Value of Urodynamics Before Stress Urinary Incontinence Surgery

A Randomized Controlled Trial

*Sanne Adriana Lucia van Leijsen, MD, PhD, Kirsten B. Kluivers, MD, PhD, Ben Willem J. Mol, MD, PhD, Joanna in 't Hout, Alfredo L. Milani, MD, PhD, Jan-Paul W. R. Roovers, MD, PhD, Jan den Boon, C. Huub van der Vaart, MD, PhD, Paul H. Langen, MD, PhD, Francis E. Hartog, MD, Viviane Dietz, MD, PhD, E. Stella M. Tiersma, MD, PhD, Marina C. Hovius, MD, Marlies Y. Bongers, MD, PhD, Wilbert Spaans, MD, PhD, John P. F. A. Heesakkers, MD, PhD, and Mark E. Vierhout, MD, PhD, for the Dutch Urogynecology Consortium**

OBJECTIVE: To estimate whether a strategy of immediate surgery was noninferior to a strategy based on discordant urodynamic findings followed by individually tailored therapy in women with stress urinary incontinence (SUI).

METHODS: A multicenter diagnostic cohort study with an embedded noninferiority randomized controlled trial was conducted in six academic and 24 nonacademic Dutch hospitals. Women with predominant SUI eligible for surgical treatment based on clinical assessment were included between January 2009 and November 2010. All patients underwent urodynamics. In patients in whom urodynamics were discordant with clinical assessment, participants were randomly allocated to receive either immediate surgery or individually tailored therapy based on urodynamics. The primary outcome was clinical improvement assessed by the Urogenital Distress Inventory 12 months after baseline. Analysis was by intention to treat; a difference in mean improvement of 5 points or less was considered noninferior.

RESULTS: Five hundred seventy-eight women with SUI were studied, of whom 268 (46%) had discordant findings. One hundred twenty-six patients gave informed consent for randomization and were allocated to receive immediate surgery (n=64) or individually tailored therapy (n=62). The mean improvement measured with the Urogenital Distress Inventory after 1 year was 44 points (±24) in the group receiving immediate surgery and 39 (±25) points in the group receiving individually tailored treatment. The difference in mean improvement was 5 points in favor of the group receiving immediate surgery (95% confidence interval $-\infty$ to 5). There were no differences with respect to cure or complication rate.

CONCLUSION: In women with uncomplicated SUI, an immediate midurethral sling operation is not inferior to individually tailored treatment based on urodynamic findings.

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Stress urinary incontinence (SUI), defined as involuntary loss of urine on effort, physical exertion, coughing, or sneezing, is a common problem among adult women with an estimated prevalence between

**For a list of members of the Dutch Urogynecology Consortium, see the Appendix online at http://links.lww.com/AOG/A369.*

From the Radboud University Nijmegen Medical Centre, Nijmegen; Academic Medical Centre, Amsterdam; Reinier de Graaf Groep, Delft; Isala Klinieken Zwolle, Zwolle; University Medical Centre Utrecht, Utrecht; VieCuri Hospital Venlo, Venlo; Rijnstate Hospital Arnhem, Arnhem; Catharina Hospital, Eindhoven; VU Medical Centre, Amsterdam; Onze Lieve Vrouwe Gasthuis, Amsterdam; Maxima Medical Centre, Veldhoven; and Gelre Hospital, Apeldoorn, The Netherlands.

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Corresponding author: Sanne Adriana Lucia van Leijsen, MD, PhD, Radboud University Nijmegen Medical Centre, 791 Department of Obstetrics & Gynecology, Post Box 9101, 6500 HB Nijmegen, The Netherlands; e-mail: s.vanleijsen@obgyn.umcn.nl.

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25% and 57%.[1,2] International guidelines of professional organizations and authorities are not uniform with the indication for urodynamics before surgical treatment for SUI.[3–6]

Urodynamics try to enhance the understanding of lower urinary tract function and reveal the underlying pathophysiology responsible for the patient's complaints. The information gained from urodynamics may confirm or alter the clinical diagnosis, ie, based on medical history and physical examination, and may influence the choice of the intervention. However, many women perceive urodynamics as painful or embarrassing[7] and urodynamics are associated with a risk of causing urinary tract infections between 6% and 22%.[8–11] Moreover, urodynamics are time-consuming and costly.

