical materials were left to surgeon discretion. Participants, research staff, and telephone interviewers were masked to assignment for a minimum of 3 months, with the intent of maintaining masking for 2 years after surgery.

Outcome measures included anatomical measures (Q-tip test, Pelvic Organ Prolapse Quantified [POP-Q] staging, and standardized stress test), pelvic floor disorder symptoms and impact measures (MESA Questionnaire,[5] Incontinence Severity Index,[6] Pelvic Floor Distress Inventory [PFDI], Pelvic Floor Impact Questionnaire,[7] Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire,[8,9] SF-36 Version 2,[10] and patient satisfaction items), and adverse events. Research nurses assessed anatomical measures at 3 months, 1 year, and 2 years. Trained interviewers conducted quality of life interviews by telephone at 3, 6, 12, and 24 months. Instruments were reliable for use by telephone interview.[11] We aimed to maintain blinding until our primary outcome at 3 months. At 2 years, 123 participants (Burch 59, control 64) reported that they became unblinded. Group assignment was identified correctly in 48 Burch and 44 control participants, incorrectly in 1 Burch and 10 control participants. The remaining participants stated that they did not know their group assignment.

The primary outcome, as previously reported, was stress incontinence at the 3-month assessment point.[1] Participants were characterized as having stress incontinence if any of the following were present:

1. Symptoms, as defined by a "yes" response to any of three questions in the PFDI stress incontinence subscale assessing leakage with coughing, sneezing, or laughing; physical exercise; and lifting or bending over
2. Stress incontinence during a standardized stress test at maximum bladder capacity or 300 mL, whichever was less
3. Any treatment for stress incontinence after the study surgery

A symptom recorded on the PFDI was considered bothersome when participants reported "moderate" or "quite a bit" of bother. Participants met our "urge endpoint" when they reported bothersome urge incontinence, urgency, frequency, nocturia, or enuresis, or if they reported treatment for urge incontinence after the index surgery. Stress and urge symptoms also were assessed using the stress subscale and the irritative voiding subscale of the PFDI, respectively. A higher score represents more symptoms and bother.

Serious adverse events were defined as untoward medical occurrences that were life-threatening or resulted in death or that required hospitalization or prolonged hospitalization for the index surgery, any condition that resulted in persistent or significant disability, or any other important medical condition. Serious adverse events were categorized by the body system affected, such as gastrointestinal or urogenital. Because surgical treatment for stress incontinence was a component of the stress endpoint, this was not included among the adverse events.

The Pelvic Floor Disorders Network's independent Data and Safety Monitoring Board recommended that enrollment stop when 3-month results of the first of two planned interim analyses became available. Significance levels were adjusted to account for the interim analysis. Data were analyzed by a central data-coordinating center using SAS (Cary, NC). The groups were compared at baseline by age, body mass index, and prolapse stage; subsequent analyses were not adjusted for these measures because they were similar in both groups. Proportions were compared using Mantel-Haenszel χ^2 statistic adjusted for surgeon and paravaginal repair. Quality of life measures were compared using a general linear model with the same covariates (surgeon, paravaginal repair). Numbers do not necessarily total the entire sample size because not all participants completed every aspect of data collection; 10 participants in each treatment group withdrew without having been retreated for either stress urinary incontinence (SUI) or prolapse.

Antiincontinence surgery (including bulking agents) or repeat prolapse surgery could affect the outcomes at the postoperative assessments. To ensure that we did not enhance results, we imputed values for the quality of life responses occurring after retreatment by using the more negative (worse) response of either the interview after retreatment or the previous observation carried forward. In this way, we tried to eliminate responses that were good specifically because the participant underwent retreatment for incontinence or prolapse. In the three cases in which retreatment occurred before the 3-month interview, we still used the 3-month interview results. Ten participants in each group withdrew before 24 months without reporting any retreatment; these participants are not included in the 24-month analysis. Similarly, the earlier analyses do not include participants who withdrew before the time of the analysis (3 months or 12 months) without reporting any retreatment. All tests performed and *P*values reported were two-tailed. Results are presented as percentages or as mean±standard deviation.

