

# Protective effect of suburethral slings on postoperative cystocele recurrence after reconstructive pelvic operation

Roger P. Goldberg, MD, MPH, Sumana Koduri, MD, Robert W. Lobel, MD,  
Patrick J. Culligan, MD, Janet E. Tomezsko, MD, Harvey A. Winkler, MD, and Peter K. Sand, MD  
Evanston, Ill

**OBJECTIVE:** The purpose of this study was to evaluate the independent effect of suburethral sling placement on the risk of cystocele recurrence after pelvic reconstructive operation.

**STUDY DESIGN:** One hundred forty-eight women with cystoceles to or beyond the hymenal ring underwent pelvic reconstructive operation, with or without incontinence procedures, and were evaluated at 12 and 52 weeks after operation with a standardized pelvic examination. Rates of recurrent prolapse, at all sites, were statistically compared between subjects with and without suburethral slings. A multiple regression analysis was used to determine the independent effect of sling placement on the risk of recurrent cystoceles.

**RESULTS:** Suburethral sling placement was associated with a 54.8% reduction in the mean rate of postoperative cystocele recurrence ( $P = .004$ ). This protective effect was observed as early as 12 weeks and remained significant at 1-year follow up (42% vs 19%). A markedly reduced risk of cystocele recurrence was observed when women with sling procedures were compared with all other women, with those women who underwent other incontinence operations, and even with those women who had undergone prolapse repair with no incontinence procedure. The protective effect of the sling procedure remained highly significant (odds ratio, 0.29;  $P = .0003$ ), even after controlling for potentially confounding variables in a multiple logistic regression model.

**CONCLUSION:** Suburethral sling procedures appear to significantly reduce the risk of cystocele recurrence after pelvic reconstructive operation, in contrast with the effect of retropubic urethropexy and needle suspensions. These findings should be considered when the surgical treatment of stress incontinence that accompanies pelvic organ prolapse is being planned. (Am J Obstet Gynecol 2001;185:1307–13.)

**Key words:** Cystocele, suburethral sling, prolapse, recurrence, genuine stress incontinence

The successful long-term correction of cystoceles poses a considerable challenge in pelvic reconstructive surgery, with reported recurrence rates between 20% and 30%.<sup>1,2</sup> Some investigators have suggested that these poor outcomes may result from a failure to recognize and repair paravaginal defects, leading to a loss of anterior vaginal wall support. Yet, even using paravaginal repairs along with colporrhaphy, Shull et al<sup>3</sup> and Elkins et al<sup>4</sup> have reported recurrent cystocele rates of 24% and 32%, respectively. In determining the risk factors for surgical failure, several authors have demonstrated that needle suspensions and retropubic urethropexy procedures, when accompanying the repair of pelvic organ prolapse, signif-

icantly increase the likelihood of postoperative cystocele recurrence.<sup>5,6</sup> This risk of concurrent anti-incontinence operations carries significant implications for the gynecologist, considering the frequency with which genuine stress incontinence accompanies pelvic organ prolapse, which requires a combined surgical approach. Because the operative treatment of these highly prevalent conditions within the female population continues to evolve, there is a need to address these significant risk factors for surgical failure and to identify the most effective long-term strategies. The purpose of this present study was to examine the effect of suburethral sling placement on the recurrence of cystoceles beyond the mid vaginal plane, in women with significant cystoceles before the operation.

## Material and methods

The study sample consisted of all of the women who were planning to undergo reconstructive pelvic surgery with or without anti-incontinence operations at our center between September 1995 and April 1999 and who had a cystocele protruding to or beyond the hymenal ring in the standing position while coughing or straining. Inclusion criteria included age at enrollment of more than 18

*From the Department of Evanston Continence Center, Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics and Gynecology, Northwestern University Medical School, Evanston Northwestern Healthcare.*

*Presented at the Twenty-seventh Annual Meeting of the Society of Gynecologic Surgeons, Orlando, Fla, March 5-7, 2001.*

*Reprint requests: Roger P. Goldberg, MD, MPH, 1000 Central Ave, Suite 730, Evanston, IL 60201. E-mail: rgoldberg@enh.org.*

