

Two Minimally Invasive Surgeries Equally Effective for Bladder Control in Women

Study Helps Physicians and Patients Choose Best Procedure

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Two minimally invasive operations for stress urinary incontinence (SUI) help women achieve equivalent levels of dryness, according to researchers at University of California San Diego, School of Medicine and a multicenter team of urologists and urogynecologists who partnered in the U.S. trial. The study, supported by the National Institutes of Health (NIH), will be released online May 17, 2010, by the *New England Journal of Medicine (NEJM)*.

"This is the largest trial to date comparing the two most commonly performed versions of the mid-urethral sling procedure," said Michael Albo, MD, co-author and principal investigator of the clinical trial based at UC San Diego Medical Center. "We found that the two surgeries are equal in effectiveness but vary in potential side effects. This information allows patients and physicians to select one surgery over another based upon a woman's individual anatomy and health profile # without worrying about efficacy."

Urinary incontinence is a common and costly condition that reduces quality of life for American women. Another study funded by the NIH reports that approximately half of women have some degree of incontinence, and the direct cost of incontinence for women was \$12.4 billion in 1995, the last year for which estimates are available.

Women with SUI experience leakage of urine when coughing, laughing, sneezing, running or lifting heavy objects. The condition is often treated with one of two versions of a procedure called a mid-urethral sling. Performed with two tiny incisions, the "sling" provides support to the bladder neck and urethra. Mid-urethral slings are made up of a synthetic mesh material that acts as a "hammock" to support the urethra. The "retropubic" sling passes material under the urethra and behind the pubic bone. The "transobturator" passes the material under the urethra.

The Trial of Mid-Urethral Slings (TOMUS) found that the sling procedures are similar in their chance of cure. Twelve months after surgery, women who received the transobturator sling and women who received the retropubic sling had equivalent levels of treatment success: 78 to 81 percent of women achieved dryness as defined by clinical tests.

The study also demonstrated that each type of surgery had different risks and side effects. More bladder perforations during surgery and serious bladder emptying problems requiring surgical correction occurred in the retropubic group while more vaginal perforations and neurological problems like upper leg weakness occurred in the transobturator group. Blood loss during surgery, duration of surgery, and likelihood of post-surgery urinary tract infections were all modestly higher in the retropubic group, compared to the transobturator group.

Albo, co-director of the Women's Pelvic Medicine Center at UC San Diego Medical Center, said that this trial clearly shows that top-notch randomized surgical trials for patients are possible and should be the standard against what new procedures are judged.

"We found that patients and surgeons nationally were willing to participate in the trial in order to identify the most effective treatment for incontinence," said Albo, a nationally recognized expert in minimally invasive surgery for pelvic disorders. "Here in southern California, we were able to create a top-notch team of investigators at UC San Diego Medical Center and Kaiser Hospital who worked together to treat a diverse group of patients while fulfilling our mutual research and teaching missions."

UC San Diego School of Medicine researchers who participated in this study included Charles Nager, MD, co-director of the UCSD Women's Pelvic Medicine Center and Emily Lukacz, MD. Kaiser researchers included Shawn Menefee, MD, Emily Whitcomb, MD and Karl Luber, MD.

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