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ONE YEAR RESULTS OF COLPORRAPHY ANTERIOR VERSUS A TROCAR GUIDED TRANSOBTURATOR SYNTHETIC MESH IN PRIMARY CYSTOCELE REPAIR: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study
To compare the one year anatomical and functional results between the anterior colporraphy and trocar-guided transobturator mesh in primary cystocele repair.

Study design, materials and methods
From June 2007 till May 2009 this randomized study was conducted in three large teaching hospitals in the Netherlands. Women, 40-80 years of age, with a cystocele ≥ 2 (according to POP-Q) needing surgical correction were eligible. Women with a history of urogynaecological surgery for pelvic organ prolapse or incontinence, cancer of COPD, concomitant urinary stress incontinence with an indication for surgical correction, recurrent lower urinary tract infections (> 3 culture proven infections/year), maximum bladder capacity < 300 ml, an indication for hysterectomy, and women with childbearing potential and inadequate birth control measures were excluded. Primary outcome was the number of women with an anatomical recurrence defined as a stage ≥ 2 cystocele at 12 months follow up. Secondary outcomes were the changes in urogenital symptoms (measured with the Urogenital Distress Inventory), disease specific quality of life (measured with Incontinence Impact Questionnaire) and the short and middle term complications. Women were randomly assigned to a classical colporraphy anterior or an anterior repair with a transobturator mesh kit (Avaulta® anterior, Bard, USA) by computerised randomisation. Stratification was performed for the presence of uterine descensus ≥ 2. No blinding of group assignment was performed. Assuming that in the standard anterior colporrhaphy group 35% of women will have a recurrent cystocele stage 2 or higher at the 1 year follow up and an estimated recurrence rate of 10% in the Avaulta anterior group, 50 women had to be assigned to each group (power 0,80, alpha 0.05). With an estimated drop-out of 25% in 5 year follow up, a total of 125 women had to be randomized.

Results
A total of 125 women were randomized, with 64 women allocated to anterior colporraphy and 61 to Avaulta® anterior mesh kit. After randomisation and before surgery 4 women withdrew from further participation. At present 104 women are available for 12 months follow up evaluation. Patients' characteristics and pre-operative prolapse staging (POP-Q) were similar between groups, with a majority of women having stage 3 cystoceles (>75%). Comparable surgical and peri-operative data for both treatment arms were found (data not shown). A statistical significant better anatomical outcome after 12 months is found in the mesh group (Table 1). Functional outcome (UDI and IIQ scores) improved significantly at 12 months, with no significant differences between groups (Table 2). Erosions occurred in 2 (4%) cases in the Avaulta® group, both treated with local excision. De novo dyspareunia was reported in 3/20 (15%) women in the Avaulta® group versus 2/21 (9%) in the colporraphy group (p>0.05).

Interpretation of results
Our high anatomical cure rate with mesh is comparable with literature. However, most studies report on a mixed population of women having primary and repeat surgery for cystoceles. The recurrences in the anterior colporraphy group mainly consisted of stage 2 cystoceles without complaints needing re-operation. Only 2 women in this group needed repeated surgery. Both operations proved to be safe in terms of major complications. Compared to literature our erosion rate is low. Our de novo dyspareunia rate is not significantly different between both groups.

Concluding message
This RCT shows a highly effective anatomical outcome after a transobturator mesh kit (Avaulta®) in primary cystocele repair as compared to a colporraphy anterior at 1 year follow up. With comparable functional outcome parameters, primary vaginal mesh use is still questionable. Our planned 5 year follow up will answer the question whether mesh use in primary prolapse surgery is to be recommended.

Table 1.

Anatomical outcome		**Pre-operative**			**12 months postoperative**			
Prolapse stage		Avaulta anterior	Colporraphy anterior	p-value	Avaulta anterior	Colporraphy anterior	RR (95%CI)	p-value
		n=59	n=62		n=53	n=51		
Anterior	<2	0 (0%)	0 (0%)	0.83	48 (91%)	18 (35%)	0.15 (0.06-0.34)	0.00
	2	15 (25%)	14 (23%)		5 (9%)	26 (51%)		
	3	44 (75%)	48 (77%)		0 (0%)	7 (14%)		
Uterine/vault	<2	30 (51%)	31 (50%)	1.00	52 (98%)	49 (96%)	0.57 (0.12-2,62)	0.61
	≥2	29 (49%)	31 (50%)		11 (2%)	2 (4%)		
Posterior	<2	43 (73%)	49 (79%)	0.52	40 (75%)	43 (84%)	1.56 (0.71-3.45)	0.33

≥2	16 (27%)	14 (21%)	13 (25%)	8 (16%)

Values are numbers (percentage). All p-values calculated with chi-square test.

Table 2.

Domain scores of the UDI and IIQ					
	Before surgery			**12 months after surgery**	
	Avaulta anterior	Colporraphia anterior		Avaulta anterior	Colporraphia anterior
UDI domains	n=57	n=59	p-value	n=53	n=50	p-value
Genital prolapse	67 (33-67)	67 (33-67)	0.82	0 (0-0)	0 (0-0)	0.79
Obstructive micturation	22 (11-44)	22 (0-44)	0.75	0 (0-11)	11 (0-22)	0.27
Urinary Incontinence	17 (0-33)	17 (0-33)	0.60	17 (0-33)	0 (0-17)	0.22
Obstructive micturation	17 (0-33)	17 (0-33)	0.68	0 (0-0)	0 (0-0)	0.46
Discomfort/pain	33 (0-50)	17 (0-50)	0.36	0 (0-17)	0 (0-17)	0.83
IIQ domains					
Emotional functioning	11 (0-33)	11 (0-22)	0.14	0 (0-11)	0 (0-11)	0.90
Physical functioning	17 (0-33)	8 (0-33)	0.64	0 (0-13)	0 (0-0)	0.44
Mobility	22 (11-33)	22 (8-33)	0.75	11 (0-22)	0 (0-14)	0.27
Social functioning	11 (0-22)	11 (0-22)	0.87	0 (0-0)	0 (0-11)	0.20
Embarrassment	0 (0-17)	0 (0-17)	0.18	0 (0-0)	0 (0-0)	0.28

Data presented as median (p25-p75). All p-values calculated with Mann Withney test.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Trial registry:www.trialregister.nl. Identifier: NTR1376**
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 Ethics Comittee UMC Utrecht, The Netherlands**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**