RESULTS

Of 322 women enrolled and randomized, 157 underwent Burch procedure with abdominal sacrocolpopexy and 165 were controls (abdominal sacrocolpopexy without Burch). Seventy percent had prior hysterectomy. Most participants were Caucasian (94%), with a mean age of 62±10 years (mean±standard deviation). There were no significant differences between the groups in baseline characteristics, and these characteristics are similar to those reported in the primary paper.[1]

Three hundred two of the 322 randomized participants completed some part of the 2-year assessment or were treated for SUI after study surgery; 250 completed all outcome measures (cough stress test, physical examination, and quality of life and symptom instruments), and 52 completed only quality of life and symptom assessment. The noncompleters did not differ significantly between groups.

The primary outcome measures for this study are summarized in Table 1. To demonstrate the effect of imputation, two sets of results are presented for three of the outcome measures—the results without imputation and then the results with imputation. Nine participants in the Burch group had treatment for either stress incontinence or prolapse, whereas 20 participants in the control group had one of these treatments. Therefore, the results in the control group are more affected by the imputation. Using the imputed data, women in the Burch group had a lower rate of the overall stress incontinence endpoint (Burch 32.0% versus control 45.2%, *P*=.026), lower bothersome SUI (Burch 11.6% versus control 25.2%, *P*=.004), and a trend toward a lower rate of the urge endpoint (Burch 32.0% versus control 44.5%, *P*=.085).

The anatomical outcomes, based on the Pelvic Organ Prolapse Quantified evaluation, are shown in Table 2. Two years after surgery, the apex was well supported (point C within 2 cm of total vaginal length) in 95% of women, and this was not affected by concomitant Burch (*P*=.18). As expected, the anterior wall was slightly higher and the posterior wall slightly lower in the Burch group compared with the control group.

Results of other validated outcome measures are shown in Table 3. The Burch group had less SUI bother and less incontinence severity. There were no other statistically significant differences between the groups in terms of symptom bother, symptom impact, or sexual function, although there were trends toward improvement in all bladder measures in the Burch group. We did not detect any differences between SF-36 results or health utility scores 2 years after surgery.

Most women were satisfied with their treatment. The mean scores for the question, “In your opinion, has the treatment of your pelvic floor condition been … ” (scale of 1–5, 1=very successful) were 1.37±0.71 and 1.48±0.78 in the Burch and control groups, respectively. The mean scores for the question, “Compared to how you were before your pelvic floor operation, would you say that now you are … (scale of 1–5, 1=much better) were 1.22±0.67 and 1.34 ±0.86 in the Burch and control groups, respectively.

Complications related to the surgery are summarized in Table 4. Whereas some complications, such as ileus or small bowel obstruction and wound problems, were most common during the initial postoperative period, others, such as incisional hernias and mesh erosion, continued to be reported during the second year after surgery. Most women with ileus or small bowel obstruction were treated successfully with intravenous fluids and bowel rest; the four who returned to the operating room for treatment did so 3, 4, 10, and 163 days after surgery. Within 2 years, four patients experienced deep vein thrombosis or pulmonary embolism, including one such complication during transvaginal mesh removal. At this time, 20 women have been diagnosed with complications from surgical materials (mesh, sutures, or both), although not

all have undergone treatment. Eight women have undergone reoperation for prolapse—four in the posterior compartment, one in the anterior compartment, one in both the anterior and posterior compartments, and two in the apical compartment.

DISCUSSION

The effectiveness of a prophylactic Burch colposuspension at the time of sacrocolpopexy in stress-continent women remains at 2 years, with decreased SUI bother, decreased SUI severity, and a trend toward improvement in urge outcomes. Because approximately 1 in 10 women in the Burch group still reported bothersome SUI, it is tempting to suggest an alterative prophylactic procedure. Investigators from the Urinary Incontinence Treatment Network recently reported a randomized trial demonstrating that, in women with SUI, the Burch colposuspension results in fewer objective SUI cures compared with the fascial sling.[3] However, this trial does not provide evidence that the same is true in the setting of transabdominal prolapse surgery.

