



SPOTLIGHT ON URINARY INCONTINENCE

Just 2 years ago, when Brubaker and colleagues published initial findings from the colpopexy and urinary reduction efforts (CARE) trial in the *New England Journal of Medicine*,¹ Burch colposuspension was a well-established anti-incontinence procedure utilized by many urogynecologists. The procedure remains a

reliable intervention, although midurethral sling procedures have surpassed it in popularity and (some would say) efficacy. This issue's installment of Examining the Evidence highlights two recent investigations of the anti-incontinence procedure:
▶ 2-year follow-up from the CARE trial, which compared

sacrocolpopexy, with and without a concomitant Burch procedure, in women who did not have symptoms of stress urinary incontinence (SUI) at the time of surgery
▶ a comparison of laparoscopic Burch colposuspension and the tension-free vaginal tape (TVT) technique.

Is Burch colposuspension needed at the time of sacrocolpopexy to prevent SUI?

Sometimes Although prophylactic Burch colposuspension at the time of sacrocolpopexy significantly reduces symptoms of SUI at 2 years, based on follow-up data from the randomized CARE trial,¹ the Burch procedure has largely been replaced by the midurethral sling—specifically, the TVT. The TVT has lower morbidity than Burch colposuspension and similar, if not higher, long-term efficacy. Burch urethropexy is now commonly reserved for women in whom a synthetic sling is contraindicated or who desire a future pregnancy.²

Brubaker L, Nygaard I, Richter HE, et al, for the Pelvic Floor Disorders Network. Two-year outcomes after sacrocolpopexy with and without Burch to prevent stress urinary incontinence. Obstet Gynecol. 2008;112:49-55.

▶ EXPERT COMMENTARY

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cine and Reconstructive Surgery, Washington Hospital Center, and Associate Professor, Departments of Obstetrics and Gynecology, Georgetown University, Washington, DC. Dr. Iglesia serves on the OBG MANAGEMENT Board of Editors.

With prevalence reported to range from 18% to 46% in women 25 to 64 years old, SUI is a serious problem. Concomitant anti-incontinence procedures are typically considered in women who have documented SUI at the time of surgical prolapse repair. The decision is less straightforward in women who do not have preoperative symptoms of SUI at the time of surgery for prolapse.

The CARE trial was designed to determine whether prophylactic concomitant Burch colposuspension is indicated in these women when they undergo planned abdominal sacrocolpopexy. In this latest update, CARE investigators present 2-year outcomes.

Functional and anatomic findings

The addition of a Burch procedure at the time of sacrocolpopexy reduced the rate of

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Burch colposuspension significantly reduces symptoms of SUI at 2 years, but is now reserved for cases in which a synthetic sling procedure is contraindicated



postoperative SUI symptoms to a greater degree than sacrocolpopexy alone (control group) did, with 32% of women in the Burch group experiencing symptoms (versus 45.2% of controls; $p=.026$). Women in the Burch arm also had a lower rate of bothersome SUI (11.6% versus 25.2%; $p=.004$) and a tendency to a lower rate of urge symptoms (32% versus 44.5%; $p=.085$). In addition, the study demonstrated that sacrocolpopexy played a beneficial role in reducing bothersome irritative and obstructive urinary symptoms after surgery, regardless of concomitant Burch.

Anatomic outcomes were similar in both arms of the trial, with the apex within 2 cm of total vaginal length in 95% of women ($p=.18$).

Strengths, limitations of this study

The strengths of this randomized trial include the generalizability of its results, with multiple geographic sites and surgeons participating and with long-term follow-up of patients. Its major limitation is that Burch colposuspension is now somewhat obsolete. More data on prophylactic sling procedures are needed. 📌

References

1. Brubaker L, Cundiff GW, Fine P, et al, for the Pelvic Floor Disorders Network. Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. *N Engl J Med*. 2006;354:1557–1566.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Concomitant prophylactic Burch colposuspension confers sustained protection against SUI in women who are continent at the time of sacrocolpopexy. And mid-urethral synthetic slings—which require a shorter operative time and hospital stay and carry a low rate of perioperative complication—offer success rates similar, if not superior, to Burch. Both procedures require specialized training to perform safely.

It is reasonable to consider a prophylactic, concomitant anti-incontinence procedure in the form of a Burch colposuspension at the time of sacrocolpopexy. We believe that a concomitant or staged (interval) midurethral sling operation is a sound alternative 1) depending on the patient's preference and 2) after review of the available evidence and potential risks and benefits.

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FAST TRACK

Four to 8 years after surgery, the TVT and laparoscopic Burch techniques produced similar efficacy rates for treatment of SUI

2. Fatton B. Is there any evidence to advocate SUI prevention in continent women undergoing prolapse repair? An overview. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 [Epub ahead of print].

Is long-term outcome with TVT comparable to that of laparoscopic Burch colposuspension?

