54

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RANDOMIZED CONTROLLED TRIAL COMPARING ANTERIOR COLPORRHAPHY TO ABDOMINAL PARAVAGINAL DEFECT REPAIR FOR ANTERIOR VAGINAL WALL PROLAPSE

Hypothesis / aims of study
Anterior colporrhaphy and paravaginal defect repair are two surgical procedures used to repair anterior vaginal wall prolapse. We hypothesized that there exists no difference in success rate between an anterior colporrhaphy and paravaginal defect repair. The aim of our study was to compare the post-operative objective and subjective outcomes between the two procedures up to two years after surgery.

Study design, materials and methods
We performed a prospective randomized controlled trial comparing anterior vaginal colporrhaphy to abdominal paravaginal defect repair in patients with symptomatic anterior vaginal wall prolapse. Inclusion criteria were women over the age of 18 with symptomatic cystoceles scheduled for reconstructive surgery. Patients were excluded if they were pregnant or planning to have a future pregnancy, two previous failed anterior vaginal wall repairs, or unwilling to give informed consent. The study received IRB approval and enrolment occurred after obtaining an informed consent. Randomization was performed using a computer generated random number table with type of surgery indicators placed in sealed opaque envelopes. Envelopes were opened at random by the research assistant on the pre-operative exam (consent day), typically a week before surgery. The POP-Q staging system was used as well as validated prolapse quality of life (PFDI and PFIQ) and sexual function (PISQ12) questionnaires pre and post-operatively. Women were followed up to two years. Baseline demographics, health characteristics, and surgical parameters were also measured. POP-Q measurements, questionnaires, and all data were collected by the research assistant who had no involvement with the actual surgery. Two surgeons performed all the surgical procedures. The surgical steps of each procedure were standardized: For the anterior colporrhaphy, plication of the cystocele in the midline was performed with 0-polydioxanone interrupted mattress sutures over a polyglactin 910 (vicryl) mesh within the imbricated fold of vaginal muscularis and adventitia; for the paravaginal defect repair, 0-polydioxanone sutures were used to attach the pubovesical fascia to that of the obturator and pubococcygeus muscle, also over a vicryl mesh. Additional prolapse and incontinence procedures were allowed and performed in a standardized fashion in both groups. The primary outcome was anterior vaginal wall POP-Q stage, with failure defined as stage II or more (most dependent part of the anterior vaginal wall protruding to 1 cm above the hymen or beyond). Sample size needed was 64 patients (32 in each group) using an alpha of 0.05, 80% power, and a difference in success rates of 25% between the two groups for clinical significance. Accounting for a 10% drop out rate, we planned to enrol a total of 70 patients. Chi-square or Fisher's exact tests were used for categorical data, Mann-Whitney U test for ranked data, and student *t* test for continuous data. To measure the change in stage of prolapse and quality of life questionnaires before and after surgery, repeated measure Wilcoxon signed rank test was used. Logistic regression analysis was used to predict failure rate controlling for potential baseline and demographic confounders including the most recent follow-up time from surgery. Kaplan-Meier survival and Cox regression analysis were used to estimate the proportion of failure rate by most recent follow-up time between the two surgeries.

