

RE-ANALYSIS OF A RANDOMIZED TRIAL OF THREE METHODS OF ANTERIOR COLPORRHAPHY USING MORE CLINICALLY RELEVANT DEFINITIONS OF SUCCESS

Hypothesis / aims of study

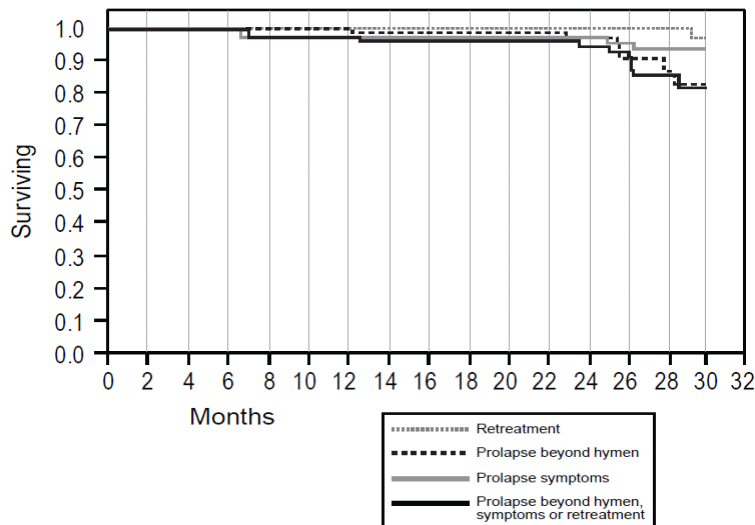
In 2001, Weber et al published a randomized trial comparing three techniques of anterior colporrhaphy and, using a definition of success of POPQ point Ba \leq -2, found success rates of 30%, 46% and 42%, respectively.[1] Studies since have suggested that the definition of success used in this trial may be too strict and that the hymen is a more clinically relevant threshold for anatomic success. Moreover, recent evidence suggests that 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.[2] As such the NICHD Pelvic Floor Disorders Network has recommended that any definition of success after pelvic organ prolapse surgery should include the absence of bulge symptoms in addition to anatomic criteria and the absence of re-treatment.[2] The specific aim of this research is to reanalyze the results of this previously published randomized trial comparing three different techniques for surgical correction of anterior vaginal prolapse using more clinically relevant definitions of anatomic and symptomatic prolapse recurrence.

Study design, materials and methods

This is a secondary analysis of the trial by Weber et al [1] that included 114 subjects undergoing surgery for anterior vaginal prolapse who were randomly assigned to one of three surgical techniques: standard anterior colporrhaphy (n=38), ultralateral colporrhaphy (n=38), and standard anterior colporrhaphy plus polyglactin 910 mesh (n=38) from June 1996-May 1999. 1996 CONSORT guidelines were followed. Pre- and postoperative data were abstracted from the original trial case report forms. Subjects underwent a POPQ evaluation and completed several questionnaires at baseline and 6, 12 and 24 months after surgery. Postoperative examinations were performed by a blinded examiner. At follow-up, subjects completed a prolapse symptom visual analog scale (VAS): “how much are you bothered by symptoms related to vaginal prolapse” (range: 0 “not at all” to 100 “extremely”) *A priori*, we defined clinically relevant prolapse symptoms as a VAS >20. For this analysis, treatment success was defined according to recent recommendations by the NICHD Pelvic Floor Disorders Network: 1) POPQ points Ba, Bp, and C \leq 0 cm; 2) the absence of prolapse symptoms (VAS \leq 20); and 3) the absence of re-treatment for prolapse with either surgery or pessary. This study was originally powered to detect a 30% difference between groups with 80% power and alpha=.05. Given that no significant differences were noted between groups in the original trial, we did not anticipate finding difference between groups for this analysis. As such, the primary analysis was performed on all subjects in aggregate in order to determine the overall proportion of subjects who developed anatomic recurrence beyond the hymen, symptomatic recurrence or required retreatment.

Results

Of 114 patients enrolled, 107 received surgery as allocated and 97 (85.1%) returned for follow-up. Mean age was 64.9 \pm 10.9 years. At entry, median POPQ scores were Ba = 2 (range: -1 to 8), C = -2 (-12 to 10), and Bp = -1 (-3 to +8). Preoperative prolapse symptoms were present in 93/107 (86.9%) women. In addition to the study procedure, 53% (58/110) received a hysterectomy, 45% (50/110) underwent a vaginal vault suspension (iliococcygeus (n=46); sacrospinous (3) and uterosacral (1)) and 91% (100/110) received a posterior colporrhaphy. At one-year follow-up, the median POPQ scores were Ba = -1 (-3 to +4), C = -6 (-10 to +4), Bp = -3 (-3 to +4) overall with no differences between groups. Ninety percent (69/77) of subjects had no prolapse beyond the hymen and 95% (80/84) were without prolapse symptoms at one year, leading to an overall one-year treatment success of 86%. No differences between the three treatment groups were noted for any of these outcomes. Only 1 subject (1%) underwent surgery during the study follow-up at 29 months after surgery. No patient underwent surgery for postoperative complications. Time to treatment failure is shown in the figure.



Interpretation of results

The definition of success substantially affects treatment success rates following POP surgery.[2] The original Weber et al trial has been cited frequently in the literature since its publication (182 citations, Scopus search 3/29/2010) and, given the relatively low success rates found in the trial, is often used as evidence that anterior colporrhaphy should either be augmented by synthetic mesh or another approach used altogether for treatment of anterior vaginal prolapse. The definition of success used originally in this trial is consistent with the 2001 NIH National Consensus Panel's recommendation that POPQ stage 0 or 1 represent "satisfactory" anatomic outcomes. However, the NIH panel's recommendation was arbitrary and made without the benefit of more recent data demonstrating that over 40% of women presenting for annual gynaecologic examination would not meet this criteria, that the hymen may be a more clinically relevant threshold for success, and that symptomatic recurrence is more relevant to patients than anatomic recurrence.[2, 3] This re-analysis of the Weber et al trial reveals that anterior colporrhaphy performed in conjunction traditional vaginal prolapse repairs results in anterior vaginal support that is not perfect (median Ba point -1) however clinically relevant recurrence one year after surgery is uncommon (14%) with 10% of subjects developing anatomic recurrence beyond the hymen, 5% of subjects developing symptomatic recurrence and no patients requiring surgery for recurrence or complication in the first year.

Concluding message

The success rate of anterior colporrhaphy varies considerably depending upon the definition of treatment success used. In the frequently-cited study by Weber et al (2001), when strict anatomic criteria are used the success rate is low. However when more contemporary, clinically relevant criteria for success are used, treatment success is considerably better with only 10% of subjects developing anatomic recurrence beyond the hymen and 5% of subjects developing symptomatic recurrence and no subjects requiring surgery for recurrence or complication at one year.

References

1. Weber, AM, Walters, MD, Piedmonte, MR, Ballard, LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol 2001; 185:1299-1305.
2. Barber MD, Brubaker L, Nygaard I, Wheeler TL 2nd, Schaffer J, Chen Z, Spino C; Pelvic Floor Disorders Network. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol. 2009 Sep;114(3):600-9.
3. Swift S, Woodman P, O'Boyle A, et al. Pelvic Organ Support Study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. Am J Obstet Gynecol 2005;192:795-806

<i>Specify source of funding or grant</i>	none
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Cleveland Clinic Institutional Review Board
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes