

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 13, 2006

VOL. 354 NO. 15

## Abdominal Sacrocolpopexy with Burch Colposuspension to Reduce Urinary Stress Incontinence

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### ABSTRACT

#### BACKGROUND

We designed this trial to assess whether the addition of standardized Burch colposuspension to abdominal sacrocolpopexy for the treatment of pelvic-organ prolapse decreases postoperative stress urinary incontinence in women without preoperative symptoms of stress incontinence.

#### METHODS

Women who did not report symptoms of stress incontinence and who chose to undergo sacrocolpopexy to treat prolapse were randomly assigned to concomitant Burch colposuspension or to no Burch colposuspension (control) and were evaluated in a blinded fashion three months after the surgery. The primary outcomes included measures of stress incontinence (symptoms, stress testing, or treatment) and measures of urge symptoms. Enrollment was stopped after the first interim analysis because of a significantly lower frequency of stress incontinence in the group that underwent the Burch colposuspension.

#### RESULTS

Of 322 women who underwent randomization, 157 were assigned to Burch colposuspension and 165 to the control group. Three months after surgery, 23.8 percent of the women in the Burch group and 44.1 percent of the controls met one or more of the criteria for stress incontinence ( $P < 0.001$ ). There was no significant difference between the Burch group and the control group in the frequency of urge incontinence (32.7 percent vs. 38.4 percent,  $P = 0.48$ ). After surgery, women in the control group were more likely to report bothersome symptoms of stress incontinence than those in the Burch group who had stress incontinence (24.5 percent vs. 6.1 percent,  $P < 0.001$ ).

#### CONCLUSIONS

In women without stress incontinence who are undergoing abdominal sacrocolpopexy for prolapse, Burch colposuspension significantly reduced postoperative symptoms of stress incontinence without increasing other lower urinary tract symptoms.

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\*Other members of the Pelvic Floor Disorders Network participating in the Colpopexy and Urinary Reduction Efforts (CARE) trial are listed in the Appendix.

N Engl J Med 2006;354:1557-66.

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**P**ELVIC-ORGAN PROLAPSE, IN WHICH THE pelvic organs (uterus, bladder, and bowel) protrude into or past the vaginal introitus, is a condition often treated with surgery.<sup>1,2</sup> Women have an 11 percent risk of surgery for prolapse or urinary incontinence by 80 years of age, and of this 11 percent, almost one third of the women have a second surgery.<sup>3</sup> This fact points to the need for improved treatment of pelvic-floor disorders.

Prolapse commonly coexists with lower urinary tract dysfunction, such as stress urinary incontinence.<sup>1-3</sup> Stress incontinence occurs when increased intraabdominal pressure, such as with coughing or sneezing, forces urine to leak through the urethra. Whereas some women with prolapse have concomitant stress incontinence, others do not, in part because of the obstructive effect of the prolapsed pelvic organs, creating urethral kinking. When prolapse is treated with the use of a pessary or surgery, stress incontinence may develop. The risk of symptoms of stress incontinence after surgery ranged from 8 to 60 percent in small series.<sup>4-9</sup>

One option for patients who require surgery to correct prolapse but who do not have symptoms of stress incontinence is to perform a prophylactic continence operation at the time of prolapse repair. Other options are to perform only the prolapse repair (which in some women will result in the need for a subsequent surgery later to treat stress incontinence) or to perform preoperative testing in an attempt to predict which patients will have postoperative incontinence and selectively perform continence procedures on the basis of the test results. Uncontrolled trials suggest that performing stress-incontinence procedures at the time of the initial surgery may reduce postoperative stress incontinence.<sup>9,10</sup> However, up to 20 percent of women who undergo these procedures have complications, including difficulty voiding, urinary urgency or urge incontinence, or urinary tract injuries.<sup>11-13</sup> Thus, the relative benefit and harm of routinely adding a continence operation in women undergoing prolapse surgery require evaluation.

Sacrocolpopexy is an abdominal-prolapse repair that restores pelvic anatomy in most women, although data on long-term (5 to 10 years) durability are limited.<sup>14</sup> In sacrocolpopexy, graft material is attached between the vagina and sacrum, supporting the vagina (Fig. 1A). Burch colposuspension (Fig. 1B) is effective in treating stress

incontinence, and there is evidence of its durability during 10 years of follow-up.<sup>13,15-17</sup> Performed through the same incision as the sacrocolpopexy, the Burch colposuspension consists of suturing periurethral vaginal tissue to the iliopectineal (Cooper's) ligaments on each side to support the urethra.

Paravaginal repair, in which the lateral vagina is reattached to the pelvic sidewall, can be performed with sacrocolpopexy. Although paravaginal repair alone is less effective than Burch colposuspension to treat stress incontinence,<sup>18</sup> some surgeons combine paravaginal repair with sacrocolpopexy and Burch colposuspension with the goal of enhancing vaginal support, although efficacy data are lacking for this approach.

We designed the Colpopexy and Urinary Reduction Efforts (CARE) trial to evaluate whether performing Burch colposuspension at the time of abdominal sacrocolpopexy for prolapse reduces postoperative symptoms of stress incontinence in women who do not report preoperative symptoms of stress incontinence. We also evaluated the effect of adding the Burch colposuspension on other lower urinary tract symptoms.

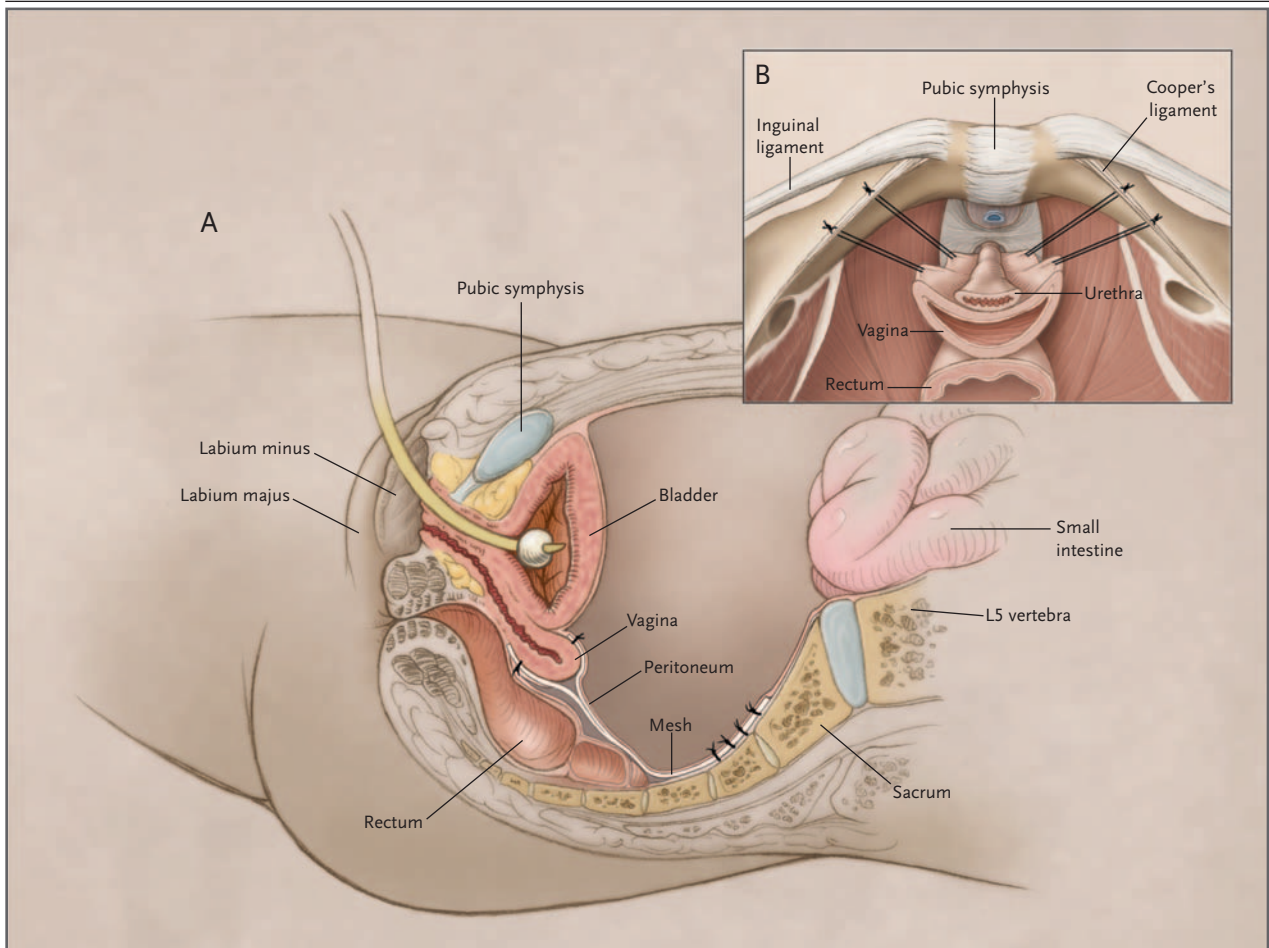
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## METHODS