In the United States in 2010, approximately 260,000 women underwent surgical treatment of SUI.[12] At expected costs of approximately 335 Euro per test,[13] urodynamics account for substantial health insurance charges. In view of this massive use of urodynamics, the evidence that urodynamics add either to clinical decision-making or to prediction of the outcome of treatment is limited.[14,15] This results in decreased adherence to guidelines and strong practice variation.[16,17]

We previously published an underpowered randomized controlled trial (RCT) comparing a strategy with urodynamics and a strategy of immediate surgery in women with SUI that indicated no benefit of urodynamics in the preoperative workup of women with SUI.[18] In two previous observational studies, findings on urodynamic investigation did not predict stress continence outcome of surgery.[19,20] Based on this evidence gap, the authors of a Cochrane Review on the value of urodynamics recommended that RCTs on the subject are eagerly needed.[21] Recently, the results of the VALUE trial have been published, which showed that preoperative office evaluation alone was not inferior to evaluation with urodynamic testing.[22] That RCT allocated women with SUI to a workup with or without urodynamics. We conducted a multicentre RCT titled "the Value of Urodynamics before Stress Incontinence Surgery (VUSIS 2) study," in which all women with SUI underwent urodynamics and only those women with a discordant result from urodynamics and the medical history were randomized. By choosing such a design, we kept the group of women with concordant findings out of the randomized comparison, thereby focusing on women who might benefit from urodynamics. When comparing two diagnostic treatment strategies with unknown benefits but known disadvantages, a noninferiority trial is more appropriate than the typical superiority design.[23] We investigated whether a strategy of immediate surgery was noninferior to a strategy based on urodynamic findings followed by individually tailored therapy.

PATIENTS AND METHODS

A multicenter, diagnostic cohort study with an embedded noninferiority RCT was conducted in six academic and 24 nonacademic hospitals in The Netherlands that were cooperating in the Dutch Urogynecology Consortium (www.studies-obsgyn.nl). Ethical approval for this study was obtained from the institutional review board of the Radboud University Nijmegen Medical Centre (2006/197), and boards of participating centers approved the study. Written informed consent was obtained from all patients before enrollment. This study was registered under number NCT00814749. The study protocol has been published previously.[24]

Between January 2009 and November 2010, we recruited women with uncomplicated SUI considered as symptoms of pure SUI or mixed urinary incontinence (UI) with predominant stress incontinence symptoms, who had previously failed conservative therapy and were candidates for surgical therapy. Stress incontinence was defined as self-reported complaints of involuntary loss of urine on effort, physical exertion, on coughing or sneezing. Women were considered to have predominant stress incontinence in cases in which they reported the complaint of SUI and also involuntary loss of urine associated with urgency symptoms but experience the most bother of the stress component. Stress urinary incontinence must have been demonstrated on physical examination or indicated on bladder diary, or both. A cough stress test was performed in the lithotonic position with a subjective full bladder. The residual was measured by catheterization, ultrasonography, or bladder scan.

Patients were excluded if they had prior incontinence surgery, pelvic organ prolapse with the leading edge of prolapse at least 1 cm beyond the level of the hymen, or if a postvoid residual bladder volume of 150 mL or more was present on ultrasonography or catheterization.

At study entry, baseline characteristics, symptoms and clinical examination, 48-hour bladder diary, Dutch validated quality-of-life questionnaires (Urogenital Distress Inventory), and measurement of a postvoid residual were recorded. On a bladder diary patient report, besides a frequency–volume chart, fluid intake, pad use, the degree of incontinence, the activities being performed during or immediately preceding the involuntary loss of urine, and episodes of urgency and sensation might also be recorded.

The Urogenital Distress Inventory consists of 11 items and five subscales on subjective bother related

to micturition and prolapse symptoms.[25] The subscale scores were transformed in a continuous scale ranging from 0 to 100 points.[26] A high score on the Urogenital Distress Inventory subscales indicates more bothersome symptoms on that particular subscale.

All eligible women underwent urodynamics performed according to International Continence Society standards.[27] Urodynamic findings were considered discordant if SUI was not confirmed or if detrusor overactivity, weak flow, postvoid residual, small cystometric maximum capacity, or a reduced bladder sensation was present. Free flow was assessed by using the Liverpool diagram; a velocity below p10 was considered as weak flow. Because no cutoff levels for normal and abnormal values of small cystometric maximum capacity and a reduced bladder sensation have been defined, classification was left to the discretion of the observer.