*Copyright © 2001 by Mosby, Inc.*

*0002-9378/2001 \$35.00 + 0 6/6/119080*

*doi:10.1067/mob.2001.119080*

years, no significant ambulatory restrictions, and willingness to comply with return visits. Women were excluded from participation if they were pregnant, contemplating pregnancy in the next 12 months, or found to have only an anterior enterocele or paravaginal defect, instead of a central cystocele, at the time of operation. The study sample was initially recruited to participate in a prospective randomized trial that would compare the use of polyglactin 910 mesh (Ethicon, Somerville, NJ) during anterior and posterior colporrhaphy with colporrhaphy without mesh. This study represents a further analysis of the sample, to assess the effect of suburethral slings on the risk of recurrent prolapse.

A standardized pelvic examination was performed at enrollment and at 2, 6, 12, and 24 weeks after operation, to evaluate the site and degree of pelvic relaxation with a modified Baden-Walker scale.<sup>7</sup> Cystoceles, rectoceles, enteroceles, and uterine and vaginal vault prolapse were graded on a 0 to 4 scale (0 was indicative of no prolapse; 2 was indicative of prolapse to the mid vaginal plane; 3 was indicative of prolapse to the hymenal ring, and 4 was indicative of prolapse beyond the hymenal ring). Demographic data regarding age, parity, previous surgical procedures, and menopausal and hormonal status were analyzed. Concomitant surgical procedures that accompanied anterior colporrhaphy were recorded for all subjects.

Subjects were placed in dorsal lithotomy position, and a midline incision was made in the anterior vaginal wall from the apex to the level of the urethrovesical angle. This incision was preceded by vaginal hysterectomy and McCall culdoplasty in women with uterine prolapse; for those women who had undergone hysterectomy already, the repair commenced with a transverse incision through the vaginal epithelium just distal to the cuff. Anterior colporrhaphy involved a standard mattress suture repair of the anterior endopelvic connective tissue with 1-0 polyglactin sutures, after careful dissection of the anterior vaginal epithelium and smooth muscle away from the underlying endopelvic connective tissue. This dissection was extended laterally to the medial border of the descending pubic rami and posteriorly to the posterior endopelvic connective tissue or rectal reflection, if no enterocele was present. All cases of vaginal vault prolapse were repaired with a right-sided sacrospinous vaginal vault suspension, either through the anterior vaginal wall dissection (anterior sacrospinous vault suspension), or through the posterior vaginal wall (conventional, or posterior sacrospinous vault suspension). Excess vaginal epithelium was then excised, and the epithelium was closed with 2-0 polyglactin interrupted figure-8 sutures.

Posterior colporrhaphy was similarly performed with a small triangle of epithelium that was excised from the perineum at the posterior fourchette. A vertical posterior vaginal wall incision then facilitated the mobilization of

the endopelvic connective tissue away from the overlying vaginal epithelium and smooth muscle laterally to the rectal pillars and anteriorly to the vaginal apex. The endopelvic connective tissue was plicated to the midline with interrupted 1-0 polyglactin mattress sutures. Similar sutures were placed for midline plication of the superficial and deep transverse perineal muscles and the bulbocavernosus muscles, thus rebuilding the perineum. Excess vaginal epithelium was then resected, and the epithelium was closed with 2-0 polyglactin running sutures.

All subjects were randomly assigned in the operating room either to receive or not to receive polyglactin 910 mesh folded into the imbricated tissue of their anterior and posterior vaginal wall plication. For patients who were randomly assigned to receive mesh, one 2 × 6-cm piece of mesh was folded beneath the imbricated endopelvic connective tissue at the level of the trigone, and a second 2 × 6-cm mesh segment was folded beneath the imbricated endopelvic connective tissue just anterior to the vaginal cuff. A third piece of the same size was used during posterior colporrhaphy, in a similar fashion just cephalad to the deep transverse perineal muscles.

Patients were seen at 2, 6, 12, and 52 weeks after operation. Data from standardized pelvic examinations at 12 and 52 weeks after the operation were evaluated for the purpose of this study. Patients were questioned about any adverse effects; continence and voiding function were assessed. The primary outcome was recurrent cystoceles to the midvaginal plane or beyond (grade 2-4). Recurrent enteroceles, rectoceles, and apical prolapse were also evaluated in patients with and without slings.

