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A RANDOMIZED CONTROLLED TRIAL OF ANTERIOR COLPORRAPHY AND PERIGEE™ AS A PRIMARY SURGICAL CORRECTION OF SYMPTOMATIC CYSTOCELE.

Hypothesis / aims of study
We randomly compared the short term morbidity and the anatomical and functional out outcome at 12 months follow-up of anterior colporraphy and Perigee™ as primary surgical correction of symptomatic cystocele.

Study design, materials and methods
The use of a non-absorbable synthetic polypropylene mesh that is applied by a transobturator approach appears to be more effective in patients with a recurrent cystocele. However no previous studies have been performed in patients with a primary cystocele. Therefore we conducted a multi-center, multi-national randomized controlled trial to compare anterior colporraphy and Perigee™ as a primary surgical correction of cystocele stage 2 or more. All patients were included between January 2006 and April 2009. Patients in whom the anterior vaginal wall was not the most descending part of the prolapse were excluded. In patients with a stage 2 or more uterine prolapse we performed concomitant a hysterectomy or a sacrospinous ligament fixation (SSF). In patients with a proven stress-urinary incontinence a mid-urethral sling was simultaneously performed. We compared morbidity and pain scores during/after surgery as well as anatomical and functional outcome at 12 months follow-up. Pain scores (VAS) and activities of daily life (ADL) were registered during the first 6 weeks after surgery. The total ADL score expresses the ability of the patient to perform daily activities i.e. dressing and undressing, picking an object from the floor, walking. After 6 weeks, 6 months and 1 year after surgery POP-Q staging was performed and the patients completed the questionnaires of the urogenital distress inventory (UDI) and defecation distress inventory (DDI). These questionnaires assess the presence and experienced bother of pelvic floor symptoms [1,2]. The aim of the statistical analysis was to test the differences between both interventions for statistical significance. The trial was powered to observe a difference of 20% (9 points) between both interventions in the prolapse domain score of the UDI at 1 year follow-up. The calculated sample size per group was 38 patients (power 90%, $\alpha = 0.05$). The primary outcome was disease specific quality of life (DSQOL) and as the domain scores expressing the DSQOL were measured at several follow-up moments we performed repeated measurement analysis to test the differences for statistical significance during the total follow-up period.

Results
In this RCT 96 patients were included of whom 48 patients underwent Perigee™ and 48 patients underwent anterior colporraphy. In the Perigee™ group 34 patients had only surgery of the anterior wall compared to 33 patients in the anterior colporraphy group. We performed 5 SSF and 5 hysterectomies in the anterior colporraphy group and 4 SSF and 8 hysterectomies in the Perigee™ group. One patient in the Perigee™ group received simultaneously a mid-urethral sling versus 6 patients in the anterior colporraphy group (Table 1). Intra- and post operative results of the total group show significant more blood loss in the Perigee™ group (median 100cc) compared to the anterior colporraphy (median 50cc) (p=0.01).Nevertheless, when we excluded the cases with concomitant interventions this difference was not observed (75 vs. 50 cc, P=0.13). In the anterior colporraphy groups there was one patient with a sever bleeding (blood loss >500cc) whereas 3 patients in the Perigee™ group has a complication during surgery (one with sever blood loss >500cc, one with a perforation of the tape through the lateral fornix and one with a laceration of the anterior wall). During admission, 1 urinary tract infection and 1 bladder retention (> 150cc post-residual bladder volume) occurred after anterior colporraphy and 2 bladder retentions occurred after Perigee™. Median VAS scores (0-100) in the Perigee™ group were significantly higher at 3 to 6 days after surgery (Table 1). ADL scores were comparable between groups. After 1 year a significant difference was found in the anatomical result (POP-Q) of the anterior wall between both interventions. Significant differences in the posterior and apical compartment were not observed (Table 2). There was also no significant difference in quality of life related to pelvic floor function (UDI domain scores and DDI domain scores) with and without concomitant interventions between both groups (Table 2). At 1 year after surgery we had performed 5 mid-urethral sling procedures in the anterior colporraphy group compared to 2 procedures in the Perigee™ group. Nine (19%) patients in the Perigee™ had mesh complaints/erosion of whom 4 patients (8%) had to go to theatre again.