Our results clearly demonstrate that sacrocolpopexy has a beneficial role in reducing bothersome irritative and obstructive urinary symptoms after surgery, regardless of concomitant Burch. This finding suggests that prolapse repair itself has a beneficial effect on certain urinary symptoms. Multiple geographic sites and multiple surgeons increase the generalizability of our findings and are an important strength of our study. Differences in nomenclature, preoperative testing conditions, and diagnostic terms limit comparisons of our study with prior small case series. In one retrospective study of women undergoing sacrocolpopexy, a Burch procedure was done in all participants whether incontinent or not.[12] Thirty-three of 47 (70%) were continent and 14 (30%) incontinent preoperatively. The authors reported that all participants remained continent at a mean of 34 months postoperatively. Similarly, Lefranc et al[13] performed a Burch colposuspension in all women undergoing sacrocolpopexy. About 10 years later, no patients who previously had been continent and underwent a prophylactic Burch developed de novo SUI; however, 23 of the 57 initially incontinent patients had recurrent SUI despite the Burch, four within the first year, five after 1 year, 11 at 5 years, two at 10 years, and one at 15 years.

Our results and those few studies addressing stress-continent women at the time of sacrocolpopexy suggest that an incontinence procedure does provide benefit, does not result in adverse side effects, and should be recommended at the time of sacrocolpopexy. The risk/benefit ratio of other procedures can be explored in future randomized surgical trials. Sacrocolpopexy is known to have high apical success rates.[14] Our apical success rate of 95% is consistent with those findings, regardless of whether concomitant Burch was performed. In this trial, surgeons could choose whether or not to repair all anterior and posterior defects. The proportion of women with stage II prolapse at 24 months represents, in part, these surgical decisions rather than surgical failure of an operated compartment. Some investigators have suggested that the Burch colposuspension challenges apical and posterior support. This effect also has been noted at the time of laparoscopic sacrocolpopexy with concomitant Burch.[15, 16] Although we detected a statistical difference in the mean position of points Ba and Bp, we do not believe that these differences are clinically significant. However, eight patients underwent subsequent prolapse surgery for the anterior or posterior vaginal compartments.

In the existing literature, the median overall short-term rate of mesh erosion was 3.4% with a range of 0–5% for all mesh types.[14] Our rate of foreign body complications, including both sutures and mesh, is at the upper end of this range and likely reflects the careful follow-up of this patient population. Clearly, the occurrence of mesh erosions is not limited to the immediate postoperative setting,[17] and longer term follow-up is important to determine what type of mesh

and which type of patient remain at risk. Other adverse events are within previously reported prevalence rates.

Two years after surgery, we found that the majority of patients were satisfied, overall, with their surgeries and symptom control. This satisfaction corresponds to the overall improvement in lower urinary tract and prolapse symptoms, sexual function, and effect on symptom-specific and overall quality of life after the prolapse surgery. The findings in our study should be extrapolated with caution to other prolapse procedures and/or other continence procedures. Many of these participants have agreed to continued longitudinal observation so that we can determine characteristics of those patients predisposed to recurrent symptomatic prolapse, foreign body complications, and other pelvic floor abnormalities.

Sacrocolpopexy with concomitant Burch colposuspension confers sustained lower urinary tract symptom improvement with improvement of stress incontinence symptoms and no clinically significant deleterious effects due to the colposuspension. Based on these results, we propose that a prophylactic Burch colposuspension should be recommended at the time of sacrocolpopexy for stress-continent women who have a mobile urethra.