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The methods used in the trial have been reported previously.<sup>19</sup> Women planning sacrocolpopexy for stage II, III, or IV prolapse were invited to participate if they did not have symptoms of stress incontinence. Potential participants were excluded if they were unable to undergo the Burch colposuspension on the basis of the assessment of the mobility of the urethrovesical junction. All women provided written informed consent to participate, and eligible women were enrolled between March 2002 and February 2005. Enrollment and outcomes are summarized in Figure 2.<sup>20</sup>

Prolapse was staged with the use of the pelvic-organ-prolapse quantification (POP-Q) system, a standardized quantitative method for assessment of prolapse.<sup>21</sup> At enrollment, all women were categorized as stress continent on the basis of their responses of "never" or "rarely" to the first six questions regarding symptoms of stress incontinence of the Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire.<sup>22</sup> None of the women had a contraindication to Burch colposuspension in the opinion of her surgeon, and all had evidence of some loss of



**Figure 1. Sacrocolpopexy and Burch Colposuspension.**

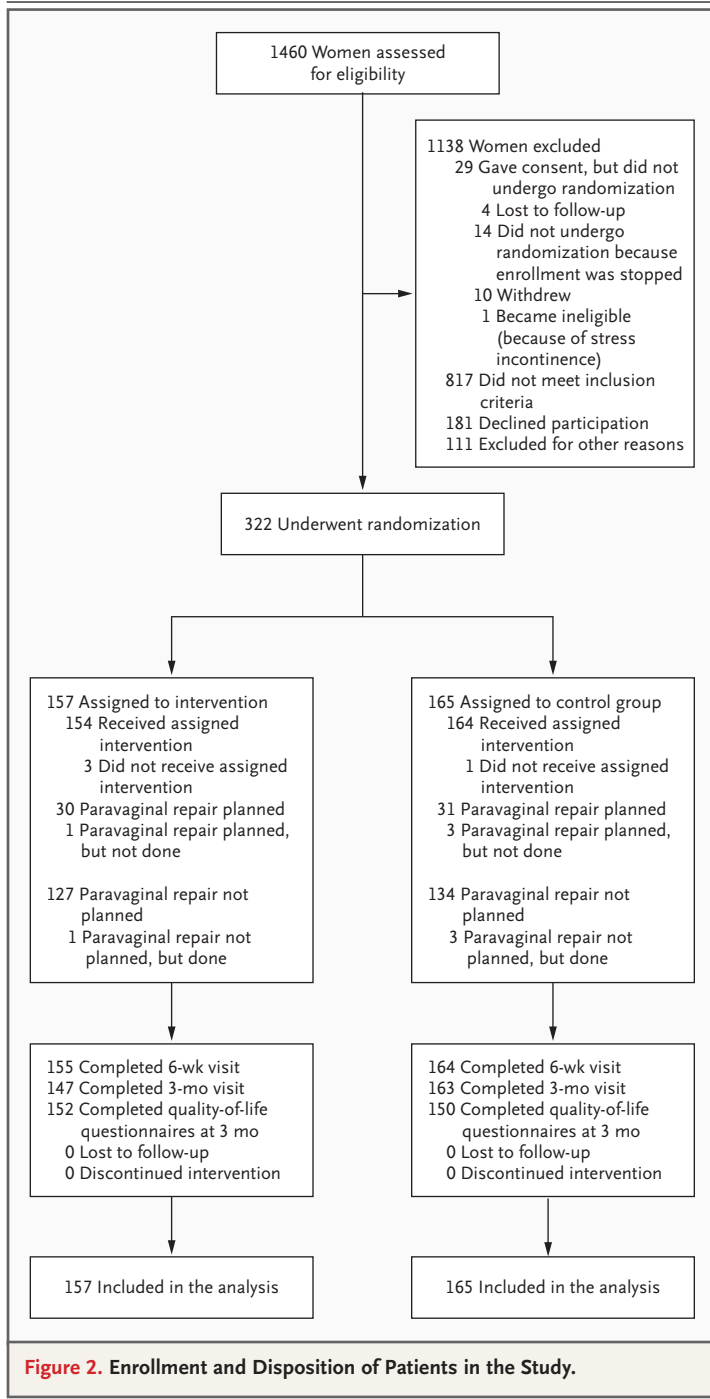
Pelvic-organ prolapse of the vaginal apex, due to the loss of normal support, results in invagination into the vagina and in more severe stages of prolapse, outside the vaginal introitus. In the abdominal sacrocolpopexy (Panel A), grafts sutured to the posterior and anterior aspects of the vagina suspend the vaginal vault. The other end of the graft is sutured to the anterior longitudinal ligament of the sacrum. In the Burch colposuspension (Panel B), the urethra is supported by sutures in the vagina at the level of the midurethra and urethrovesical junction to the iliopectineal line (Cooper's ligament) with the use of suture bridges.

anterior vaginal support, implying that the urethra was not fixed behind the pubic bone.

