371

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Anterior colporrhaphia compared with collagen coated transvaginal mesh for anterior wall prolapse. A three year follow-up study.

Hypothesis / aims of study
The study was designed as a randomized controlled study. In total six departments of Obstetrics and Gynecology in Norway; Sweden, Finland and Denmark participated in the study. Only women 55 years or older, admitted to surgery in the anterior vaginal compartment due to stage ≥2 vaginal prolapse was included. After verbal and written information and acceptance of the study by the patients were randomized between conventional anterior colporrhaphy and surgery with a collagen coated prolene mesh (Avaulta Plus® Biosynthetic system). All patients were evaluated using Pelvic Organ Prolapse Quantification (POP-Q) measurement. Degree of impact on daily life and bother caused by pelvic organ prolapse was evaluated using the short forms of the Pelvic Floor Impact Questionnaire, PFIQ-7, and Pelvic Floor Distress Inventory, PFDI-20. Sexual function was evaluated by Pelvic Organ Prolapse/Urinary incontinence Sexual Questionnaire (PISQ-12). Patients were seen at inclusion and post operative at three months, 1 year and 3 years for follow-up.

Study design, materials and methods
Of 164 women originally included (1) 124 women (63 from the conventional group and 61 from the mesh group, Table 1) resubmitted questionnaires and attended the physical examination at the 3-years follow-up so far. Residual urine volume (median and range) declined in the conventional and mesh groups from 42.5 ml (0–272) and 41.7ml (0–275), respectively at inclusion to 25 ml (18-33) and 17ml (10-24) at 3 years follow-up. Objective cure rate was 39.8% at one-year and 42.9% at 3-year follow-up, respectively in the conventional group compared to 88.1% and 90.1% in the mesh group ($p<0.001$). Vaginal mesh exposure was observed at one-year follow-up in 10 patients (13.3%) and in 9 (14,7%) at 3 years follow-up and all were minor (Table 2). Thus, in the period from inclusion until 12 months follow-up five patients had the mesh revised due to erosion, and in one patient the mesh was revised twice. In total two patients from the conventional group had recurrence of cystocele and underwent reoperation, whereas none in the mesh group had recurrence in the anterior compartment. The PFIQ-7, PFDI-20 and PISQ-12 questionnaires did not show any significant difference between the two groups at 3 years follow-up.

Results
Of 164 women originally included (1) 124 women (63 from the conventional group and 61 from the mesh group, Table 1) resubmitted questionnaires and attended the physical examination at the 3-years follow-up so far. Residual urine volume (median and range) declined in the conventional and mesh groups from 42.5 ml (0–272) and 41.7ml (0–275), respectively at inclusion to 25 ml (18-33) and 17ml (10-24) at 3 years follow-up. Objective cure rate was 39.8% at one-year and 42.9% at 3-year follow-up, respectively in the conventional group compared to 88.1% and 90.1% in the mesh group ($p<0.001$). Vaginal mesh exposure was observed at one-year follow-up in 10 patients (13.3%) and in 9 (14,7%) at 3 years follow-up and all were minor (Table 2). Thus, in the period from inclusion until 12 months follow-up five patients had the mesh revised due to erosion, and in one patient the mesh was revised twice. In total two patients from the conventional group had recurrence of cystocele and underwent reoperation, whereas none in the mesh group had recurrence in the anterior compartment. The PFIQ-7, PFDI-20 and PISQ-12 questionnaires did not show any significant difference between the two groups at 3 years follow-up.

Interpretation of results
Although the two groups differed regarding objective outcome at the 3-year follow-up, no difference was observed regarding subjective assessment according to the results obtained from the questionnaires. The impact of subjective outcome may override the experience or sense of prolapse according the POP-Q assessment since none in the two groups underwent any further surgery related to the prolapse. Regarding erosions, our study demonstrates that only minor erosions occurred and that patients only needed minor surgical corrections. No major adverse events were detected during the follow-up.

Concluding message
Our study emphasizes the discrepancy between objective and subjective outcomes. We think that the POP-Q system needs to be re-evaluated and adjusted especially taking the lack of surgery in both groups. Furthermore, our study indicates that mesh surgery may not be associated with severe complications.

Table 1. Prolapse stage at 3 years follow-up

	Anterior colporrhaphy N=63 (50.8%) N %	Mesh N=61 (49.2%) N %	P-value
0	10 (15.9)	39 (63.9)	0.001
1	17 (27.0)	16 (26.2)	0.001
2	28 (44.4)	3 (4.9)	0.001
3	8 (12.7)	3 (4.9)	0.001
4	0	0	
Aa (median and range)	-1.05 (-1.15-0.61)	-2.37 (-2.72-2.00)	0.001
Ba (median and range)	-0.805 (-.88-1.00)	-2.67 (-2.67 -1.954)	0.001
C (median and range)	-5.11 (-5.752-4.47)	-5.5 (-6.52-4.48)	0.009

Mann-Whitney U-test; Chi square test or Fischer´s exact test when appropriate.

Table 2. Complication rate at 3 years follow-up

	Anterior colporraphy N=63 (50.8%) N %	Mesh N=61 (49.2%) N %	P-value
UVI	4 (6.3)	4 (6.5)	NS
Vaginal discharge	17 (27.0)	16 (26.2	NS
SUI (De novo)	1 (2)	3 (4.9)	0.001
Ophørt SUI	8 (12.7)	3 (4.9)	NS
Reoperation	0	0	
Erosion	0	9 (14.7)	0.001
Dyspareuni (De novo)	N= 39	N=23	NS
PISQ12 question 5 (Scale from 0-4,where 4 is no pain, (Median and range)	3.5 (3.21-3.72)	3.4 (3.05-3.73)	

Mann-Whitney U-test; Chi square test or Fischer´s exact test when appropriate

References
1. Rudnicki M, Laurikainen E, Pogosean R, Kinne I, Jakobsson U, Teleman P. Anterior colporrhaphy compared with collagen-coated transvaginal mesh for anterior vaginal wall prolapse: a randomised controlled trial. BJOG 2014;121:102-10

Disclosures
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