

### 3935/4200 Character count (without spaces)

Defining “success” after surgery for pelvic organ prolapse.

L. Brubaker, M.D. Barber, I. Nygaard, T.L. Wheeler II, J. Schaffer, Z. Chen, and C. Spino

Objective: The objective of this study was to compare success rates using different definitions of surgical success after surgery for Stage 2 to 4 pelvic organ prolapse in women undergoing abdominal sacrocolpopexy with or without Burch colposuspension enrolled in the Colpopexy and Urinary Reduction Efforts (CARE) trial.

Background: Despite the frequency of pelvic organ prolapse surgery, there is no standardized definition of surgical success. This has resulted in highly variable estimates of treatment success. Some investigators view resolution of symptoms as treatment success, others use restoration of normal anatomy, and others use a combination of symptoms and anatomy. In 2001, the NIH Workshop on Standardization of Terminology for Researchers in Pelvic Floor Disorders provided recommended definitions of treatment outcomes for a number of pelvic floor disorders including pelvic organ prolapse. These definitions are likely to be too strict as over 75% of women presenting for annual gynecologic examinations without symptoms of pelvic organ prolapse would not meet the definition of “optimal anatomic outcome” and almost 40% would not meet the definition of “satisfactory anatomic outcome.”

Methods: We analyzed 2 year follow-up data from the CARE trial, a randomized trial designed to evaluate whether a standardized modified Burch colposuspension, when added to abdominal sacrocolpopexy (ASC) to treat pelvic organ prolapse (POP), improves urinary stress continence in subjects without preoperative symptoms of stress urinary incontinence. We created 18 different definitions of surgical success using data from the POPQ examinations, responses to Pelvic Floor Distress Inventory (PFDI) questions regarding vaginal bulging (POPDI) and Pelvic Floor Impact Questionnaire question on prolapse (POPIQ), and data on re-treatment (surgery or pessary) using data from the CARE trial. The proposed definitions of treatment success consist of those recommended in the NIH Standardization Workshop and several used by clinical trials or prospective cohorts evaluating treatment success after prolapse surgery including one from an ongoing clinical trial being conducted by the PFDN (the OPTIMAL trial). Definitions assessing anatomic outcomes used POPQ measurements at 2 year follow-up to determine treatment success or failure. In order to evaluate definitions that employed the Baden-Walker system<sup>14</sup>, POPQ measurements were used to assign Baden-Walker Grades (0-3). Two years after surgery, subjects underwent an evaluation of pelvic support using the POPQ and completed the PFDI. Subjects rated their overall improvement relative to baseline from “much better” to “much worse” and the success of their treatment from “very successful” to “not at all successful.” We assessed whether the subject’s assessment of overall improvement and rating of treatment success differed between surgical success and failure for each of the definitions studied.

Results: 322 CARE subjects who completed at least a portion of the 2-year follow-up that allowed assessment of at least one definition of treatment success are included in this analysis. Treatment success varied widely depending upon definition used (19.2% to 97.2%). 71.4%

considered their surgery “very successful” and 85.2% considered themselves “much better” than before surgery. Definitions of success requiring all anatomic support to be proximal to the hymen had the lowest treatment success (19.2% to 57.6%). 94.3% achieved surgical success when it was defined as the absence of prolapse beyond the hymen. Subjective cure (absence of bulge symptoms) occurred in 92.1% while absence of retreatment occurred in 97.2% of subjects. Subjective cure (absence of vaginal bulging symptoms) was associated with significant improvements in the patient’s assessment of both treatment success and overall improvement, more so than any other definition considered ( $p = .0002$  and  $<.0001$ , respectively). Similarly, the greatest difference in symptom burden and HRQOL as measured by the POPDI and POPIQ scores between treatment successes and failures was noted when success was defined as subjective cure (-55 and -29 points respectively,  $p<.0001$ ).

Conclusions: Success rates after surgery for pelvic organ prolapse vary widely depending on stringency of anatomic success criteria and inclusion of symptoms or patient-reported outcomes. The definition of success has a substantial effect on the rate of treatment success and in studies of POP surgery. The absence of vaginal bulge symptoms postoperatively has a significant relationship with a patient’s assessment of overall improvement, while anatomic success alone does not.

Grant Support: Supported by grants from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institute of Diabetes, Digestive and Kidney Diseases and the NIH Office of Research on Women’s Health (U01 HD41249, U10 HD41250, U10 HD41261, U10 HD41267, U10 HD54136, U10 HD54214, U10 HD54215, and U10 HD54241).