Randomization to sacrocolpopexy with or without Burch colposuspension was performed with the use of computer-generated random numbers in blocks of various sizes, and groups were stratified according to surgeon and intention to perform paravaginal repair (done at the surgeon's discretion and disclosed before randomization). The assignment was revealed in the operating room (as information contained in sealed, opaque envelopes) after the woman was anesthetized. The women, research staff, and telephone interviewers were unaware of the treatment assignments for a minimum of three months, and blind-

ing was intended to be maintained for two years after surgery. Follow-up examinations with the use of the POP-Q were performed by research nurses.

Preoperative urodynamics were completed in accord with the study protocol without prolapse reduction and then again with placement of the prolapsed vagina into the more normal anatomical position (prolapse reduction). Preoperative urodynamic results were withheld from the surgical team. The women completed validated questionnaires by telephone<sup>23</sup> at baseline and again at follow-up, including the Hunskar measure for the severity of urinary incontinence<sup>24</sup> and the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor



**Figure 2. Enrollment and Disposition of Patients in the Study.**

Impact Questionnaire (PFIQ) for the assessment of pelvic symptoms and their effect on the quality of life.<sup>25</sup>

The primary outcomes were stress incontinence and urge symptoms three months after surgery. Women were characterized as having stress incontinence if any of the following were

present: first, symptoms, as defined by a “yes” response to any of three questions on the PFDI stress incontinence subscale regarding leakage with coughing, sneezing, or laughing; physical exercise; and lifting or bending over; second, stress incontinence during standardized stress testing at maximal bladder capacity or 300 ml, whichever was less, in either the supine or standing position with Valsalva’s maneuver or cough provocation; or third, any treatment for stress incontinence after the study surgery. We considered women to have bothersome symptoms of stress incontinence if they reported being bothered “quite a bit” or “moderately” in response to one of the three questions on stress incontinence on the PFDI. The urge end point was defined as any one of the following bothersome symptoms (defined as “moderately” or “quite a bit” according to the PFDI): urge incontinence, urgency, frequency, nocturia, or enuresis; or treatment for any of these symptoms identified after the index surgery. Stress and urge symptoms were also described with the use of the stress subscale and the irritative-voiding subscale of the PFDI, respectively. Higher scores represent increasing level of symptoms and increasingly bothersome symptoms.

Serious adverse events were defined as untoward medical occurrences that were life-threatening or fatal, required prolonged hospitalization or readmission for the index surgery, any condition that resulted in persistent or clinically significant disability, or any other important medical condition. Since surgical treatment for stress incontinence was a component of the stress-incontinence end point, it was not included among the adverse events. Serious adverse events were reviewed by a committee of three investigators (all of them independent of the clinical sites and unaware of the women’s treatment assignments) to determine which events were plausibly related to the Burch intervention.

The null hypothesis was that there was no significant difference in the proportion of women with stress incontinence three months after sacrocolpopexy with Burch colposuspension as compared with sacrocolpopexy without Burch colposuspension. We planned to enroll 480 women in order to identify a difference in stress incontinence between the two groups as small as 10 percent. Two interim analyses were planned, the first after 50 percent of the women had reached the three-

month end point after surgery, to be performed with the use of a 0.0042 level of significance for stopping, and the second after 75 percent of the women had reached three months after surgery, to be performed with a 0.019 level of significance. The data and safety monitoring board of the Pelvic Floor Disorders Network recommended stopping enrollment after the first interim analysis, when outcomes were available for 232 women. All 322 women who had undergone randomization were followed to the three-month end point.

Case-report forms completed at the clinical sites were sent to the data-coordinating center for double data entry. The two groups were compared at baseline according to age, body-mass index (defined as the weight in kilograms divided by the square of the height in meters), and prolapse stage. Subsequent analyses were not adjusted for these measures, since these characteristics were similar in the two groups. Proportions were compared with the use of the Mantel-Haenszel chi-square test and adjusted for surgeon and the presence or absence of paravaginal repair. Quality-of-life measures were compared with the use of a general linear model with the same covariates (surgeon and the presence or absence of paravaginal repair). Data collection was not complete for all women.

Except for the three analyses of the stress-incontinence end point, all reported results were based on observed data without imputation of missing data. All tests performed and all reported P values were two-sided. Results are presented as percentages or as means  $\pm$ SD.