Statistical evaluation was performed with the Statistical Package for the Social Sciences (SPSS for Windows; SPSS Inc, Chicago, Ill). Groups were compared for recurrent genital prolapse with 2-tailed *t* tests for independent samples. Simple and multiple logistic regression analyses were used to explore the independent effect of sling placement on the development of recurrent cystoceles, while statistically controlling for potentially confounding variables. One-way analysis of variance (ANOVA) was used to evaluate for differences in recurrent prolapse rates across subgroups, which were defined by specific sling types.

## Results

One hundred sixty-one women were enrolled in the trial; 143 women completed the 1-year follow-up and were included in this analysis. One patient was excluded because she was found to have an anterior enterocele, without cystocele, at the time of examination in the operating room. Seventeen patients failed to return for the 1-year visit. Of these, 5 women had moved from the region; 1 woman was deceased; 2 women were in the midst of cancer treatment; 3 women refused to return because of billing issues, and 3 women reported no problems but

refused to return because of inconvenience. Two women refused further participation because they were dissatisfied with complications that were associated with their anti-incontinence operations; one of these women voided by Valsalva only and had postoperative retention after a sling operation; the other woman had pubic osteomyelitis that resulted from a bone-anchored sling procedure.

The sample was characterized by a mean age of 63.8 years (range, 31-88 years) and a mean parity of 2.8; 51.7% of the women were using hormone replacement therapy. Fifty-three women (37% of the total sample) had a suburethral sling placed; 90 women did not undergo a sling procedure. Sling types consisted of rectus fascia pubovaginal slings (23.5%), bone-anchored pubovaginal fascial patch (41.2%), Raz vaginal wall (7.8%), bone-anchored vaginal wall (25.5%), and Gore-Tex (W. L. Gore & Associates Inc, Newark, Del) pubovaginal slings (2.0%). Thirty-three women (23.1%) had no anti-incontinence operation, and 40% of the women had either a Burch colposuspension or needle suspension. The women who received slings were, on average, younger (61.4 vs 67.7 years;  $P = .002$ ) and less likely to be postmenopausal (73% vs 91%;  $P = .01$ ), which corresponded to lower rates of hormone replacement therapy use (46% vs 62%;  $P = .05$ ). With respect to past operative history, sling recipients had higher rates of previous anterior colporrhaphy (23% vs 10%;  $P = .04$ ), abdominal hysterectomy (36% vs 20%;  $P = .04$ ), and retropubic urethropexy (15% vs 4.4%;  $P = .03$ ). There were no differences in the rates of previous posterior colporrhaphy, vaginal vault suspension, needle suspension, retropubic urethropexy, or sling procedures.

The rates of concomitant prolapse repairs, by site, are summarized for patients with and without sling placement in the Table. The groups were comparable with respect to most procedures, with the exception of sling recipients who underwent fewer vaginal hysterectomies (34% vs 63%;  $P = .001$ ) and fewer paravaginal repairs (0% vs 12%;  $P = .0008$ ). Among patients not receiving slings, retropubic urethropexy was performed in 38%, and needle suspensions were performed in 26%. For obvious reasons, no patients who received a sling underwent either of these other anti-incontinence procedures.

At the 12-week postoperative evaluation, the mean rate of cystocele recurrence was significantly lower among subjects who had received a sling (2% vs 14%;  $P = .005$ ). There were no differences between those women who had or had not undergone sling operations with respect to rectoceles (6.0% vs. 2.4%;  $P = .34$ ), enteroceles (0% vs 1.2%;  $P = .32$ ), or vault prolapse (2.0% vs 1.2%;  $P = .70$ ).