In a central audit of urodynamic quality, all urodynamic traces were assessed for quality using a standardized checklist based on the guideline on Good Urodynamic Practice,[27] and a reassessment of interpretation of all urodynamic traces was performed. The results of this audit will be published separately.

Women with discordant findings between the history and clinical examination and urodynamics were requested to participate in the RCT and were randomly assigned to either immediate surgery or to individually tailored treatment. Possible treatment options other than a midurethral sling in the individually tailored treatment arm were anticholinergics for detrusor overactivity, prolonged pelvic floor exercises or bladder training in case of dysfunctional voiding, a pessary, expectant management, intravesical botulinum toxin injections, or pretibial nerve stimulation. The choice for the kind of treatment in the individually tailored treatment group was left to the discretion of the physician.

A web-based application was used for block randomization with a variable block size between two and eight. This block randomization was performed by a computer-generated random number list prepared by a database designer. The block sizes were blinded for researchers and health professionals. Randomization was stratified per center with a 1:1 allocation. Participants and health professionals were not blinded to the allocated arm and the urodynamic results. Patients who had discordant findings and agreed to outcome registration but did not give informed consent for randomization, and patients with concordant urodynamic findings, were enrolled in the observational cohort (Fig. 1). Patient data were entered into a password-protected web-based database. During follow-up, questionnaires were sent to the patients and collected centrally. Data input of subjective outcome measurements was performed by researchers who were blinded to the treatment allocation.

The primary outcome of this study was effect in terms of improvement as measured with the Dutch validated version of the Urogenital Distress Inventory at 1 year after baseline.

In the randomized patients, effects of treatment were evaluated at 6, 12, and 24 months. Follow-up was composed of a doctor's visit, completion of questionnaires (Urogenital Distress Inventory, Patient Global Impression of Improvement Scale), and a bladder diary. The Patient Global Impression of Improvement scale is rated on a 7-point Likert scale with a range of responses from 1 (very much improved) to 7 (very much worse).[28] A response better than "equal" was counted as "improved" and worse than "equal" was counted as "impaired."

The women in the observational cohort completed the questionnaires 12 months after the first intervention. Subjective cure of SUI was defined as a negative answer on the Urogenital Distress Inventory question concerning urine leakage related to physical activities. Any amount of leakage was considered as a failure. Objective cure was defined as a negative stress test on physical examination. De novo postoperative voiding dysfunction was defined as an improvement score below zero on the Urogenital Distress Inventory subscale obstructive symptoms.

We hypothesized that a strategy not based on urodynamic findings would be noninferior to a strategy based on urodynamic findings. The mean improvement of the Urogenital Distress Inventory UI subscale score was expected to be 35 points ($\pm$10).[29] A difference in mean improvement of 5 points or less was considered as noninferior. We selected the 5-point noninferiority margin on the basis of clinical judgment that this was a reasonable cutoff between a potential decrease in the success rate and the potential benefits of the omission of preoperative urodynamics.

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 of three eligible women was expected to have discordant urodynamic findings.[24] 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.

The primary analysis of the RCT group was according to intention to treat and was reported according to the number of valid observations. In

