

THE COLPOPEXY AND URINARY REDUCTION EFFORTS TRIAL: TWO YEAR OUTCOMES

Hypothesis / aims of study

This study tested the null hypothesis that there is no difference in the proportion of women who reach the a priori stress urinary incontinence endpoints when undergoing sacrocolpopexy with or without concomitant Burch colposuspension.

Study design, materials and methods

In this trial, stress continent women undergoing sacrocolpopexy were randomized to receive or not receive a Burch colposuspension. This trial complied with the CONSORT statement. The primary outcomes were a stress urinary incontinence endpoint (SUI: symptoms, stress testing or treatment) and an urge endpoint. Masked examiners performed POP-Q examinations and administered validated outcome measures including the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) before surgery and at regular intervals to 24 months afterwards. Data were analyzed by a central data-coordinating center.

Results

292 of the 322 randomized participants have completed the two-year assessment. Participants were predominantly Caucasian (94%) with a mean age of 62±10 years (mean ± SD). At 24 months, 32.4% of women in the Burch group and 46.0% of controls had SUI by the defined endpoints (p=0.023). Most had SUI symptoms only: 26.2% Burch vs. 33.3% no Burch (p=0.26), while SUI treatment was given to 10.2% and 20.1% (p=0.022) and 8.3% and 7.0% had a positive stress test at 300 cc volume (p=0.97) in the Burch and no Burch groups, respectively. The urge endpoint was met by 30.3% of women in the Burch group vs. 41.2% in the no Burch group (p=0.14). Two years after surgery, the apex was well supported (POP-Q point C within 2 cm of total vaginal length) in 95% of women and this was not affected by concomitant Burch (p=0.18). POP-Q point Ba was higher in the Burch group (-2.2±0.9 vs. -1.7±1.1, p=0.0001) while Bp was slightly lower (-1.9 ±1.3 vs. -2.3±0.9, p=0.014). Ten women (3%) were treated for mesh erosion. There were no statistically significant differences between the groups for other lower urinary tract symptoms or serious adverse events.

Interpretation of results

The protective benefits of the Burch colposuspension in stress continent women that were seen at three months persist at two years; however, at 3 months the primary difference was in symptoms whereas at two years the primary difference was in the number with additional treatment for SUI. Apical anatomic success rates are high in both groups and treatment for mesh erosions is infrequent

Concluding message

Burch colposuspension should be offered at the time of sacrocolpopexy in women who are stress continent.

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CLINICAL TRIAL REGISTRATION: Clinical trials.gov NCT00099372

HUMAN SUBJECTS: This study was approved by the Principal Investigator - Loyola University Chicago LU# 10624.2 and IRB approved at all enrolling sites and the data center. and followed the Declaration of Helsinki Informed consent was obtained from the patients.