Results
Seventy patients were enrolled with 35 in each group and a median follow-up of one year. In the anterior colporrhaphy group, 12 women completed 2 years follow-up, 19 are at different stages of follow-up (6-weeks to one-year), three women withdrew or were lost to follow-up, and one patient did not receive the intended procedure. In the paravaginal defect group, 13 women completed 2 years follow-up, 18 women are at different stages of follow-up, and four women withdrew or were lost to follow-up. Final analysis data were available for 34 patients in the anterior colporrhaphy group and 35 patients in the paravaginal defect repair group. The mean age (+/-SD), BMI (+/-SD), and median parity (interquartile range) were similar between the anterior colporrhaphy and the paravaginal defect repair groups: 54(+/-11) vs 53(+/-13), 28(+/-4) vs 29(+/-5), and 2(2,3) vs 2(2,3), respectively (P=0.16). All other health parameters including menopausal status, HRT use, smoking history, previous hysterectomy or bladder repair were also similar between the 2 groups. Moreover, all intra and post-operative parameters including number of concomitant procedures, blood loss, catheter use, and hospital stay were similar (P=0.11). Vault suspension in the form of sacrocolpopexy was performed in an equal number of 24(70%) patients in each group (P=0.86). Complication rates were also similar: 6 for anterior colporrhaphy and 13 for paravaginal defect repair (P=0.11). Most complications were minor such as post-op UTI. The only intra-operative statistically significant difference was the time for cystocele repair with a median of 35 minutes for anterior colporrhaphy vs 50 minutes for the paravaginal defect repair (P<0.001).
Pre-op anterior wall POP-Q stage was similar between the 2 groups with a median (interquartile range) of 3(2,4). The overall objective failure rate by most recent follow-up was 12/34 (35.3%) for anterior colporrhaphy and 10/35 (28.6%) for paravaginal defect repair (P=0.61) (table 1a). Of those objective failures, only 1/12 for anterior colporrhaphy and 3/10 for paravaginal defect repair reported subjective symptoms of bulge or pressure. There was also no statistically significant difference in failure rates by change in point Ba between the two surgery types by time of follow-up (table 1b). The logistic regression model predicting failure at most recent visit showed that only parity was a risk factor predicting failure, with each birth increasing the odds of failure by 2.9 folds (CI: 1.4-6.2; P=0.06).

Table 1a. Failure Counts and Rates by Surgery Type

Time	Colporrhaphy (n=34)	Paravaginal (n=35)	P-value
6 weeks (n, %, N)	2 (6.7%, 30)	1 (3.3%, 30)	1.0

3 months (n, %, N)	4 (15.4%, 26)	2 (7.1%, 28)	0.42
1 year (n, %, N)	5 (25.0%, 20)	5 (26.3%, 19)	1.0
2 years (n, %, N)	5 (45.5%, 11)	6 (42.9%, 14)	0.9
Most recent (n, %, N)	12 (35.3%, 34)	10 (28.6%, 35)	0.61
Table 1b. Change in Point Ba Before and After Surgery			
Pre-op mean (SD, N)	1.4 (1.5, 34)	1.8 (1.9, 34)	0.29
6 weeks mean (SD, N)	-3.9 (1.3, 30)	-4.4 (2.1, 30)	0.31
3 months mean (SD, N)	-3.6 (1.7, 26)	-4.1 (1.9, 28)	0.29
1 year mean (SD, N)	-3.2 (1.7, 20)	-3.4 (2.2, 19)	0.73
2 years mean (SD, N)	-2.7 (1.6, 11)	-3.8 (1.9, 14)	0.16

Finally, comparing QOL questionnaires including the PFDI, PFIQ, and the PISQ-12 (for those who were sexually active) before and after surgery showed a significant improvement *within* each surgical group (P<0.05); however, there was no significant difference in the change in score of any of the questionnaires *between* the two surgical groups (P=0.15).

Interpretation of results

Anterior colporrhaphy and abdominal paravaginal defect repair have similar success rates, with roughly one third objective failure rates in either group. Most failures are asymptomatic. Complication rates are also similar with the majority being minor. Parity increases risk of failure. Only a minority of patients had isolated anterior vaginal vault prolapse repair; most had a concomitant sacrocolpopexy. We did not have enough power to compare failure rates of isolated anterior colporrhaphy to paravaginal defect repair in the absence of other pelvic floor repair. Since most women with anterior vaginal wall defects also have concomitant defects in other compartments, it is difficult to conduct randomized controlled surgical trials for isolated cystoceles. Because of the surgical nature of the procedures, this study was not blinded. Finally, only one third of our cohort has completed the two year post-operative visit. We continue to follow and collect data on all patients to completion of their follow-up.

Concluding message

At a median follow-up of one year, there is no difference in objective and subjective success rates between anterior colporrhaphy and abdominal paravaginal defect repair in women with anterior vaginal wall prolapse.

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Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**