

LONG-TERM FOLLOW-UP OF ANTERIOR VAGINAL REPAIR: A COMPARISON AMONG COLPORRAPHY, COLPORRAPHY WITH REINFORCEMENT BY XENOGRAFT, AND MESH.Hypothesis / aims of study

The aim of our study was to assess the long-term efficacy, the subjective and objective outcomes, and the complications in patients treated for pelvic organ prolapse (POP) with transvaginal anterior colporrhaphy alone, with transvaginal anterior colporrhaphy and the reinforcement by porcine Xenograft (Pelvisoft® Biomesch), and with transvaginal anterior repair with the use of a polypropylene mesh.

Study design, materials and methods

A retrospective study was performed at a single centre. A total of 123 women underwent cystocele repair between 2000 and 2015. Follow-up was completed in 109 patients aged 46-80 years: 42 patients underwent a transvaginal anterior colporrhaphy alone (**TAC**), 19 patients underwent a transvaginal anterior colporrhaphy with an associated reinforcement by the use of Pelvisoft® Xenograft (**TAC-P**), and 48 patients underwent an anterior repair with a polypropylene mesh (**TAM**). Some patients had an associated surgical procedure. The characteristics of patients are listed in Table 1. Mean follow-up was 87.7 months (12-184). Subjectives outcomes have been evaluated by validated questionnaires: Patient Global Impression of Improvement (PGI-I) and Patient Perception of Bladder Condition (PPBC) – Italian. The personal patient satisfaction rate was also measured by the question “are you satisfied with the surgical procedure?” and asking if they would confirm the same surgical choice at the time of the counseling before surgery. Objective outcomes have been evaluated for each patient by two different surgeons, considering a failure an anterior vaginal wall recurrence ≥ 2 POP-Q and Baden-Walker Halfway System. Statistical analysis was performed using the chi-square or Fisher’s exact test and the two-sample *t* test. All calculated *p* values were considered statistically significant when <0.05 .

Variables	TAC (n=42)	TAC-P (n=19)	TAM (n=48)
Age, yrs (mean \pm sd)	65.4 (9.78)	67.1 (6.6)	64.5 (8.6)
Follow-up, months (mean \pm sd)	101.5 (44.9)	85.4 (29.5)	76.7 (61.2)
POP grade, n (%)			
II°	9 (21.4)	-	13 (27)
III°	30 (71.4)	14 (73.6)	31 (64.6)
IV°	3 (7.2)	5 (26.4)	4 (8.4)
Associated procedures, n			
Hysterectomy	14	6	-
Sacrospinous suspension	6	3	-
Posterior repair	7	2	4
TVT/TVT-O	18	9	9
Other procedures	3	2	3

Table 1: Patients characteristics.

Results

In all the surgical techniques used the results of PGI-I questionnaire showed a general perceived benefit of treatment as well as the results of PPBC questionnaire indicated an improvement from the previous bladder condition. The personal patient’s satisfaction rate was higher in the TAC-P group. In all groups most of the interviewed women would confirm the same surgical choice fixed at the time of the counseling before surgery. The best anatomical outcomes have been achieved with TAC-P, followed by TAM and finally by TAC with no statistically significant correlation. Data showed a higher rate of complications in the TAM group with statistically significant difference. All the results are listed in table 2, and the complications are reported in table 3.

Outcomes	TAC (n=42)	TAC-P (n=19)	TAM (n=48)	P value
PGI-I	1.42 (1-5)	1.21 (1-5)	1.56 (1-7)	0.0789
PPBC	1.38 (1-5)	1.15 (1-4)	1.45 (1-5)	0.1253
Personal patient satisfaction, n (%)	40 (95.2)	19 (100)	40 (83.3)	0.370
Pts. that would repeat surgery, n (%)	39 (92.8)	19 (100)	45 (93.7)	0.503
Objective success, n (%)	34 (80.9)	17 (89.4)	40 (83.3)	0.572
Patients Complicated, n (%)	2 (4.7)	3 (15.7)	14 (29.1)	0.0095

Table 2: Patients outcomes.

Complications	TAC	TAC-P	TAM
Pain	1	-	3*
Severe vaginal adhesions	1	-	-
Extrusion	-	1	8*§
Hematoma	-	1	1
Urinary retention	-	-	4§

Table 3: Number of complications. Two patient (*, §) developed both.

Interpretation of results

Our study is based on a long-term follow-up, longer than 5 years in all the groups. All group had similar characteristics except for the higher rate of associated surgery in TAC group, and for a lower number of patients in TAC-P group. The lower population in TAC-P group could explain the better subjective and objective results ($p > 0.05$). The higher associated procedures for apical support in TAC group could have improved the results in anterior vaginal wall repair. The larger number of complications in TAM group ($p < 0.05$) could explain the lower subjective satisfaction of patients.

Concluding message

Considering the recent FDA order to reclassify surgical mesh from class II to class III (1), and the recent SCENHIR document on "Safety of surgical meshes used in urogynecological surgery" (2) our data show that it is possible to revalue transvaginal anterior colporrhaphy technique alone or associated with a Xenograft. Actually our patients treated without the use of a polypropylene mesh have objective and subjective outcomes noninferior or superior respect to those treated by mesh. Moreover, also complication rate is lower in patients underwent surgery without mesh.

References

1. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm479732.htm>
2. http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihir_consultation_27_en.htm

Disclosures

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