

Diokno A C<sup>1</sup>, Richter H E<sup>2</sup>, Kenton K<sup>3</sup>, Norton P<sup>4</sup>, Albo M<sup>5</sup>, Kraus S<sup>6</sup>, Moalli P<sup>7</sup>, Chai T<sup>8</sup>, Zimmern P<sup>9</sup>, Litman H<sup>10</sup>, Tennstedt S<sup>10</sup>

1. William Beaumont Hospital-Royal Oak, MI, 2. University of Alabama at Birmingham - Birmingham, AL, 3. Loyola University Medical Center - Maywood, IL, 4. University of Utah-Salt Lake City, UT, 5. University of California - San Diego, CA, 6. University of Texas Health Sciences Center at San Antonio, 7. University of Pittsburgh - Pittsburgh, PA, 8. University of Maryland - Baltimore, MD, 9. University of Texas Southwestern - Dallas, TX, 10. New England Research Institutes, Inc. - Watertown, MA

## **RISK FACTORS ASSOCIATED WITH FAILURE OF SURGICAL TREATMENT FOR STRESS URINARY INCONTINENCE AT 24 MONTHS FOLLOW-UP**

### Hypothesis / aims of study

To identify baseline demographic, social and clinical factors associated with treatment failure in women undergoing surgical treatment of stress urinary incontinence (SUI) in a multisite randomized clinical trial.

### Study design, materials and methods

Baseline data were examined from 655 women participating in a large randomized trial of Burch colposuspension or pubovaginal sling using autologous rectus fascia for the treatment of SUI. Of those, 520 (80%) completed outcome assessment at 24 months: 255 Burch, 265 sling. "Stress-specific treatment failure (n=261) was defined by any of the following: self-report of SUI by the Medical, Epidemiologic and Social aspect of Aging (MESA) questionnaire, positive stress test, or re-treatment for SUI. "Non-stress" related failure (n=66) was defined as positive 24-hr pad test (>15 ml) or any incontinent episodes by 3-day voiding diary with none of the three criteria for "stress-specific" failure. Subjects not meeting any failure criteria were considered a "treatment success" (n=185). After adjusting for surgical treatment group and clinical site, logistic regression models were developed to predict the probability of treatment failure by the following statistically or clinically significant variables: age, socioeconomic status, body mass index, preoperative stress UI and urge UI severity measured by MESA scores (where stress incontinence subscale score was based on 9 questions, maximum score 27 and urge incontinence subscale score was based on 6 questions, maximum score 18), prior UI surgery, vaginal deliveries, pelvic organ prolapse stage, menopausal status with and without HRT. It was also tested whether risk factors of failure differed significantly by type of surgery.

### Results

For stress specific failure, three factors were found to be significant predictors: severity of urge UI symptoms (p=0.023), prolapse stage (p=0.011), and menopause status and HRT (p=0.020). For every 10 point increase on the MESA urge UI score, the odds of failure nearly doubled (OR 1.93, CI 1.10-3.41) and was 2.5 times greater for women with stage III-IV prolapse than with stage 0-1 prolapse (OR 2.52, CI 1.34-4.75). Post-menopausal women not taking HRT were nearly twice as likely to experience treatment failure as those taking HRT (OR 1.86, CI 1.18, 2.93). For non-stress treatment failure, severity of urge and stress symptoms were found to be significant predictors but in opposite directions. Odds of non-stress failure quadrupled for every 10 point increase in MESA urge UI score (OR 4.18, CI 1.57-11.10) and decreased over 2 times for every 10 point decrease in stress UI score (OR 0.35, CI 0.15-0.78). The associations described between the risk factors and failure remained similar regardless of surgical group.

### Interpretation of results

This 2 year large multicenter well powered study reports on the importance of urge UI, advanced pelvic organ prolapse and non use of HRT in post-menopausal women to be predictors of stress-related failure, and of urge UI for the non-stress related failure of both Burch and sling operations for stress UI. For women with mixed stress and urge UI, our finding suggests that a strong urge UI component could be a harbinger for post-operative stress-related as well as non-stress related failure following stress UI operations. A possible explanation for these 3 factors to explain the predisposition to failure is that they could be the surrogate or the manifestation of an occult intrinsic dysfunction possibly due to neuromuscular dysfunction in the case of urge UI, collagen dysfunction in the case of advanced prolapse and tissue atrophy in the case of lack of HRT overlapping with the obvious hypermobility of the bladder neck. Of interest is that this study did not find age, BMI, prior UI surgery and vaginal deliveries to be risk factors for failure in this multivariate analysis

### Concluding message

Two years after surgery, risk factors for stress-specific treatment failure are similar in women undergoing Burch and sling procedures and included greater baseline urge UI symptoms, more advanced pelvic organ prolapse, and post-menopausal women not on HRT. Higher urge scores were predictive of failure by outcome measures not specific for SUI. This information will assist in counselling patients regarding long term efficacy of these surgical procedures and may prompt more aggressive alternative strategies for women with concurrent urge incontinence. Furthermore, investigation into the mechanism/s by which these factors predispose women to failure following these operations is warranted.

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**HUMAN SUBJECTS:** This study was approved by the Beaumont Hospital Institutional Review Board and followed the Declaration of Helsinki Informed consent was obtained from the patients.