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Table 1

Urinary Outcomes at 3, 12, and 24 Months*

Variable	3-Mo Data			12-Mo Data			24-Mo Data		
	Burch	Control	$p^{\dagger}$	Burch	Control	$p^{\dagger}$	Burch	Control	$p^{\dagger}$
SUI									
SUI composite endpoint	35/156 (22.4)	67/164 (40.9)	.002	42/155 (27.1)	71/161 (41.6)	.005	47/147 (32.0)	70/155 (45.2)	.026
SUI symptoms[‡]	29/153 (19.0)	60/151 (39.7)	<.001	33/155 (21.3)	63/158 (39.9)	.001	38/147 (25.9)	63/155 (40.6)	.016
Positive cough stress test	7/148 (4.7)	14/162 (8.6)	.14	5/141 (3.5)	9/154 (5.8)	.60	11/116 (9.5)	9/134 (6.7)	.43
Treatment for stress incontinence at any time	9/156 (5.8)	18/164 (11.0)	.10	16/155 (10.3)	26/161 (16.1)	.16	19/147 (12.9)	31/155 (20.0)	.11
Bothersome[§] SUI	9/153 (5.9)	37/151 (24.5)	3.001	12/155 (7.7)	32/158 (20.3)	.001	17/147 (11.6)	39/155 (25.2)	.004
MESA[‖] stress score	13.3±19.0	23.3±24.7	<.001	15.3±20.0	27.2±25.7	<.001	19.0±20.9	26.7±25.3	.004
Urge outcomes									
Urge composite endpoint[¶]	50/156 (32.1)	59/164 (36.0)	.85	51/155 (32.9)	66/161 (41.0)	.29	47/147 (32.0)	69/155 (44.5)	.085
Prevalence of bothersome[§] symptoms									
Urge incontinence	10/143 (6.5)	18/151 (11.9)	.17	9/155 (5.8)	17/158 (10.8)	.23	10/147 (6.8)	19/155 (12.3)	.30
Enuresis	0/153	1/152 (0.7)	.30	1/155 (0.6)	3/158 (1.9)	.30	1/147 (0.7)	1/155 (0.6)	.94
Frequency	17/153 (11.1)	16/152 (10.5)	.74	13/155 (8.4)	20/158 (12.7)	.47	14/147 (9.5)	21/155 (13.5)	.62
Urgency	9/153 (5.9)	14/152 (9.2)	.52	10/155 (6.5)	16/158 (10.1)	.46	13/147 (8.8)	25/155 (16.1)	.17
Nocturia	24/153 (15.7)	21/152 (13.8)	.53	24/155 (15.5)	28/158 (17.7)	.86	25/147 (17.0)	38/155 (24.5)	.26
Treatment for urge incontinence	5/156 (3.2)	9/164 (5.5)	.45	6/155 (3.9)	7/161 (4.3)	.80	1/147 (0.7)	7/155 (4.5)	.035
Prevalence of urge symptoms— regardless of bother	122/153 (79.7)	123/152 (80.9)	.94	122/155 (78.7)	123/158 (77.8)	.91	111/147 (75.5)	122/155 (78.7)	.60
MESA urge score[‖]	11.8±14.0	16.8±18.8	.007	11.6±14.8	17.8±20.6	.002	13.7±15.5	18.1±19.2	.030

SUI, stress urinary incontinence; MESA, Medical, Epidemiological, and Social Aspects of Aging questionnaire; PFDI, Pelvic Floor Distress Inventory.

Data are n/N (%) or mean±standard deviation unless otherwise noted.

[*] All results are after imputation as indicated in the Methods section (results without imputation are available on request).

[†] Adjustment was by surgeon and whether or not paravaginal procedure was done.

[‡] SUI symptoms were based on a positive response to any one of three PFDI questions about SUI with coughing, sneezing, or laughing; physical exercise; or lifting or bending over.

[§] Bother was defined as “moderate” or “quite a bit” on the PFDI questionnaire.

[‖] Reported scores are based on an average of the scores for each participant with responses of “never” (0 points), “rarely” (1 point), “sometimes” (2 points), and “often” (3 points) for the nine stress and six urge questions on the MESA questionnaire. Higher scores indicate more frequent symptoms of incontinence.

[¶] Urge endpoint was met if any one of the following bothersome symptoms (defined as “moderately” or “quite a bit” by PFDI) were present: urge incontinence, urgency, frequency, nocturia, or enuresis, or treatment for any of the five preceding symptoms after the index surgery.

Table 2

Anatomic Outcomes at 3, 12, and 24 Months

	3 Mo			12 Mo			24 Mo		
POP-Q	**Burch n=149**	**No Burch n=164**	**Statistical Test**	**Burch n=140**	**No Burch n=149**	**Statistical Test**	**Burch n=117**	**No Burch n=133**	**Statistical Test**
Point C	−8.3±1.8	−8.5±1.6	.07	−8.3±1.7	−8.3±1.5	.78	−8.0±1.5	−8.2±1.3	.46
Point Ba	−2.6±0.7	−2.0±0.9	<.001	−2.4±0.8	−1.8±1.1	<.001	−2.2±0.9	−1.8±1.1	<.001
Point Bp	−2.4±0.9	−2.4±0.9	.70	−2.0±1.2	−2.3±1.0	.04	−2.0±1.3	−2.3±0.8	.006
Stage			<.001			.10			.55
0	55 (37.7)	29 (17.8)		32 (22.9)	19 (12.9)		24 (20.5)	23 (17.4)	
1	70 (47.9)	80 (49.1)		65 (46.4)	75 (51.0)		43 (36.8)	51 (38.6)	
2	19 (13.0)	53 (32.5)		41 (29.3)	51 (34.7)		46 (39.3)	57 (43.2)	
3	2 (1.4)	1 (0.6)		2 (1.4)	2 (1.4)		4 (3.4)	1 (0.8)	

POP-Q, Pelvic Organ Prolapse Quantified.

