

## A RANDOMISED CONTROLLED TRIAL ON THE VALUE OF URODYNAMICS PRIOR TO STRESS INCONTINENCE SURGERY.

### Hypothesis / aims of study:

It is advised to perform urodynamics in women prior to stress urinary incontinence (SUI) surgery. However, there is limited evidence for the added value of urodynamics for either clinical decision-making or prediction of outcome of treatment in women with SUI. The aim of this study was to determine whether clinical outcome of surgery is non-inferior to outcome of individually tailored therapy in women with a discrepancy between urodynamic findings and signs and symptoms of (predominant) SUI.

### Study design, materials and methods:

We performed a multicentre, diagnostic cohort study with a non-inferiority randomised controlled trial embedded. The study was conducted between January 2009 and November 2010. This study was registered under number NCT00814749.

Women with (predominant) SUI who were thought to be suitable for surgical treatment on the basis of clinical assessment underwent urodynamics. Women in whom findings during urodynamics were discordant with signs and symptoms were randomized to either immediate surgery or to individually tailored therapy as based on urodynamics.

Patient data were entered into a password-protected web-based database and a web-based application with a variable block size was used for randomization. Participants and health professional were not blinded for the allocated arm.

The primary outcome of this study was clinical improvement as measured with the Urinary Distress Inventory (UDI) with a mean improvement of the subscale urinary incontinence score in both groups expected to be 35 points. A difference in mean improvement of 5 points or less was considered as non-inferior. The power calculation was performed prior to the study using the non-inferiority assumption. In each arm 51 women were needed to reach a power of 80% using one-sided testing and risk of type 1 error at 0.05. Informed consent was expected in 50% of eligible women and one out of three eligible women was expected to have discordant urodynamic findings. The calculation of the sample size of the cohort showed that 600 women were needed to assess 102 women in the randomized controlled part of the study.

### Results:

Of the 578 included women, 268 women (46%) had discordant findings during urodynamics, 126 patients gave informed consent for randomization and were allocated to immediate surgery (n=64) or to individually tailored therapy as based on urodynamic findings (n=62). The mean improvement of urinary continence after one year was 39 and 44 points after a strategy with and without urodynamics (difference -5 points, 95% CI -∞ to 3). During the one year follow-up period 531/578 women (92%) underwent a midurethral sling procedure. In 3 women (0,5%) surgical management was abandoned because of urodynamic findings, namely the presence of detrusor overactivity (2) and dysfunctional voiding (1).

Table 1 shows improvement and the subjective outcome one year after baseline.

### Interpretation of results:

Consequences of discordant urodynamic findings on treatment selection are very limited. In the women in whom the results of urodynamics were discordant from those of the initial history, the outcome in women undergoing immediate a mid-urethral sling operation was not inferior to the outcome in women undergoing individually tailored treatment based on urodynamic findings.

### Concluding message:

In women with complaints of SUI, immediate mid-urethral sling operation is not inferior to an individually tailored treatment based on urodynamic findings. Since urodynamics are costly, invasive and may induce urinary tract infections, urodynamics should no longer routinely be advised prior to primary surgery in women with predominant SUI.

**Table 1. Outcome after 12 months of follow-up**

		Randomized patients*			Non-randomized patients**		
		Immediate surgery	Individual treatment	[95%CI]	Urodynamics concordant	Discordant	
<b>Outcome UDI subscales</b>		(n=64)	(n=62)		(n=282)	(n=125)	
Mean improvement UDI-UI		44 (±24)	39 (±25)	[-∞; 5]	48 (±26)	41 (±27)	
<b>Subjective outcome</b>		<b>RR [95% CI]</b>					
Global Impression	Improvement	50 (91%)	52 (91%)	1.00 [0.89-1.12]	207 (93%)	92 (89%)	
	Equal	2 (4%)	2 (4%)		12 (5%)	8 (8%)	
	Impairment	3 (6%)	3 (5%)		3 (1%)	3 (3%)	
	Missing	9	5		60	22	
Subjective cure (UDI)	No presence of SUI	43 (74%)	42 (75%)	0.99 [0.80-1.23]	171 (74%)	71 (68%)	
	Missing	6	6		52	20	
	No presence of UI	41 (71%)	37 (68%)	1.05 [0.82-1.35]	161 (70%)	64 (61%)	
	Missing	6	7		52	20	

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\*ITT analysis \*\* per protocol analysis.

CI, confidence interval; RR, relative risk, UDI, urogenital distress inventory; SUI, stress urinary incontinence; UI, urinary incontinence

Disclosures

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