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UT Southwestern investigators perform head-to-head comparison of incontinence treatments

DALLAS – June 2, 2010 – As part of a national clinical trial, UT Southwestern Medical Center researchers found little difference in effectiveness between two popular treatments for one of the most common ailments among American women: stress urinary incontinence.

Stress incontinence affects up to 50 percent of women in the U.S. at some point in their lives. Women with stress incontinence experience leakage during increases in abdominal pressure typically brought on by sneezing, coughing, lifting heavy objects or other types of physical activities. UT Southwestern surgeons and colleagues at eight other sites compared the outcomes of two surgical procedures designed to alleviate symptoms of stress urinary incontinence. UT Southwestern was the only site in North Texas to participate in the trial.

The study, available online in the *New England Journal of Medicine*, shows that both surgical procedures – transvaginal sling (TVT) and transobturator midurethral sling (TOT) – appear to be similarly effective in women up to 12 months after the procedures were performed.

"Both procedures are done using minimally invasive techniques, but until now there haven't been any large prospective head-to-head randomized trials comparing the two popular techniques," said Dr. Gary Lemack, professor of urology and neurology and co-principal investigator at the UT Southwestern site.

The TVT sling, introduced in 1996, involves placing a thin strip of polypropylene mesh weave transvaginally and behind the urethra and pubic bone. The strip acts as a kind of scaffolding that supports the urethra, diminishing urine leakage.

The more recently developed TOT sling reduces the risk of bladder or bowel injury by passing the sling laterally into the groin through two small incisions in the upper thigh. This method works in the same way as the TVT, by supporting the urethra. Controversy exists as to which sling is more effective and which might be associated with a greater risk of complications.

"At one year, the two groups of patients were assessed both objectively and subjectively about the success of their procedures," said Dr. Lemack. "The outcomes appear very similar at one year regardless of the severity of the patient's stress incontinence symptoms."

Objective measures of success included testing whether or not there was any urine leakage with (MORE)

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straining or coughing during an exam with a full bladder. Patients also were asked to wear a pad for 24 hours to determine if leakage occurred. Subjective self-reported criteria required patients to keep a three-day diary and record any symptoms of stress incontinence. They also reported the need for any further treatments.

"The rates of success using objective measures in patients with the transvaginal sling were around 81 percent, and 78 percent for patients who had the TOT procedure – equivalent by our preset criteria," Dr. Lemack said. "Rates of subjectively reported success were slightly higher in the transvaginal group and thus did not quite meet the criteria for equivalence."

Both procedures carry associated risks, albeit infrequently, and the key difference between procedures may be the rate of adverse events associated with each. For example, the TVT was associated with a greater likelihood of intraoperative bladder injury and postoperative voiding dysfunction, while the TOT was more likely to be associated with postoperative numbness and pain.

As a result, although the procedures are similar in effectiveness, Dr. Lemack says physicians could use the information gleaned from this study to more fully counsel patient about the risks and benefits of either operation.

Dr. Lemack said that future studies should help determine if any other parameters, such as bladder function studies, may help in predicting treatment success.

Other UT Southwestern faculty participating in the multi-center incontinence network included Dr. Philippe Zimmern, professor of urology; Dr. Joseph Schaffer, professor of obstetrics and gynecology; Dr. Marlene Corton, associate professor of obstetrics and gynecology; and Dr. Clifford Wai, associate professor of obstetrics and gynecology.

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