Data are mean±standard deviation unless otherwise noted.

Table 3

Symptomatic and Quality of Life Responses (With Imputation)

Variable (Range)	3 Mo			12 Mo			24 Mo		
	Burch (n=153)	Control (n=152)	*P*	Burch (n=155)	Control (n=158)	*P*	Burch (n=147)	Control (n=155)	*P*
PFDI									
UDI (0–300)	22.2±27.3	33.0±38.8	.006	20.1±26.2	34.3±40.4	<.001	23.2±31.1	33.9±38.5	.009
Subscales (0–100)									
Stress	6.2±13.6	14.8±22.6	<.001	5.7±13.9	15.5±23.0	<.001	8.0±16.7	15.1±22.1	.002
Obstructive	6.6±9.9	7.3±11.9	.59	5.9±9.9	7.8±12.1	.12	6.7±12.0	7.6±11.1	.51
Irritative	9.5±11.4	11.0±11.6	.25	8.8±10.1	11.4±13.1	.052	8.9±11.5	12.1±14.1	.037
POPDI (0–300)	30.3±38.8	30.2±41.2	1.0	28.7±35.0	32.0±41.6	.43	32.8±44.4	31.0±40.1	.70
CRADI (0–400)	34.1±47.8	34.9±47.2	.85	32.2±34.6	39.2±49.5	.14	36.3±43.5	37.1±48.5	.89
PFIQ									
Bladder (0–100)	6.3±10.8	9.2±14.3	.04	4.4±9.3	8.6±14.5	.002	5.1±11.7	8.0±13.6	.052
Bowel (0–100)	3.7±11.1	5.2±11.6	.25	2.9±9.1	4.4±9.2	.16	4.0±13.1	4.7±11.5	.61
Pelvis (0–100)	3.5±8.4	4.1±9.3	.50	2.4±9.1	4.0±8.9	.11	2.8±9.8	3.6±10.4	.49
Incontinence Severity Index (0–12)	1.9±2.5	2.9±3.1	.003	1.9±2.5	2.9±3.1	.002	2.0±2.5	2.8±3.1	.010
PISQ (0–48)	37.5±4.4 n=68	37.7±6.1 n=69	.80	37.3±5.3 n=96	37.4±5.1 n=98	.90	37.2±5.0 n=98	37.3±5.5 n=96	.88

PFDI, Pelvic Floor Distress Inventory; UDI, Urogenital Distress Inventory; POPDI, Pelvic Organ Prolapse Distress Inventory; CRADI, Colorectal and Anal Distress Inventory; PFIQ, Pelvic Floor Impact Questionnaire; PISQ: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.

Data are mean±standard deviation unless otherwise noted.

Notation about instruments:

PFDI: lower scores indicate better function.

PFIQ: lower scores indicate better function.

Incontinence Severity Index: lower scores indicate better function.

PISQ: higher scores indicate better function.

Table 4

Procedure-Related Complications (Cumulative Totals) Including Serious Adverse Events

Complication	3 Mo		12 Mo		24 Mo	
	Burch (n=157)	Control (n=164)	Burch (n=157)	Control (n=162)	Burch (n=153)	Control (n=158)
All SAEs (number of SAE participants)	27 (24)	31 (27)	36 (33)	47 (38)	56 (42)	64 (49)
SAEs plausibly related to surgery	8	9	10	17	15	22
Mesh or suture erosions	2	5	4	10	8	12
Gastrointestinal SAEs	11	12	14	14	15	15
Ileus or SBO (four required surgery)	10	10	11	10	11	10
Incisional hernia	2	2	2	2	3	4
Wound complication, not including hernia	4	5	4	6	5	6
Reoperation for prolapse	1	2	1	4	2	6
Reoperation for other complications of surgery	2	1	2	1	2	2
Treatment failures (TVT, injectable agents)	3	7	5	14	7	15

SAE, serious adverse event; SBO, small bowel obstruction; TVT, tension-free vaginal tape.