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DEFINING "SUCCESS" AFTER SURGERY FOR PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

Despite the frequency of pelvic organ prolapse surgery, there is no consensus definition of surgical success, which has resulted in highly variable estimates of treatment success in the literature. The objective of this study is to compare 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.[1] Specifically our objectives were to: 1) compare how using different definitions affect estimates of treatment success; 2) evaluate how using different definitions affect comparisons of anatomic success between those who received a Burch colposuspension and those who did not; 3) compare different definitions of surgical success to determine their relationship to patients' subjective assessments of improvement and treatment success and improvements health-related quality of life and 4) determine which definitions of treatment success result in the least amount of missing data 2 years after surgery.

Study design, materials and methods

We analyzed 322 women who completed 2 year follow-up in 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. All subjects provided written informed consent. CONSORT guidelines were followed. CARE participants were assessed before surgery and at 2 year follow-up for pelvic organ support using the Pelvic Organ Prolapse Quantification System (POP-Q). In addition, pelvic symptoms and severity (Pelvic Floor Distress Inventory, PFDI) along with condition-specific life impact (Pelvic Floor Impact Questionnaire, PFIQ) were measured via validated instruments.[2] Two years after surgery subjects rated the overall success of their treatment ("In your opinion, has the treatment of your pelvic floor condition been _____?") on a 4 point scale from "very successful" to "not at all successful" and similarly a global assessment of improvement ("Compared to how you were doing before your recent pelvic floor operation, would you say that now you are _____?") on a 5 point scale from "Much better" to "much worse." For this analysis, we considered 18 different definitions of surgical success using data from the POPQ examinations, responses to PFDI questions regarding vaginal bulging, and data on re-treatment alone or in combination. The proposed definitions of treatment success consisted of those recommended in the U.S. NIH Workshop on Standardization of Terminology for Researchers in Pelvic Floor Disorders [3] and several used by clinical trials or prospective cohorts evaluating treatment success after prolapse surgery. For each of 18 dichotomous definitions of treatment success, the proportion of subjects that had a successful outcome was reported for all analyzed CARE women. Additionally, the proportion of subjects with missing data that precluded a determination of success or failure for each definition was determined. In order to evaluate the clinical relevance of each definition from a patient's perspective, we assessed whether the of subjective assessment of treatment success, the global impression of improvement and change the prolapse scales of the PFDI and PFIQ differed between surgical successes and failures for each of the definitions studied.

Results

322 CARE subjects completed the 2-year follow-up and are included in this analysis All enrolled subjects completed at least a portion of the 2-year follow-up that allowed assessment of at least one definition of treatment success considered in this analysis; 53 women (16.5%) completed only questionnaire data at year 2 and 24 women (7.4%) only provided data on retreatment. At baseline, 13.7% had stage 2 POP, 67.4% were stage 3 and 18.9% stage 4. Treatment success varied widely depending upon definition used (18.8% to 97.2%). 71% considered their surgery "very successful" and 85% 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%). 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. Missing data were more frequent for definitions requiring POPQ values (24% to 25%) than for those requiring data from patient interview alone (0% to 10%). No significant difference in successful treatment of POP was found in those subjects who received a Burch compared to those who did not for each of the 18 definitions considered

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 ($p<0.05$) while definitions that included anatomic data alone demonstrated no such relationship ($p>.41$) Similarly, definitions that included the absence of vaginal bulge symptoms also had the strongest relationships with the patients' assessment of overall improvement and improvements in POPDI and POPIQ.

Interpretation of results

In this study, we demonstrated that cure rates 2 years after ASC vary dramatically depending upon the definition of treatment success used. Almost three-fourths of subjects considered their surgery "very successful," re-treatment was uncommon (2.8%) and less than 10% of subjects complained of symptomatic vaginal bulging postoperatively, yet cure rates using strict anatomic criteria such as those found in the NIH Workshop definitions of optimal (Stage 0) and satisfactory (Stage 1) anatomic outcome were only 19% and 57%, respectively. Cure rates using definitions with less stringent anatomic criteria for all segments or that considered only support of the vaginal apex were appreciably higher (90.6% - 95.5%) and more consistent with subjective cure rates. One of the most important findings in our study is that definitions that included the absence of vaginal bulge symptoms had the strongest relationships with the patients' assessment of overall improvement and treatment success as well as improvements in symptom bother and HRQOL. Few of the definitions using anatomic criteria alone to define treatment success demonstrated any such relationships and when they did they were relatively weak. Thus, as a general rule, definitions of treatment success that require patients be free of vaginal bulging symptoms postoperatively are more clinically relevant and meaningful to the patient than those that include only anatomic criteria to define success.

Concluding message

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. Based on these data we recommend that any consensus definition of success after POP surgery include the absence of bulge symptoms in addition to anatomic criteria as well as the absence of re-treatment.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**This trial is registered at clinicaltrials.gov under Registration #NCT 00065845**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Approved by the Institutional Review Boards at each participating institution**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**