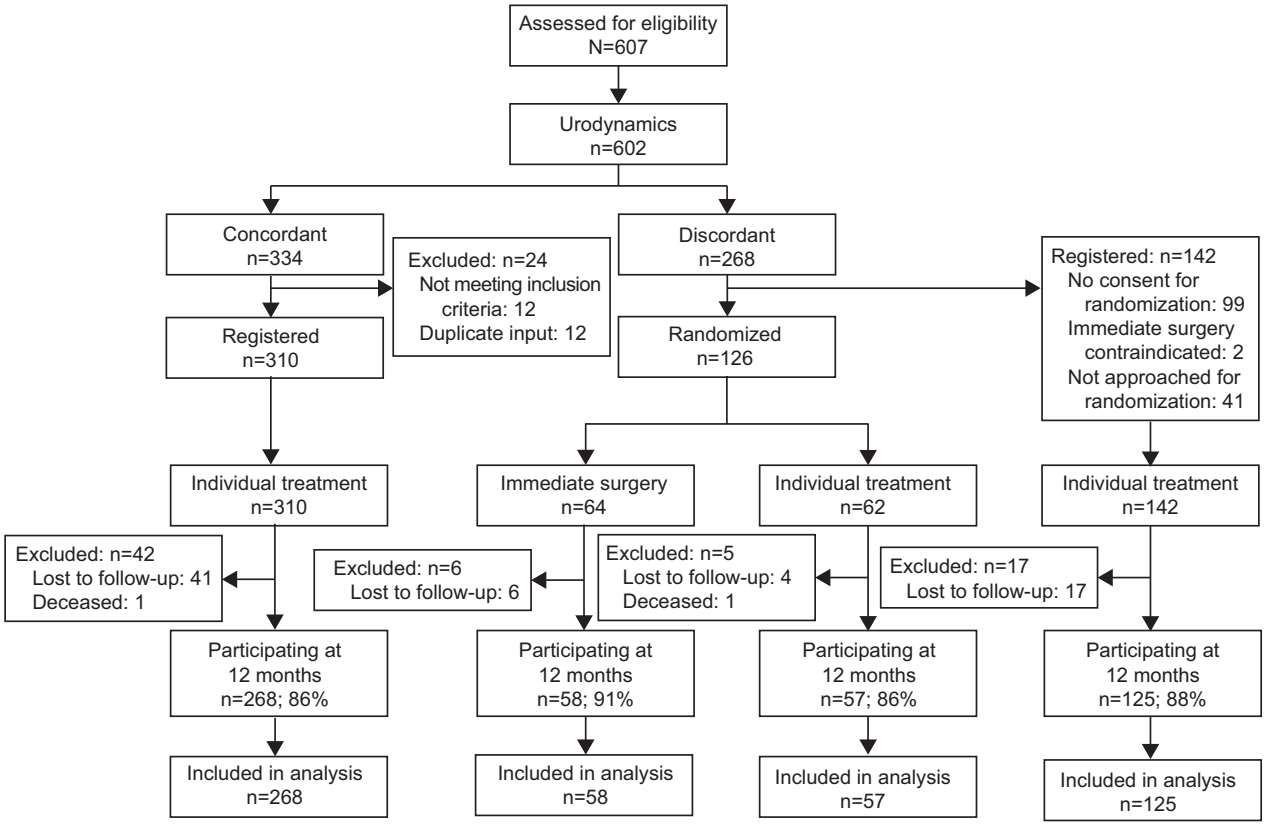

Fig. 1. Trial profile.

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a secondary per-protocol analysis, we analyzed those women in whom the protocol had been strictly followed. Data analysis in the observational cohort study was based on the treatment received.

Analysis of covariance with group, center, and the baseline covariates as independent variables was used to estimate differences in cure and improvement of the Urogenital Distress Inventory after 1 year with 95% confidence interval (CI). For dichotomous outcomes, the relative risks with 95% CI were assessed. Calculation of the percentages was based on the number of valid observations.

A secondary objective of this study was to estimate whether postoperative outcome could be predicted by urodynamic parameters. Associations between urodynamic parameters and improvement of complaints and the persistence of UI were analyzed using logistic regression analysis and are presented as odds ratios with 95% CI. All patients (randomized and nonrandomized) were included in this analysis.

Data were analyzed by using Statistical Package for the Social Sciences 18.0. For all statistical tests, differences were considered significant at $P<.05$.

The CONsolidated Standards Of Reporting Trials (CONSORT) statement on the reporting of noninferiority trials was followed.[23]

RESULTS

Between January 2009 and November 2010, 607 women with predominant SUI were approached to participate in the trial, of whom 578 were eligible and gave their informed consent for outcome registration. The study profile is depicted in Figure 1.

The baseline characteristics are shown in Table 1. Baseline characteristics were not significantly different between the two arms. The baseline characteristics of the women with discordant urodynamic findings who were randomized were not significantly different from those women with discordant urodynamics in the nonrandomized arm. Sixty-four percent (368 of 578 women) had urinary loss during physical activity, coughing, or sneezing and leakage when experiencing a feeling of urgency and were considered to have mixed UI.

