## Title: Defining "success" after surgery for pelvic organ prolapse

**Objectives**: Successful surgery has been variably defined for pelvic organ prolapse (POP); however, there is no consensus on the most appropriate definition. The objective of this study is to compare different definitions of surgical success after POP surgery to determine their effect on estimates of treatment success and relationship to patients' subjective assessments of improvement.

Materials and Methods: We analyzed two-year outcomes of the Colpopexy And Urinary Reduction Efforts (CARE) trial, a prospective randomized trial evaluating the effect of Burch colposuspension in stress continent women undergoing abdominal sacrocolpopexy for advanced POP. Two years after surgery, subjects underwent an evaluation of pelvic support using the POPQ and completed the Pelvic Floor Distress Inventory (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 considered 15 different definitions of surgical success and used data from the POPQ examinations, responses to PFDI questions regarding vaginal bulging, and data on re-treatment on treatment success as appropriate for each definition. We assessed whether the subject's assessment of her overall improvement and rating of treatment success differed between surgical success and failure for each of the definitions studied.

**Results**: 322 subjects randomized in CARE completed the 2-year follow-up, allowing assessment of at least one definition of treatment success considered. Missing data were more frequent for definitions requiring POPQ values (22 to 25%) than for those requiring data from patient interview alone (0% to 10%). Treatment success varied widely depending upon definition used (18.8% to 97.2%). 71% of subjects considered their surgery "very successful" and 85% of subjects considered themselves "much better" than before surgery. Definitions of success requiring anatomic support proximal to the hymen had the lowest treatment success (18.8% to 57.6%). In contrast, 84% 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. We did not detect a significant difference in the patients' subjective assessment of overall improvement between those who were considered a surgical success and those considered failures for each definition that was based solely on anatomic outcomes (p>0.41). In contrast, when the absence of bulge symptoms was included in the definition of treatment success, significant improvements in the patients' subjective assessments of overall improvement were noted between those who met the definition of success and those who did not (p<0.05).

**Conclusion**: The definition of success has a substantial effect on the rate of treatment success and on the proportion of missing data in long-term 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.