Interpretation of results
Patients who received Perigee™ report more post-operative pain. This pain can be explained by the transobturator approach of the mesh. The anatomical results of the anterior compartment are superior with Perigee™ compared to anterior colporraphy, but it seems not to be clinical relevant. Explanation may be that pelvic floor function does not depend on pelvic floor anatomy. Several studies have shown that the prevalence of stage 2 or more POP exceeds 30%. Not all these women undergo surgery suggesting that anatomical abnormalities do not necessarily results in pelvic floor dysfunction.

Concluding message
The morbidity of anterior colporraphy and perigee is similar although patients treated with Perigee™ report more pain. Perigee™ results in a better anatomical outcome of the anterior compartment. However, functional outcome is similar following both surgical techniques. Our data show that the anterior colporraphy is still a viable option for primary anterior compartment repair, and patients should be counselled in that way.

Table 1 Peri- and post operative complications and pain scores

	AC	(n=48)	Perigee™	(n=48)	P-value
Concomitant surgery (n)	15	31.3	14	29.2	0.43 [2]

*Apical compartment repair**	*10*		*12*		
*Posterior compartment repair**	*3*		*4*		
*Mid-urethral sling**	*6*		*1*		
Pain scores after surgery					
VAS score evening after surgery	25	0-100	45	0-100	0.07[1]
VAS score 1 day after surgery	15	0-100	35	0-80	0.08[1]
VAS score 2 days after surgery	9	0-95	15	0-80	0.21[1]
VAS score 3 days after surgery	5	0-55	15	0-80	0.01[1]
VAS score 4 days after surgery	5	0-52	15	0-55	0.01[1]
VAS score 5 days after surgery	5	0-55	15	0-45	0.03[1]
VAS score 6 days after surgery	5	0-35	10	0-45	0.02[1]
VAS score 7 days after surgery	5	0-35	7	0-35	0.15[1]
VAS score 2 weeks after surgery	0	0-55	5	0-35	0.17[1]
VAS score 6 weeks after surgery	0	0-55	5	0-45	0.49[1]

Data are median (variance) or numbers (%). [1] Mann-Whitney test, [2] Pearsons Chi-square.
* Some patients had undergone more than one concomitant surgery.

Table 2 Anatomical and functional outcome

	AC (N=35)	**Perigee™ (N=39)**	**AC (N=29)**	**Perigee™ (N=31)**	**AC (N=32)**	**Perigee™ (N=30)**	**P-value**
	Baseline		***6 months***		***1 years***		
POP –Q							
Ba*	2 -1 / 6	1 -1 / 6	-2 2 / -3	-2 0 / -3	-2 4 / -3	-2 -1 / -3	0.01
Bp*	-2 -3 / -1	-2 -3 / 2	-2 0 / -3	-3 0 / 3	-2 1 / -3	-3 1 / -3	0.21
C*	-4 -8 / 4	-4 -9 / 4	-7 -4 / -11	-7 -4 / -10	-7 -2 / -10	-7 -4 / -10	0.51
UDI							
Discomfort/pain	27 (24)	27 (23)	12 (19)	8 (9)	13 (19)	8 (12)	0.60
Overactive bladder	34 (30)	41 (33)	16 (25)	15 (23)	21 (29)	18 (22)	0.96
Obstructive micturition	28 (32)	19 (20)	17 (29)	2 (6)	15 (23)	11 (19)	0.29
Prolapse	56 (30)	58 (35)	12 (22)	1 (4)	10 (20)	7 (15)	0.35
Incontinence	23 (24)	19 (20)	18 (29)	16 (23)	17 (22)	14 (17)	0.31

Data are mean (standard deviation). * These data are median (variance). P-value: repeated measurements.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
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**
Specify Name of Ethics Committee	**Medical Ethical Department of the Academic Medical Center Amsterdam**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**