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A RANDOMIZED COMPARISON OF INCONTINENCE PROCEDURES PERFORMED CONCOMITANTLY WITH ABDOMINAL SACROCOLPOPEXY: THE BURCH VERSUS MID-URETHRAL SLING TRIAL.

Background
The CARE trial demonstrated that stress **continent** women have significantly less bothersome stress incontinence symptoms following sacrocolpopexy combined with a Burch urethropexy compared to sacrocolpopexy alone.[1] However, it is not clear which surgical approach to address urinary incontinence is optimal in women who have **symptomatic SUI** and are undergoing sacrocolpopexy.

Hypothesis / aims of study
To compare the efficacy and safety of Burch retropubic urethropexy and retropubic mid-urethral sling (MUS) in women with symptomatic stress (SUI) or stress predominant mixed incontinence (MUI) undergoing concomitant pelvic floor repairs with an abdominal sacrocolpopexy. Specifically we hypothesized that there is no difference in the proportion of continent patients between groups at 6 month follow up.

Study design, materials and methods
This study was an IRB-approved, randomized, single-blinded trial comparing Burch with MUS in women with symptomatic stress urinary incontinence and pelvic organ prolapse undergoing an abdominal sacrocolpopexy. Patients were randomized using a dynamic allocation approach to achieve balance between intervention groups regarding age, BMI, history of prior incontinence surgery, pre-operative diagnosis, and prolapse stage.

Two primary outcomes were assessed at 6 months during a medical visit with completion of validated questionnaires and blinded standardized cough stress test. Patients were **objectively** continent if at follow-up they 1) had a negative standardized stress test performed by a masked observer; 2) no interim re-treatment for stress urinary incontinence; and 3) no self-reported urinary incontinence (International Consultation on Incontinence Questionnaire[2]- short form score of 0). As SUI surgery is not meant to address urge incontinence symptoms, patients were considered to have **stress-specific continence** if they fulfilled criteria 1 and 2 above and 3) had no self-reported stress-related leakage of urine ("never" or "rarely" response to all 6 questions from the SUI subscale of the Medical, Epidemiological, Social Aging questionnaire).[3] Comparisons were evaluated using the chi-square test or Fisher's exact test, as appropriate.

Results
There was no difference in age, BMI, history of prior incontinence surgery, pre-operative diagnosis, prolapse stage, or baseline incontinence severity between groups. Six-month follow-up was available on 104 patients (92%) of the 113 patients randomized (53/57 MUS and 51/56 Burch). Although there was no difference in **objective continence** between MUS and Burch patients in the intention to treat analysis (objective continence: 61.4% (35/57) vs. 50.0% (28/56), p=0.22), patients who had a MUS had higher **stress-specific continence** at 6 months (75.4% (43/57) vs. 57.1% (32/56), p=0.04). The findings remained consistent when the analysis was restricted to patients with completed 6 months follow up (within protocol analysis) were compared: (**objective continence**: 66.0% (35/53) vs. 54.9% (28/51), p=0.25; **stress-specific continence**: 81.1% (43/53) vs. 62.7% (32/51); p=0.04). There was no difference in the rate of de novo urge incontinence between MUS and Burch (10.7% (3/28) vs. 7.7% (2/26), p=0.99).

Amongst patients with baseline urgency urinary incontinence (answered "a few times a month" or worse to question 6 of the overactive bladder symptom score[4] [22 MUS and 22 Burch]), 77.3% of the MUS patients had improvement, 13.6% reported no change, and 9.1% had exacerbation of their symptoms, compared to 59.1%, 27.3%, and 13.6%, respectively, for the Burch patients (p=0.52). Patients who had a MUS procedure had higher satisfaction (answered "somewhat" or "completely": 93.8% vs. 72.3%: p=0.005), higher patient perception of improvement (rated 10 on 10-point VAS: 71.4% vs. 51.1%, p=0.04) and were more likely to report having had a successful surgery for SUI (rated 10 on a 10-point VAS: 72.3% vs. 47.8%; p=0.02). There was no difference in patient global impression of severity, the rate of complications or mesh exposures between groups.

Interpretation of results
In women with baseline SUI undergoing concomitant prolapse repairs with an abdominal sacrocolpopexy, MUS results in higher stress-specific urinary continence rates, higher patient satisfaction and perception of improvement and similar complication rates as the Burch.

Concluding message
Mid-urethral sling is superior to Burch when performed concomitantly with an abdominal sacrocolpopexy in patients with combined prolapse and urinary incontinence symptoms.

References
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Disclosures
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