## RESULTS

Of the 322 women who underwent randomization, 157 were assigned to the Burch colposuspension with abdominal sacrocolpopexy and 165 were assigned to the control group and underwent abdominal sacrocolpopexy without the Burch colposuspension. Of the 322 women, 70.1 percent had previously undergone hysterectomy. There were no significant differences between the two groups in baseline characteristics (Table 1).

All women were eligible on screening on the basis of a response of "rarely" or "never" to six questions on stress incontinence in the MESA questionnaire. However, 19.2 percent reported stress leakage of urine preoperatively when queried by telephone interviewers using predeter-

mined questions on stress incontinence in the PFDI questionnaire. (A similar proportion was obtained in telephone interviews with women responding to the MESA questionnaire, but the study end point was defined by the PFDI.) Baseline urinary symptoms and test results are shown in Table 2.

Three women in the Burch group and one in the control group did not receive the assigned treatment, and for two women in the Burch group and six in the control group, plans regarding paravaginal repair were changed (Fig. 2). The overall rate of concomitant hysterectomy did not differ significantly between the two groups: 29.0 percent in the Burch group as compared with 28.0 percent in the control group ( $P=1.00$ ). The study assignment was revealed to study coordinators before the visit at three months in the case of five women and to the women themselves in two cases. In two cases, surgeons learned of the urodynamic results before surgery.

Three months after surgery, 23.8 percent (35 women) of the Burch group and 44.1 percent (67 women) of the control group met one or more criteria for stress incontinence ( $P<0.001$ ). The stress-incontinence end point could not be determined for 10 women in the Burch group and 13 in the control group. We therefore also performed three intention-to-treat analyses: an analysis in which women for whom end-point data were not available were considered to have treatment failure, an analysis in which those for whom end-point data were not available were considered to have had a successful outcome, and an analysis in which, because of the low number of treatment failures on stress testing, all women without symptoms (i.e., those for whom results of stress testing were not available) were considered to have had a successful outcome, whereas the remaining women for whom no end-point data were available were considered to have had treatment failure. Differences between the two groups were significant when these models were used.

After adjustment for surgeon and presence or absence of concomitant paravaginal procedure, the Burch colposuspension remained protective against stress incontinence (odds ratio, 0.41; 95 percent confidence interval, 0.24 to 0.70). Results based on the three components of the stress incontinence measures are shown in Table 3. "Bothering" stress incontinence was also significantly

**Table 1. Baseline Characteristics of the 322 Women in the Study Population.\***

Characteristic	Burch Group (N=157)	Control Group (N=165)	P Value
Age — yr	62.4±9.7	60.3±10.6	0.07
Race — no./total no. (%)†			0.13‡
White	151/157 (96.2)	148/165 (89.7)	
Black	5/157 (3.2)	12/165 (7.3)	
Other	1/157 (0.6)	5/165 (3.0)	
Ethnic group — no./total no. (%)			0.11
Hispanic	2/157 (1.3)	7/165 (4.2)	
Marital status — no./total no. (%)			0.30
Married or living as married	120/157 (76.4)	119/165 (72.1)	
Educational level — no./total no. (%)			0.06
Less than high school	19/157 (12.1)	8/165 (4.8)	
Completed high school or equivalent	58/157 (36.9)	67/165 (40.6)	
Some college or higher	80/157 (51.0)	90/165 (54.5)	
Health insurance — no./total no. (%)			0.17
Private insurance	54/139 (38.8)	71/141 (50.4)	
HMO	17/139 (12.2)	12/141 (8.5)	
Government assistance	48/139 (34.5)	36/141 (25.5)	
Self-pay or other	20/139 (14.4)	22/141 (15.6)	
No. of previous vaginal deliveries			0.43
Median	3	3	
Range	0–8	1–11	
No. of previous cesarean deliveries			0.35
Median	0	0	
Range	0–5	0–2	

less common in the Burch group than in the control group (6.1 percent vs. 24.5 percent,  $P<0.001$ ).

Regardless of the urodynamic finding of leakage during prolapse reduction, the addition of the Burch colposuspension was beneficial. Even if no leakage was detected with urodynamic prolapse reduction preoperatively, the Burch colposuspension reduced postoperative stress incontinence from 38.2 percent to 20.8 percent ( $P=0.007$ ) (data not shown).

When women who reported symptoms of stress incontinence in response to the PFDI questionnaire administered at baseline were excluded, rates of postoperative stress incontinence remained significantly lower in the Burch group than in the control group (19.8 percent vs. 41.3 percent,  $P<0.001$ ). In addition, rates of postoperative stress incontinence in the two groups were not significantly affected by concomitant para-vaginal repair.

