Nationwide Study Compares Surgeries to Treat Urinary Incontinence in Women

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The University of California, San Diego Medical Center along with nine other clinical research institutions across the United States has completed the largest randomized clinical trial to date comparing two commonly performed surgical procedures to treat urinary stress incontinence.

Findings reveal that a procedure that places a sling to support the bladder is significantly more effective than another common technique, called the Burch, which secures the urethra and bladder to the pelvic wall with sutures. The multi-center study, supported by the National Institutes of Health, is published in the May 24 *New England Journal of Medicine* print edition.

Known as SISTEr, the Stress Incontinence Surgical Treatment Efficacy Trial compared the fascial sling with the Burch colposuspension technique for treating stress urinary incontinence which occurs during coughing, laughing, sneezing, running or lifting heavy objects, causing urine to leak. The condition develops when the normal support structures of the urethra and bladder are weakened, causing the bladder to move down toward the bottom of the pelvis.

In the sling procedure, a strip of the patient's own tissue is placed under the urethra like a hammock and attached to the ligaments of the pubic bone to provide support. In the Burch procedure, the urethra and bladder are lifted back into their normal position and secured to tissue near the pubic bone with sutures. Both procedures provide additional support to the urethra during periods of activity to prevent urine leakage.

655 women were randomly assigned to the study: 326 to undergo the sling procedure and 329 to undergo the Burch procedure; 520 women completed the outcome assessment. Two years after surgery, overall success rates were 47 percent and 38 percent for the sling and Burch groups, respectively. Although the sling procedure may offer higher cure rates, this advantage may be offset by complications such as urinary tract infections and difficulty voiding.

"Only by comparing these surgical procedures in properly designed trials can we offer patients clear, accurate, and honest recommendations about the various treatment options," said Michael E. Albo, MD, lead author of the study, and co-director of the UCSD Women's Pelvic Medicine

Center. "Today, we have more treatments available than ever before, options which include tradeoffs between success and complications. Patients and physicians should discuss these issues early on to achieve individual goals."

The SISTEr study was performed by the Urinary Incontinence Treatment Network, a group of clinical centers and a biostatistical center, established and funded by National Institutes of Health's National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Child Health and Human Development, and Office of Research on Women's Health to conduct a series of rigorous, long-term trials of common incontinence therapies. As one of the nine sites, UCSD Medical Center partnered with Kaiser Permanente Hospital (San Diego) and Balboa Naval Hospital to recruit more patients for the trial than any other clinical site in the network.

The UCSD Women's Pelvic Medicine Center was created in 1998 by Drs. Albo and Nager as the region's first multi-specialty center designed exclusively for the diagnosis and treatment of pelvic floor disorders. The Center is currently enrolling in four active clinical trials related to treatments for incontinence and prolapse.

By some estimates, urinary incontinence affects up to 50 percent of women in the U.S. In 1995 dollars, the annual direct costs of incontinence in the U.S. were estimated to be more than $16 billion according to research published in the journal *Obstetrics and Gynecology*.

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