Yes This randomized trial found similar long-term efficacy for TVT and laparoscopic Burch colposuspension for the treatment of urodynamically confirmed SUI. Four to 8 years after surgery, a substantial percentage of women in both arms of the trial had some degree of incontinence. However, incontinence was “bothersome” in only 11% of women undergoing the Burch procedure versus 8% of women treated with

TVT—a difference that was statistically insignificant.

Jelovsek JE, Barber MD, Karram MM, Walters MD, Paraiso MFR. Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow-up. BJOG. 2008;115:219–225.

► EXPERT COMMENTARY

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Since introduction of the TVT technique by Ulmsten and colleagues in 1996, mid-urethral tension-free sling procedures have become the most commonly performed anti-incontinence operations in the world, rapidly replacing Burch colposuspension as the first choice for women who have urodynamically confirmed SUI.¹ In 2004, a prospective, randomized trial by Ward and Hilton demonstrated that the TVT was equal and perhaps even superior to the Burch procedure.² The

same year, Paraiso and associates reported on a two-center prospective randomized trial of laparoscopic Burch colposuspension versus TVT.³ Although that trial was underpowered, the investigators found a higher rate of objective urodynamic SUI and subjective urinary incontinence 1 year after laparoscopic Burch colposuspension, compared with TVT.³ The study by Jelovsek and colleagues represents the long-term follow-up of this cohort, 4 to 8 years after the original operation.

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FDA alert: Transvaginal placement of surgical mesh carries serious risks

Infection, pain, urinary problems, and erosion of mesh through vaginal epithelium are some of the most frequent complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence, according to an October 2008 US Food and Drug Administration (FDA) alert.

These complications have been documented in more than 1,000 reports from nine surgical mesh manufacturers over the past 3 years. Besides the complications described above, they include:

- recurrent prolapse or incontinence (or both)
- bowel, bladder, and blood-vessel perforation during insertion
- vaginal scarring.

In many cases, additional surgery was required, as were intravenous therapy, blood transfusion, and drainage of hematoma or abscess.

Who is at risk?

Although the FDA has not determined whether specific patient characteristics increase the risk of complication, it notes that poor health overall and low estrogen levels may contribute. Other potential variables include the specific mesh material (as well as its size and shape), the surgical technique used, and whether concomitant procedures were undertaken.

The FDA advises physicians to...

- obtain specialized training for each mesh-placement technique
- watch for potential adverse events, especially erosion and infection
- watch for complications associated with surgery itself, such as bowel perforation
- tell the patient that surgical-mesh implantation is permanent, and warn her of potential complications, including the possible need for additional surgery
- give each patient a written copy of patient labeling from the surgical mesh manufacturer.



Infection, pain, urinary problems and other complications associated with transvaginal mesh placement have been documented in more than 1,000 reports over the past 3 years

FOR MORE INFORMATION, VISIT

- www.fda.gov/cdrh/safety/102008-surgicalmesh.html (health-care providers)
- www.fda.gov/cdrh/consumer/surgicalmesh-popsui.html (consumers)

Also, return here in January 2009, when OBG MANAGEMENT features a roundtable on using mesh in prolapse repair, moderated by Mickey M. Karram, MD.



Details of the study

Seventy-two women were originally enrolled from 1999 to 2002; 74% of them (25 in the TVT group and 28 in the laparoscopic Burch group) were available for long-term follow-up 4 to 8 years after surgery. Fifty-seven percent (16/28) of women had subjective urinary incontinence after laparoscopic Burch colposuspension versus 48% (12/25) after TVT. There were no differences between the groups in subjective or objective findings or urinary incontinence. However, the study was severely underpowered to be able to show any difference between the groups.

These cure rates are low, but the authors note that only 11% of the laparoscopic Burch group and 8% of the TVT group had bothersome SUI. Quality of life on the urogenital distress inventory and incontinence impact questionnaire short forms was improved in both groups equally by 2 years and maintained throughout the rest of the trial.

These poor objective results are similar to those found in a 5-year follow-up by Ward and Hilton of their prospective, randomized, controlled trial of Burch versus TVT procedures. There, only 39% of the TVT group and 46% of the Burch group reported no incontinence.

The original trial by Paraiso and colleagues³ showed better outcomes in the TVT

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Laparoscopic Burch colposuspension and the TVT procedure appear to have equal long-term outcomes. Because placing TVT is less invasive, however, it may be the preferable procedure until larger trials or meta-analyses conclusively determine which operation is superior.

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group 1 year after surgery, but that difference did not remain 4 to 8 years later. One explanation for that observation may be type-II error resulting from the small number of subjects in the trial. ❌

References

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2. Ward KL, Hilton P, on behalf of the UK and Ireland TVT Trial Group. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. *Am J Obstet Gynecol.* 2004;190:324-331.
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57% of women had subjective urinary incontinence after laparoscopic Burch colposuspension, versus 48% after TVT

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