The percentage of women who met one or more criteria for urge outcomes at three months after surgery did not differ significantly between the two groups (32.7 percent in the Burch group vs. 38.4 percent in the control group,  $P=0.48$ ). There were no significant differences between the two groups according to the PFDI subscales for irritative voiding and obstructive voiding (data not shown) or for voiding symptoms or pain and pressure with bladder filling. Urinary retention was rare, being reported by one woman in each group at three months.

As anticipated, there was a significant difference in the duration of surgery (the interval between incision and skin closure):  $190\pm55$  minutes for sacrocolpopexy plus Burch colposuspension, as compared with  $170\pm60$  minutes for sacrocolpopexy without Burch colposuspension ( $P=0.002$ ). The groups also differed in estimated intraoperative blood loss ( $265\pm242$  ml for sacrocolpopexy

**Table 1. (Continued.)**

Characteristic	Burch Group (N=157)	Control Group (N=165)	P Value
Total no. of previous births			
Median	3	3	0.61
Range	1–10	1–11	
Prior surgery for incontinence — no./total no. (%)	11/155 (7.1)	11/165 (6.7)	0.89
Prior surgery for pelvic-organ prolapse — no./total no. (%)	69/156 (44.2)	57/165 (34.5)	0.08
Prior hysterectomy — no./total no. (%)	112/156 (71.8)	116/165 (70.3)	0.63
POP-Q stage — no./total no. (%)§			0.53
II	19/157 (12.1)	25/165 (15.2)	
III	105/157 (66.9)	112/165 (67.9)	
IV	33/157 (21.0)	28/165 (17.0)	
Body-mass index			
Mean	27.0±4.3	27.1±4.8	0.80
Body-mass index ≥35 (obesity) — no./total no. (%)	7/157 (4.5)	12/165 (7.3)	0.97

\* Plus-minus values are means ±SD. HMO denotes health maintenance organization.

† Race was self-reported.

‡ The P value for race omits the category of “other.”

§ The stages of the pelvic-organ-prolapse quantification system (POP-Q) are as follows: in stage II prolapse, the vagina is prolapsed between 1 cm above the hymen and 1 cm below the hymen; in stage III, the vagina is prolapsed more than 1 cm beyond the hymen but is less than totally everted; and in stage IV, the vagina is everted to within 2 cm of its total length.

plus Burch colposuspension vs. 192±125 ml for sacrocolpopexy alone,  $P<0.001$ ).

The percentage of women who had serious adverse events within three months after surgery was similar in the two groups (14.6 percent in the Burch group and 14.5 percent in the control group,  $P=0.79$ ). When serious adverse events were judged to be plausibly related to the Burch surgery, the proportions were 4.5 percent and 3.0 percent, respectively ( $P=0.24$ ).

The outcomes for stress incontinence and urge outcome were similar among the 231 women who completed one year of follow-up at the time of the analysis. Among these women, 24 (20.9 percent) in the Burch group, as compared with 46 (39.7 percent) in the control group, met one or more criteria for stress incontinence ( $P=0.02$ ), whereas 32 (27.6 percent) of those in the Burch group and 42 (35.0 percent) of those in the control group met one or more criteria for urge outcome ( $P=0.37$ ).

## DISCUSSION

Burch colposuspension at the time of abdominal sacrocolpopexy for prolapse significantly reduced

the risk of postoperative symptoms of stress incontinence in women three months postoperatively. This protective effect occurred regardless of the level of preoperative symptoms or of findings on objective testing. The addition of Burch colposuspension did not increase the frequency of urinary retention, urge incontinence, urgency, urinary tract infections, or intraoperative or postoperative complications. Ongoing follow-up of these women will provide further information with respect to the long-term usefulness of adding Burch colposuspension at the time of sacrocolpopexy.

Criteria for the end point of stress incontinence included symptoms, stress testing, or treatment. Most of the women reached the stress end point on the basis of reported symptoms, rather than on testing or treatment. In the literature, rates of stress incontinence vary according to the diagnostic method or instrument used.<sup>4,26-28</sup> We found this to be so in our study as well, but the marked difference between the two groups persisted whether we used a composite definition or validated symptom scales for stress incontinence. Furthermore, Burch colposuspension reduced postoperative stress incontinence regardless of preoperative urodynamic status.

