Colpopexy and Urniary Reduction Efforts (CARE): A Randomized Trial of Abdominal Sacrocolpopexy with/without Burch Colposuspension

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Objectives: The primary aim of this randomized clinical trial (RCT) is to evaluate whether a standardized modified Burch colposuspension, when added to a planned sacrocolpopexy for the treatment of pelvic organ prolapse, impacts the rate of urinary stress continence in subjects without pre-operative symptoms of stress urinary incontinence.

Methods: Women undergoing a sacrocolpopexy without symptoms of stress urinary incontinence will be recruited and randomized to the concomitant Burch colposuspension. Eligibility criteria include planned sacrocolpopexy for Stage II-IV prolapse, eligibility for the Burch colposuspension with POP-Q point Aa at a minimum of -1cm and negative stress incontinence symptoms (never or rarely on MESA questionnaire). Other indicated surgery is allowed. Standardized outcome measures include the SF-36, MESA questionnaire, Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire – short form. All questionnaires are administered by the data coordinating center by telephone. Pelvic organ prolapse will be evaluated using the POP-Q system and urethral mobility with the cotton swab test. Multichannel urodynamics evaluation of filling and emptying will employ two methods of prolapse reduction (randomized for order by site). The surgical team is masked to the urodynamic findings. The primary outcome is the result of the standardized stress test at three months. Stress continence is defined as absence of stress incontinence symptoms by PDFI and a negative standardized stress test in the absence treatment or retreatment for stress incontinence outside the study intervention. Additional follow-up occurs at 6, 12, and 24 months. This trial includes an interim analysis is the event that one arm has excess rates of incontinence (primary aim) or other clinically significant findings (secondary aims). An intent to treat analysis is planned, allowing for a 10% drop-out rate and a 10% clinical difference in stress continence rates between groups. The anticipated study population is 480 women with interim evaluations scheduled after 240 and 360 subjects have completed the three month follow-up.

Results: Accrual began March 2002 and is projected to take 3 years. This presentation will highlight the scientific aspects of trial design for this pivotal clinical research trial.

Conclusions: The optimal approach to the urinary tract in women with pelvic organ prolapse is not known. This RCT is designed to provide pelvic surgeons with scientific data regarding the utility of urodynamics, prolapse reduction and the role of colposuspension. Supported by the National Institute of Child Health and Human Development (NICHD).