At the 12-month follow-up, cystoceles beyond the mid vaginal plane recurred in 48 women (33.6%); rectoceles recurred in 13 women (9.1%); vaginal vault prolapse recurred in 5 women (3.5%), and enteroceles recurred in 3 women (2.1%). There were no cases of recurrent cystoceles beyond the hymenal ring or postoperative uterine

**Table.** Rates of concomitant operation

Concomitant operation	Sling group* (%)	No-sling group† (%)	t Test
Vaginal hysterectomy	34	63	0.001
Posterior colporrhaphy	89	94	0.21
Vaginal enterocele repair	53	66	0.14
Vaginal paravaginal repair	0	12	0.008
McCall culdoplasty	25	41	0.04
Posterior sacrospinous	7.5	7.8	0.96
Anterior sacrospinous	62	53	0.29

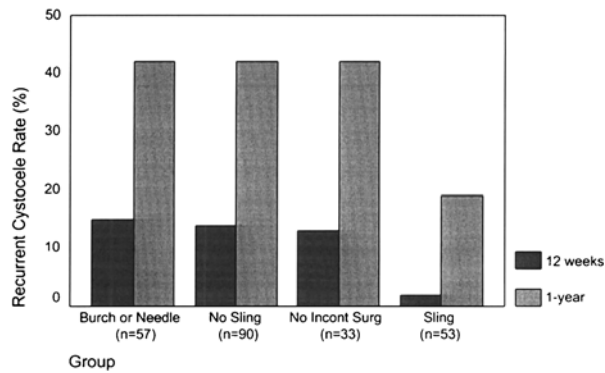
\*n = 53 women.

†n = 90 women.

prolapse. Among sling recipients, the mean rate of cystocele recurrence was 19%, versus 42% among patients with no sling ( $P = .004$ ). Simple logistic regression analysis resulted in an odds ratio of 0.31 ( $P = .005$ ), which indicated an apparent protective effect of slings against cystocele recurrence. Backwards stepwise multiple regression was then performed to control for potential confounding variables. The initial regression model included age, parity, hormone use, previous and concomitant anterior or posterior colporrhaphy, hysterectomy, paravaginal repair, culdoplasty, needle suspensions, retropubic urethropexy, and sacrospinous vaginal fixation and the presence or absence of 1-0 polyglactin mesh to reinforce the anterior and posterior colporrhaphy plication. In the final model, suburethral sling placement remained independently predictive of fewer recurrent cystoceles at 12-month follow-up (odds ratio, 0.29;  $P = .003$ ). The only other covariates found to be predictive of recurrent cystoceles were posterior sacrospinous vaginal vault suspension (odds ratio, 4.07;  $P = .05$ ) and the presence of 1-0 polyglactin mesh (odds ratio, 0.48;  $P = .05$ ), as described in a separate report.<sup>8</sup>

A second statistical analysis was performed to compare the outcome of sling recipients with patients who had not undergone any concomitant anti-incontinence operation ( $n = 33$ ; 23.1%). Recurrent cystoceles at 52 weeks remained significantly less likely after sling placement (19% vs 42%;  $P = .02$ ), and there were no differences in other sites of prolapse. The backwards stepwise multiple regression analysis was repeated, controlling for the identical set of listed covariates. Sling placement remained highly predictive of fewer cystoceles (odds ratio, 0.23;  $P = .02$ ), as did polyglactin mesh reinforcement (odds ratio, 0.45;  $P = .045$ ). Neither posterior nor anterior sacrospinous vaginal vault suspension procedures remained significantly predictive of cystocele recurrence, in this multiple regression analysis.

Finally, a third analysis was performed that compared women with a sling with those women who had undergone either Burch or needle suspension procedures for stress incontinence ( $n = 57$  women). In doing so, we intended to compare the effect of 1 stress incontinence



**Figure.** Cystocele recurrence by operative group at 12 weeks and 1 year.

procedure (slings) directly against the alternative stress incontinence operations, with respect to subsequent pelvic support. The recurrence rate for cystoceles to the mid vaginal plane at 1-year follow-up was 19% for sling recipients, significantly lower than the 42% found among women after Burch urethropexy or needle suspension procedures ( $P = .008$ ). In this analysis incidentally, a significantly higher risk of recurrent rectoceles was found among patients with a sling (15% vs 3.5%;  $P = .04$ ). No differences were found in the rates of recurrent vault prolapse or enteroceles. The Figure summarizes the protective effect of sling placement at both 12 weeks and 1 year after operation, as found by all 3 of the mentioned statistical analyses.

