editorial

What's Best in the Treatment of Stress Urinary Incontinence?

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A participant in a recent postgraduate course on urinary incontinence said to a panel of surgical experts: "Just tell us what surgery works well, without complications, so that we can take better care of our patients." Like most surgeons, the course participant was searching for the best operation for incontinence, one that had perfect success rates without complications. The panel made a complicated response to this simple request. Choosing the "best" surgery for stress urinary incontinence requires consideration of the goals, the needs, and the health of the patient, as well as the skill and training of the surgeon performing the procedure.

Stress urinary incontinence — the leakage of urine associated with increases in intraabdominal pressure — occurs commonly in women and is associated in many cases with markedly reduced quality of life. Women are often embarrassed to discuss their symptoms, and only a fraction of women with bothersome incontinence seek treatment. Not all incontinence is persistent. Recent investigations have shown that, like many functional disorders, the disease state flares up at times and recedes at other times.[1] Some women with persistent leakage are not significantly troubled by it and do not desire intervention. For women with persistent, bothersome incontinence, the options include behavioral and physical therapy and incontinence pessaries or surgical intervention.[2]

Surgery for stress incontinence is common. The number of surgical procedures for incontinence increased in the United States from 48,345 in 1979 to 103,467 in 2004. These data underestimate the increases, because midurethral-sling surgeries are performed on an outpatient basis, and outpatient procedures are not included in the above numbers.[3] Until recently, the reference standards for incontinence surgery included the Burch retropubic urethropexy and the suburethral fascial sling. As commonly performed, both the fascial-sling and the Burch urethropexy procedures require an abdominal incision and are associated with substantial postoperative recovery time and complications. Although the continence rates after surgery are higher with the fascial sling than with the Burch procedure, the fascial sling is also associated with higher rates of postoperative complications.[4] Many women are reluctant to undergo either procedure because of the strain that hospitalization and recovery places on their families and jobs.

In 1996, Ulmsten et al. introduced a synthetic midurethral sling, the tension-free vaginal tape, which could be inserted by means of a minimally invasive surgical procedure.[5] Incisions are small, most procedures are performed on an outpatient basis, and postoperative recovery is rapid. The operation is standardized with a device kit, so that variation in technique among individual surgeons is minimized. The advantages of this approach triggered widespread adoption of the tension-free vaginal tape procedure before data from randomized trials were published to support its use. In 2001, Delorme introduced a different type of midurethral sling, the transobturator tape, a sling that is placed through the obturator foramen rather than the retropubic space.[6] Again, without evidence from randomized trials, this procedure was widely adopted because of the ease of performance and the purported decreases in perioperative complications, specifically bladder perforation, as compared with the tension-free vaginal tape procedure.

In this issue of the *Journal,* Richter et al. report the results of a multicenter, randomized equiva-

lence trial with intermediate-term follow-up,[7] comparing the retropubic midurethral sling procedure with the transobturator midurethral sling procedure. Rather than aiming to prove that one procedure was better than the other, the investigators aimed to show that the two procedures were not different, a hypothesis consistent with the widespread clinical belief that the procedures vary only slightly in efficacy and in the rate of associated complications. The findings in this well-designed trial confirm this clinical belief. The rates of treatment success according to objective criteria (a negative stress test, a negative pad test, and no retreatment at 1-year follow-up) were 80.8% in the retropubic-sling group and 77.7% in the transobturator-sling group (3.1 percentage-point difference; 95% confidence interval [CI], −3.6 to 9.6%), consistent with "equivalence," defined by a maximum upper limit of 12 percentage points and a maximum lower limit of 12 percentage points for the 95% confidence interval. The rates of treatment success according to subjective criteria (self-reported absence of stress incontinence symptoms, no leakage episodes in diary, and no retreatment) were lower and did not meet the criteria for equivalence, though they were similar between the retropubic and transobturator groups (62.2% and 55.8%, respectively, 6.4 percentage-point difference; 95% CI, −1.6 to 14.3). The complications of surgery varied with the approach. The retropubic group had more serious side effects overall, mostly related to mesh exposures, bladder perforations, or postoperative voiding dysfunction requiring surgery, whereas the transobturator group was more likely to have neurologic symptoms, including numbness and weakness.

The trial confirms that patients are likely to have good results in the first year after either procedure. Are these results generalizable to procedures performed by surgeons with less training and expertise than those of the surgeons in this study? All the surgeons participating in the trial were very skilled in performing surgery for female incontinence, and previous studies have shown that the patients of surgeons who perform a low volume of female-incontinence procedures have higher complication rates than do the patients of surgeons who perform a high volume of these procedures.[8] What happens to women in the long term? The rationale for the introduction of new surgical procedures is often based on short-term outcomes, whereas patients want both short-term and long-term results. Up to a third of women who have surgery for stress incontinence undergo a second procedure during their lifetime,[9] and data regarding the long-term effectiveness and equivalence of these two procedures are critical to decision making.

Will the findings of this study change the practice of the many surgeons who offer incontinence procedures to patients? Possibly not, since this trial confirms that the procedures are very similar with respect to both efficacy and overall complication rates. What may change is how patients are counseled regarding the benefits and harms associated with the surgery, allowing surgical choices to better match a patient's goals and wishes, as well as the surgeon's abilities. What is the best incontinence surgery? It depends.

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