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Burch Colposuspension at the Time of Sacrocolpopexy in Stress Continent Women Reduces Bothersome Stress Urinary Symptoms: The CARE Randomized Trial. L. Brubaker for the Pelvic Floor Disorders Network.

Objectives: To evaluate if Burch colposuspension at the time of abdominal sacrocolpopexy improves post-operative urinary symptoms in subjects without pre-operative stress urinary incontinence (SUI) symptoms.
Methods: In this IRB-approved, multi-center randomized surgical trial, women with prolapse who were stress continent (answered "never" or "rarely" to the first 6 questions of the Medical, Epidemiological, Social Aspects of Aging (MESA) instrument) were randomized to receive or not receive a standardized Burch colposuspension at the time of sacrocolpopexy. The surgical team was masked to a standardized pre-operative multi-channel urodynamic assessment, including prolapse reduction. The primary outcome at 3 months after surgery was SUI, defined as positive stress test at 300cc bladder volume OR affirmative answers to any of the Pelvic Floor Distress Inventory (PFDI) stress incontinence subscale questions OR treatment (or re-treatment) for SUI. Due to concern that other urinary symptoms may be worsened by addition of the Burch, a parallel urge endpoint was defined as a positive response to any PFDI urgency and obstructed voiding subscale questions OR treatment for urge incontinence. Evaluators and subjects were masked to treatment assignment. The first of two interim analyses was planned with α=0.0042 using 50% of the planned number of subjects.
Results: This report summarizes the first interim analysis with 231 subjects. The participants were predominantly Caucasian (92%) with a mean age of 62 $\pm$10 years. The distribution of prolapse stage included 12% Stage II, 68% Stage III and 20% Stage IV. At 3 months, 22.6% of women in the Burch group and 42.1% of controls had SUI (p=0.0019). The difference between the 2 groups was in the report of SUI symptoms (18.1% Burch vs. 38.3% no Burch, p=0.0007). Of women with SUI, the level of "moderate" or "quite a bit" of bother was significantly lower in those receiving a Burch (28.6% vs. 65.9%, p=0.0074). There was no statistically significant difference in the proportion with a positive stress test (4.3% Burch vs 7.9% no Burch, p=0.29). There was no statistically significant difference in the urge endpoint between the groups (18.1% Burch v. 26.1% no Burch, p=0.16) although the Burch group had a lower level of urge symptoms. There were no statistically significant differences between the groups for other lower urinary tract symptoms or serious adverse events. Similar differences were also seen at one year in the 132 women who had reached that point of follow up.
Conclusions: At the time of sacrocolpopexy in stress continent women, Burch colposuspension significantly reduces bothersome SUI without an increase in other urinary symptoms.
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