When analyzed by sling type, recurrent cystoceles occurred in 4 women (33%) after rectus fascia pubovaginal slings, in 4 women (19%) after fascial patch slings with bone anchors, in 2 women (15%) after vaginal wall slings with bone anchors, and in none of the women after vaginal wall or Gore-Tex pubovaginal slings. Rectoceles were seen in 4 women (33%) after rectus fascia pubovaginal slings, in 2 women (9.5%) after fascial patch slings with bone anchors, in 1 woman (7.6%) after bone-anchored vaginal wall slings, and in none of the women after vaginal wall or Gore-Tex pubovaginal slings. Vaginal vault prolapse was seen in only 2 sling recipients: in 1 woman after bone-anchored fascial patch sling and in 1 woman after bone-anchored vaginal wall sling. One-way ANOVA was performed to explore whether a specific sling type was more beneficial than the others; this analysis, however, revealed no significant differences across sling types in the mean rates of recurrent cystoceles ( $P = .62$ ), rectoceles ( $P = .26$ ), or vaginal vault prolapse ( $P = .89$ ).

### Comment

Recurrent cystoceles have been shown to complicate the long-term outcome of several reconstructive procedures. Retropubic urethropexy procedures,<sup>9</sup> needle sus-

pensions<sup>10</sup> for the correction of stress incontinence, and vaginal vault suspensions<sup>11</sup> that include sacrospinous ligament suspension<sup>12</sup> have been found to confer significantly increased risks of subsequent anterior vaginal wall prolapse. Sze et al<sup>6</sup> reported a 24% cystocele recurrence rate and found this to be strongly dependent on the concomitant use of a needle suspension operation for stress incontinence. These authors observed a 33% recurrence rate when a modified Pereyra procedure was performed with a sacrospinous vaginal vault suspension versus 14% in the absence of the needle procedure. In a subsequent retrospective analysis of women in whom anterior colporrhaphy was performed with and without transvaginal bladder neck suspensions, the same group reported a 7% recurrent cystocele rate without and a 33% recurrence rate of cystoceles with a concomitant needle suspension ( $P < .01$ ).<sup>5</sup> Colombo et al<sup>13</sup> reported a 34% recurrent cystocele rate after Burch colposuspension; randomization to the Burch procedure conferred a markedly increased risk (odds ratio, 16;  $P = .003$ ) of recurrent cystoceles relative to an anterior colporrhaphy group. Wiskind et al<sup>14</sup> reported that, after Burch colposuspension, 26.7% of women required subsequent surgical procedures for genital prolapse, at a mean interval of 40.2 weeks, although these were primarily enteroceles and rectoceles. Our data also indicated a high risk of cystocele recurrence after Burch and needle suspension procedures (42%); however, within our sample, the magnitude of risk was no different from that among women who underwent no operation for incontinence.

Few studies, however, have examined the risk of cystocele recurrence after the placement of suburethral slings, which are an increasingly popular first-line technique for the surgical correction of genuine stress incontinence. Cross et al performed pubovaginal slings and anterior colporrhaphy on 42 patients with advanced prolapse and stress incontinence. Follow-up was completed on only 36 women, at a mean interval of only 20.4 months; nevertheless, a relatively small recurrent cystocele rate was observed (8.3%). The authors concluded that the fascial sling appeared to improve the durability of the anterior colporrhaphy.<sup>15</sup>

We found a 54.8% reduction in the mean rate of recurrent cystoceles at 1 year ( $P = .004$ ) among women with advanced prolapse who received suburethral slings during reconstructive pelvic operation. To our knowledge, this is the first study to demonstrate a significant reduction in the risk of recurrent cystoceles that is independently attributable to slings. These results sharply contrast with the elevated risks that have been reported after both needle suspension and retropubic urethropexy procedures. The benefits that are associated with sling placement remained highly significant after controlling for all other site-specific prolapse repairs and were similarly unaf-