**Table 2. Baseline Urinary Evaluation According to the Women's Responses to Two Questionnaires and Results of Stress Testing with and without Prolapse Reduction.\***

Variable	Burch Group (N=157)	Control Group (N=165)	P Value
PFDI questionnaire — no./total no. (%)			
Stress incontinence†	30/152 (19.7)	30/160 (18.8)	0.67
Bothersome stress incontinence‡	15/144 (10.4)	15/149 (10.1)	0.95
Urge symptoms§	138/154 (89.6)	145/160 (90.6)	0.76
Urge incontinence¶	42/154 (27.3)	45/160 (28.1)	0.99
Bothersome urge incontinence‡	22/145 (15.2)	24/149 (16.1)	0.98
MESA questionnaire			
Stress incontinence	13.8±17.1	11.1±14.9	0.12
Urge symptoms	12.4±17.0	12.5±15.1	1.00
Positive stress test — no./total no. (%)**			
Without prolapse reduction	3/153 (2.0)	9/159 (5.7)	0.09
With prolapse reduction	55/154 (35.7)	58/162 (35.8)	1.00
Detrusor overactivity (with or without USI) — no./total no. (%)	19/157 (12.1)	17/163 (10.4)	0.24

\* Plus-minus values are means ±SD. USI denotes urodynamic stress incontinence.

† Values were based on a response of “yes” to any one of the three questions on the Pelvic Floor Distress Inventory (PFDI) questionnaire regarding stress incontinence with coughing, sneezing, or laughing; physical exercise; or lifting or bending over.

‡ Bothersome was defined as a response of “moderately” or “quite a bit” on the PFDI questionnaire.

§ Values were based on a response of “yes” to any one of the questions on the PFDI questionnaire regarding urgency, urge incontinence, frequency, nocturia, or enuresis.

¶ Values were based on a response of “yes” to the question on the PFDI questionnaire regarding urge incontinence.

|| Scores on the Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire were based on an average of the scores for each woman, with a range from “never” (0 points), “rarely” (1 point), “sometimes” (2 points), to “often” (3 points) for the nine questions on stress incontinence and the six questions on urge, with higher scores indicating more frequent symptoms of incontinence. The potential maximal score was 27 points for stress symptoms and 18 points for urge symptoms, with a maximal total score of 45.

\*\*Stress testing was performed with the bladder volume at maximal cystometric capacity or 300 ml, whichever occurred first with bladder filling.

Approximately 90 percent of the women had at least one bladder symptom preoperatively that was not related to stress incontinence. Whereas Burch colposuspension reduced postoperative stress incontinence substantially, most of the women had some other bladder symptom postoperatively; four fifths reported at least one urge type of symptom three months after surgery. This result may not be substantially different from that in women without clinically significant prolapse. Among older (mean age, 68 years), community-dwelling women who completed a survey similar to the questionnaires used in our study, 61 percent responded “yes” to at least one question with regard to urgency and 41 percent reported at least one symptom related to obstructive voiding.<sup>2</sup> Although further analyses are under way, preoperative urodynamic testing does not seem to be of value in deciding who benefits from the addition of the Burch colposuspension,

although such testing may help identify women who would do better if they underwent continence procedures other than Burch colposuspension.

Our study was designed to assess incontinence at three months postoperatively as the primary end point. However, long-term follow-up is needed to assess the durability of the observed benefits of Burch colposuspension in combination with abdominal sacrocolpopexy. Our findings cannot be generalized to women undergoing prolapse surgery other than abdominal sacrocolpopexy (i.e., by the vaginal approach) or continence procedures other than Burch colposuspension (e.g., a sling, a procedure that probably works by a different mechanism, assisting sphincteric closure).

Our results show that in women undergoing abdominal sacrocolpopexy who do not have preoperative symptoms of stress incontinence or a fixed urethra, the addition of Burch colposuspension markedly reduces the risk of postoperative

