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ADVERSE EVENTS FROM A RANDOMIZED TRIAL FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The aim of this study is to further characterize adverse events (AE's) in women undergoing surgical treatment for stress urinary incontinence (SUI) in a 9 site randomized trial of autologous rectus fascia pubovaginal sling and Burch colpopexy. Because concomitant surgeries such as prolapse repairs were frequently performed, analyses of AE's were performed with emphasis on determining whether concomitant surgeries increased AE's. In addition, because urinary tract infections, in the form of cystitis, were the most common AE for both treatment arms, an analysis was performed on time of occurrence of cystitis relative to time of surgery. The detailed analysis of AE's from this trial will better inform surgeons performing these procedures, aid in the preoperative counseling of patients, and stimulate hypotheses for future studies.

Study design, materials and methods

This trial was IRB-approved at all sites. A list of reportable AE's was determined and defined *a priori*. Each clinical site was responsible for reporting the occurrence of these AE's as well as any other significant untoward outcomes (per surgeon's judgment) to the Data Coordinating Center. Cystitis was defined as culture proven, or in the absence of a culture, clinical suspicion of bladder infection that resulted in treatment. Patients were also counselled to call if they had symptoms of cystitis. After all patients had been randomized, all reported AE's were reviewed, classified and graded based on a modified version of Dindo classification of surgical complications (1) with the reviewers remaining blinded to the randomized treatment arm. AE's were stratified based on presence or absence of concomitant surgery and were cross classified by treatment group. Differences by concomitant surgery and treatment group were analyzed using Fisher's exact test.

Results

655 women were randomized to receive either a Burch (n=329) or sling (n=326) procedure. 380 (58%) had concomitant procedures (n=184 in Burch arm, n=196 in sling arm). Significantly more patients who had concomitant surgery had AE's compared to those who did not have concomitant surgery (230 versus 132, $p<0.01$). Serious wound complications requiring surgical intervention ($p<0.01$) and gastrointestinal AE's ($p<0.01$) were more frequent in patients who had concomitant surgery. When stratified by presence or absence of concomitant surgery, genitourinary AE's (primarily cystitis) were more frequent in sling patients ($p<0.01$ in both strata). This significant difference in cystitis rate between sling and Burch was observed during the first 6 months post-operatively.

Interpretation of results

In our cohort, wound and gastrointestinal AE's were significantly more frequent in patients who underwent concomitant procedures at the time of stress incontinence surgery. Cystitis occurred significantly more frequently in sling patients. This may be due to the higher percentage of patients requiring clean intermittent self catheterizations after slings.

Concluding message

Patients should be adequately counselled about increased risks when undergoing stress incontinence surgery with concomitant procedures. Consideration of staging concomitant surgeries could be given. Methods for reducing the incidence of cystitis after sling procedures should be explored, including trials to study the efficacy of catheterization prophylactic antibiotics and methods to decrease postoperative retention.

References

1. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004 Aug;240(2):205-13.

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CLINICAL TRIAL REGISTRATION: www.clinicaltrials.gov, Registration number NCT00064662

HUMAN SUBJECTS: This study was approved by the Local IRB at all clinical sites (9 academic health centers) and data coordinating center (New England Research Institute) and followed the Declaration of Helsinki Informed consent was obtained from the patients.