ected by previous surgical procedures for uterovaginal prolapse. Moreover, it is important to emphasize that sling procedures, in this trial, not only reduced cystocele recurrences relative to similar patients with incontinence who underwent needle suspension or Burch colposuspension procedures, but also compared with all women without slings, and even in comparison to the subgroup of women who underwent no anti-incontinence procedure. There was remarkable consistency found across each of these 3 statistical comparisons. In fact, an identical 42% cystocele recurrence rate at 1 year was found among all subjects without slings (39/90 women; 42%), women who underwent needle or Burch procedures (24/57 women; 42%), and women who underwent prolapse repair with no accompanying incontinence procedure (14/33 women; 42%). In all 3 of these statistical analyses, this 42% baseline risk was significantly greater than the 19% recurrence after sling procedures. Thus, suburethral slings were superior to the other incontinence procedures with respect to maintaining anterior vaginal wall support; beyond this, the presence of a sling appeared to confer a significant protective effect against the recurrence of cystoceles after pelvic reconstructive operation in general.

We were unable to conclude the most beneficial type of sling procedure on the basis of this study. Our sample size was more than adequate for demonstrating the independent protective effect of slings; however, when we subdivided sling procedures by type, the cell sizes afforded insufficient statistical power to detect modest differences in our main clinical outcomes.

Finally, it is interesting to note that posterior sacrospinous vaginal vault suspensions were associated with a significantly higher long-term risk of central cystocele recurrence in this sample, whereas the anterior sacrospinous technique<sup>16</sup> conferred no such risk. Although the present study was not designed to definitively analyze this potential risk factor, these results were nonetheless concordant with a previous larger series that demonstrated better long-term anterior vaginal support after the anterior sacrospinous technique, compared with the conventional posterior sacrospinous technique with the use of a posterior vaginal incision and pararectal dissection. A long-term cohort study is ongoing, at our center, to compare long-term anatomic and functional outcomes associated with these 2 vaginal vault suspension techniques.

Based on these findings, suburethral slings appear to decrease the risk of cystocele recurrence after pelvic reconstructive operations, in direct contrast to the elevated risks reported after retropubic urethropexy and needle suspension procedures. This protective effect was observed as early as 12 weeks and remained highly significant at 1 year after operation (odds ratio, 0.29). Considering the particular challenge of achieving long-term

support for anterior vaginal wall defects while effectively curing stress incontinence, these findings may be regarded as an important consideration for surgical planning. The 54.8% reduction that we observed in cystocele recurrence may ultimately necessitate fewer future surgical procedures for recurrent prolapse and perhaps result in less overall long-term morbidity. Particularly as the invasiveness of the suburethral sling operation continues to decline, the findings of this study may support a first-line role for slings in treating genuine stress incontinence accompanied by advanced uterovaginal prolapse. Ongoing investigation is warranted to further identify the safest and most effective overall operative strategies for the correction of prolapse and incontinence and to better understand the biomechanical and/or neurologic causes underlying the findings of this study.