**Table 3. Urinary Evaluation at Three Months after Surgery.\***

Variable	Burch Group (N=157)	Control Group (N=165)	P Value
Stress incontinence outcome — no./total no. (%)	35/147 (23.8)	67/152 (44.1)	<0.001
According to symptoms†	29/153 (19.0)	60/151 (39.7)	<0.001
According to stress testing‡	7/148 (4.7)	14/162 (8.6)	0.14
According to treatment	8/157 (5.1)	19/165 (11.5)	0.05
Other measures of stress incontinence			
Bothersome stress incontinence — no./total no.(%)§	9/147 (6.1)	37/151 (24.5)	<0.001
MESA score for stress incontinence¶	13.3±19.0	23.3±24.7	<0.001
Urge outcome — no./total no. (%)	50/153 (32.7)	58/151 (38.4)	0.48
Bothersome symptoms — no./total no. (%)§			
Urge incontinence	10/147 (6.8)	18/151 (11.9)	0.18
Enuresis	0/153	1/152 (0.7)	0.50
Frequency	17/153 (11.1)	16/152 (10.5)	0.74
Urgency	9/153 (5.9)	14/152 (9.2)	0.52
Nocturia	24/153 (15.7)	21/152 (13.8)	0.53
Treatment for urge outcome — no./total no. (%)	2/153 (1.3)	5/152 (3.3)	0.27
Other measures of urge symptoms			
Urge symptoms, regardless of bother — no./total no. (%)	122/153 (79.7)	123/152 (80.9)	0.94
Urge incontinence, regardless of bother — no./total no. (%)	26/153 (17.0)	35/151 (23.2)	0.30
MESA score for urge¶	11.8±14.0	16.8±18.8	0.007
Serious adverse events to 3 mo — no./total no. (%)			
All events	23/157 (14.6)	24/165 (14.5)	0.79
Urologic and gynecologic events	5/157 (3.2)	5/165 (3.0)	0.70
Plausibly related events	7/157 (4.5)	5/165 (3.0)	0.24

\* Plus-minus values are means ±SD. P values were adjusted for surgeon and performance of paravaginal repair.

† Values were based on the number of women who responded “yes” to any one of the three questions on the Pelvic Floor Distress Inventory (PFDI) questionnaire regarding stress incontinence with coughing, sneezing, or laughing; physical exercise; or lifting or bending over.

‡ Stress testing was performed with the bladder volume at maximal cystometric capacity or 300 ml, whichever occurred first with bladder filling.

§ Bothersome was defined as a response of “moderately” or “quite a bit” on the PFDI questionnaire.

¶ On the Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire, scores were based on an average of the scores for each woman, with a range from “never” (0 point), “rarely” (1 point), “sometimes” (2 points), to “often” (3 points) for the nine questions on stress incontinence and the six questions on urge, with higher scores indicating more frequent symptoms of incontinence. The potential maximal score was 27 points for stress symptoms and 18 points for urge symptoms, with a maximal total score of 45.

|| Values were based on a response of “yes” to any one of the questions on the PFDI questionnaire regarding urgency, urge incontinence, frequency, nocturia, or enuresis (see Methods).

stress incontinence without increasing the risk of adverse urinary symptoms, such as urge incontinence. Further research is needed to determine whether this finding applies to other prolapse and continence procedures.

Supported by grants from the National Institute of Child Health and Human Development (U01 HD41249, U10 HD41268, U10 HD41248, U10 HD41250, U10 HD41261, U10 HD41263, U10 HD41269, and U10 HD41267).

Dr. Brubaker reports having received research funding from Pfizer, Q-Med, Life-Tech, and Allergan; Drs. Fine, Zyczynski, and

Richter, research funding from Eli Lilly; and Dr. Cundiff, research funding from Cook OB/GYN. Drs. Brubaker and Richter report having received speaker's fees from Pfizer and Novartis; Drs. Brubaker, Richter, and Zyczynski report having served as paid consultants to Novartis; Drs. Brubaker and Richter as paid consultants to Pfizer; Dr. Cundiff reports having served as a paid consultant to CR Bard; Dr. Brubaker reports having served as a paid consultant to Astellas; and Drs. Cundiff and Fine report having served as paid consultants to Eli Lilly. No other potential conflict of interest relevant to this article was reported.

We are indebted to Dr. Robert Park, chair of the Pelvic Floor Disorders Network Steering Committee, for his contributions to the network.

APPENDIX

In addition to the authors, the following members of the Pelvic Floor Disorders Network participated in the CARE trial: University of Alabama at Birmingham, Birmingham — K. Burgio, P. Goode, R. Varner, V. Willis; Baylor College of Medicine, Houston — P. Thompson, P. Lotze, N. Frierson; University of Iowa, Iowa City — D. Brandt, D. Haury, K. Kreder, C. Bradley; Johns Hopkins Medical Institutes, Baltimore — V. Handa, M. Sauter; Loyola University, Chicago — M. FitzGerald, K. Kenton, D. Koch, C. Ball; University of Michigan, Ann Arbor — J. Wei, J. DeLancey, N. Janz, D. Smith, W. Wren, J. Imus, B. Marchant, Y. Casher; University of North Carolina at Chapel Hill, Chapel Hill — A. Connolly, M. Jannelli, M. Loomis, A. Murphy, E. Wells, W. Whitehead; University of Pittsburgh/Magee-Women's Hospitals, Pittsburgh — D. Borello-France, J. Gruss, W. Leng, P. Moalli, C. Ghetti.

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