#### REFERENCES

1. Shull BL, Capen CV, Riggs MW, Kuehl TJ. Preoperative and postoperative analysis of site-specific pelvic support defects in 81 women treated with sacrospinous ligament suspension and pelvic reconstruction. *Am J Obstet Gynecol* 1992;166:1764-71.
2. Morley GW, DeLancey JOL. Sacrospinous ligament fixation for eversion of the vagina. *Am J Obstet Gynecol* 1988;158:872-81.
3. Shull BL, Berm SJ, Kuehl TJ. Surgical management of prolapse of the anterior vaginal segment: an analysis of support defects, operative morbidity, and anatomic outcome. *Am J Obstet Gynecol* 1994;171:1429-39.
4. Elkins TE, Chesson RR, Videla F, Menefee S, Yordan R, Barksdale PA. Transvaginal paravaginal repair: a useful adjunctive procedure in pelvic relaxation surgery. *J Pelvic Surg* 2000;6:11-5.
5. Kohli N, Sze EHM, Roat TW, Karram MM. Incidence of recurrent cystocele after anterior colporrhaphy with and without concomitant transvaginal needle suspension. *Am J Obstet Gynecol* 1996;175:1476-82.
6. Sze EHM, Miklos JR, Partoll L, Roat TW, Karram MM. Sacrospinous ligament fixation with transvaginal needle suspension for advanced pelvic organ prolapse and stress incontinence. *Obstet Gynecol* 1997;89:94-6.
7. Baden WF, Walker TA, Lindsey JH. The vaginal profile. *Tex Med* 1968;64:56-9.
8. Sand PK, Koduri S, Lobel RW, Winkler HA, Tomezsko J, Culligan PJ, et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Presented at the Central Association of Obstetricians and Gynecologists, Chicago, Ill, October 19, 2000.
9. Kjolhede P, Noren B, Ryden G. Prediction of genital prolapse after Burch colposuspension. *Acta Obstet Gynecol Scand* 1996;75:849-54.
10. Kohli N, Sze E, Roat T, Karram M. Incidence of recurrent cystocele after anterior colporrhaphy with and without concomitant transvaginal needle suspension. *Am J Obstet Gynecol* 1996;175:1476-80.
11. Galloway N, Davies N, Stephenson T. The complications of colposuspension. *Br J Urol* 1987;60:122-4.
12. Shull BL, Capen CV, Riggs MW, Kuehl TJ. Preoperative and postoperative analysis of site-specific pelvic support defects in 81 women treated with sacrospinous ligament suspension and pelvic reconstruction. *Am J Obstet Gynecol* 1992;166:1764-8.
13. Colombo M, Vitobello D, Proietti F, Milani R. Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women with stress urinary incontinence and anterior vaginal wall prolapse. *BJOG* 2000;107:544-51.
14. Wiskind A, Creighton S, Stanton S. The incidence of genital prolapse after the Burch colposuspension. *Am J Obstet Gynecol* 1992;167:399-404.

15. Cross C, Cespedes D, McGuire E. Our experience with pubo-vaginal slings in patients with stress urinary incontinence. *J Urol* 1998;159:1195-8.
16. Winkler HA, Tomeszko JE, Sand PK. Anterior sacrospinous vaginal vault suspension for prolapse. *Obstet Gynecol* 2000;95:612-5.

## Discussion

**DR JEFFREY L. CORNELLA**, Scottsdale, Ariz. The original study was a prospective, randomized trial of polyglactin-910 mesh to prevent the recurrence of cystocele and rectocele. It was presented at last year's Central Association meeting in Chicago, Illinois. Today's paper was a secondary study that was derived from those data as an observational cohort study. It therefore has some inherent statistical challenges not addressed by the original well-designed study. In fact, the commentary must focus on statistics. This paper contains 2-tailed *t* tests, simple logistic regression, multiple logistic regression, and 1-way ANOVA with various statistical adjustments. I am learning statistics, so hopefully in the future I will not think ANOVA is a nature show that I saw on educational television. Therefore, I have relied on our in-house experts for help in my commentary.

I will attempt to convince you that, because of the design (and other factors), one cannot use this paper as strong evidence-based medicine that sling placement decreases the risk of subsequent cystocele. In a way I am glad of that, because it fits my bias: I do not understand why a sling should prevent high cystocele, and I believe there remains an important place for Burch urethropexy in the treatment of clinically selected patients with incontinence.

In this study, the rate of cystocele recurrence in a group of patients who had undergone a sling procedure was compared with the rate of cystocele recurrence in a group of patients with no sling procedure. This type of design does not provide direct evidence of a cause-and-effect relationship because there may be differences between the 2 groups other than the use of a sling.

In fact, there were many differences between the sling and nonsling groups. The sling group had a younger average age, fewer patients who were postmenopausal, fewer patients with hormone replacement therapy use, more patients with prior anterior colporrhaphy, more patients with prior abdominal hysterectomy, more patients with prior retropubic urethropexy, fewer patients with concomitant vaginal hysterectomies, and fewer patients with concomitant paravaginal repairs. Further, even in the sling group there were 4 different surgical techniques used, all of which were categorized as "sling."

Also, the authors report there were "no differences" between groups for other previous procedures, but the actual rates were not reported. The authors only reported rates where the probability value was  $\leq .05$ . They do not report whether the margin of error included differences that would be clinically significant. Conclusions regarding differences or equivalence appear to have been made on the basis of probability values alone. There were no indicators of measurement error or uncertainty (such as confidence intervals).

There were also some comparisons between the sling and nonsling groups that were not reported, which may have influenced the risk of cystocele recurrence. These included the use of mesh, the grades of pelvic relaxation, and parity.

Because there were so many differences between the sling and nonsling groups, the author's conclusions depend on their adjustments to the rates of recurrence. The authors report a particular method of making this adjustment. Some important variables, such as grade of relaxation, do not appear to have been considered. There is no assurance that there was adequate statistical power to assess the significance of multiple potential confounding factors. The method of adjustment does not appear to have been specified in a study protocol before beginning the analysis; rather, it may have been selected after the results from many methods were examined.

In this sample, rectocele recurrence was more than twice as high in the sling group. Even if statistical power were too low to conclusively assess differences of this size, a doubling of the risk of recurrence should probably not be described as "no difference." (The author should consider reporting confidence intervals for the differences between groups, especially when claiming the groups do not differ).

The limitations of this study are the post hoc exploratory nature of the methods of analysis and the numerous differences between the sling and nonsling groups. The unadjusted comparisons clearly have the potential for bias because of the differences between the sling and nonsling groups.

In conclusion, the study has provided preliminary valuable data and has generated an interesting hypothesis. Because of the large number of differences between groups, a randomized trial by this talented group would be best. It is important to avoid the increased use of the sling operation or the decreased use of the Burch urethropexy because of impressions derived from nonevidence-based data.

**DR GOLDBERG** (Closing). With respect to the limitations of our retrospective design, this was a post hoc statistical evaluation. I have confidence that we covered in our multivariate regression analysis all of the important potential confounding variables (including the potential effects of mesh, degree of relaxation, and parity) as mentioned. In terms of the statistical power to make conclusions, it is reflected in the statistical significance. There was clearly a large enough sample size and enough of an effect so that we were able to see statistical significance while controlling for those potential confounders. There is no question that retrospective analysis is generally inferior to a prospective randomized study design; that would be an interesting next step. With regard to the recurrence of cystoceles and why level 1 supports should be affected by the presence of a sling, I am not sure we have a good answer. We use a 2-cm wide strip of fascia for most of our slings, which I think, provides support to the distal trigone and the urethrovesical junction. But proximal to that, I am not sure that we have a clear idea of what is going on dynamically in the pelvis that would make level

1 recurrence less likely. With respect to neuropathy and intrinsic sphincteric deficiency down the road, all of the patients who were treated with slings during this time period had intrinsic sphincteric deficiency. We are dealing with a subset of patients who already have the problem. On the basis of the Indiana data,<sup>1</sup> I am not sure that the retropubic perforation provides any further denervation than the colporrhaphy itself. Finally, on the issue of rectoceles, there is no question that there was a trend seen, but it did not reach statistical significance in this analysis.

Whether exposing more posterior vaginal support to intraperitoneal forces could lead to more rectoceles is unclear. I think that future studies will have to explore the balance between slings that potentially protect against cystocele recurrence and the potential risk that recurrent rectocele rates could be higher.

#### REFERENCE

1. Benson JT, McClellan E. The effect of vaginal dissection on the pudendal nerve. *Obstet Gynecol* 1993;82:387-9.

#### **Bound volumes available to subscribers**

Bound volumes of the American Journal of Obstetrics and Gynecology are available to subscribers (only) for the 2001 issues from the publisher, at a cost of \$122.00 for domestic, \$156.22 for Canada, and \$146.00 for international for Vol. 184 (January-June) and Vol. 185 (July-December). Shipping charges are included. Each bound volume contains a subject and author index, and all advertising is removed. Copies are shipped within 60 days after publication of the last issue in the volume. The binding is durable buckram with the Journal name, volume number, and year stamped in gold on the spine. *Payment must accompany all orders.* Contact Mosby, Subscription Customer Service, 6277 Sea Harbor Dr, Orlando, FL 32887. Telephone (800)654-2452 or (407)345-4000. Fax (407)363-9661.

**Subscriptions must be in force to qualify. Bound volumes are not available in place of a regular Journal subscription.**