Of the 578 included women, 268 women (46%) had urodynamic findings that were discordant with

Table 1. Baseline Characteristics

	Randomized Patients		Nonrandomized Patients	
	Surgery (n=64)	Individually Tailored Treatment (n=62)	Urodynamics Concordant (n=310)	Urodynamics Discordant (n=142)
Medical history				
Age (y)	55±12	54±14	52±11	51±11
BMI (kg/m^2)	27±5	27±5	27±5	27±5
Parity (no. of children)	2±1	2±1	2±1	2±1
Nulliparous	2 (3)	2 (3)	13 (4)	8 (6)
Previous prolapse surgery	22 (34)	17 (27)		
Questionnaire				
Presence of SUI	21 (33)	23 (37)	110 (35)	56 (39)
Presence of mixed UI	43 (67)	39 (63)	200 (65)	86 (61)
Urogenital Distress Inventory UI	55±24	51±21	56±23	55±22
Urogenital Distress Inventory overactive bladder	28±26	31±25	23±22	21±24
Urogenital Distress Inventory obstructive symptoms	20±25	17±26	15±20	13±20
Bladder diary				
Daily micturition frequency	8±2	8±3	8±2	8±2
Nightly micturition frequency	1±1	1±1	1±1	1±1
Presence of nocturia*	38 (59)	36 (58)	142 (46)	65 (46)
Incontinence episodes/d	4±4	4±3	4±4	4±4
No. of pads/d	3±2	3±2	3±2	2±2

BMI, body mass index; SUI, stress urinary incontinence; UI, urinary incontinence.
Data are mean±standard deviation or n (%).
* Interruption of sleep one or more times because of the need to micturate.

clinical history and physical examination (Table 2). Consent for randomization was obtained from 126 of these 268 women, of which 64 were allocated to undergo immediate midurethral sling surgery and 62 to individually tailored treatment based on signs and symptoms in combination with urodynamic results. Forty-one (7%) women had a discordant urodynamic investigation based on the absence of urodynamic SUI but were not approached for randomization as a result of logistic reasons and they received a midurethral sling.

Primary outcome data were complete in 115 randomized patients (91%). Follow-up information on the subjective clinical outcome was available for

Table 2. Urodynamic Findings

	Randomized Patients		Nonrandomized Patients	
	Surgery (n=64)	Individually Tailored Treatment (n=62)	Urodynamics Concordant (n=310)	Urodynamics Discordant (n=142)
Urodynamic investigation				
Maximum free flow (mL/s)	21±12	18±11	27±13	24±12
Residual (mL)	15±35	36±91	19±42	23±41
Cystometric maximum capacity (mL)	376±148	411±138	417±126	442±140
Maximum urethral closure pressure (mmHg)	68±40	65±26	64±40	75±34
Discordant findings				
Absence of stress incontinence	50 (78)	45 (73)	NA	124 (87)
Detrusor overactivity	12 (19)	6 (10)	NA	16 (11)
Residual volume	1 (2)	4 (7)	NA	1 (1)
Small cystometric maximum capacity	1 (2)	2 (3)	NA	2 (1)
Poor flow	4 (6)	2 (3)	NA	4 (3)
Low compliance	1 (2)	1 (2)	NA	0
Dysfunctional voiding	5 (8)	5 (8)	NA	3 (2)

NA, not applicable.
Data are mean±standard deviation) or n (%).

508 patients (88%). Mean follow-up duration was 13 months (±4).

The quality control performed on all urodynamic traces showed that the technical quality of most traces was sufficient to assess the presence of SUI, detrusor overactivity, and voiding pattern. Overall agreement between local and central researchers for the various discordant findings was above 91%.

Table 3 shows the received treatments during the follow-up period. In the group randomized to immediate surgical treatment, one protocol violation occurred: an operation was postponed and the patient received drug treatment based on detrusor overactivity in the absence of urodynamic SUI . During the 1-year follow-up period, 530 of all 578 included women (92%) underwent a midurethral sling procedure (Table 3). In three women (0.5%), surgical management was abandoned because of the presence of detrusor overactivity (n=2) or dysfunctional voiding (n=1). In 45 patients, an operation was cancelled at the patient's initiative (n=41) or as a result of comorbidity (n=4).

Table 4 shows outcomes 1 year after baseline. In the women participating in the RCT, the mean improvement on the Urogenital Distress Inventory UI subscale was 39 points (±25) in the group who received individually tailored treatment compared with 44 points (±24) in the group receiving immediate surgery. The difference in mean improvement was 5 points in favor of the group receiving immediate surgery (95% CI $-\infty$ to 5). This confirms noninferiority for either one of both strategies.

Subjective cure as measured with the Urogenital Distress Inventory and objective cure as measured with the stress test and bladder diary were not different between the two arms of the randomized trial.

The difference in mean improvement and the upper limit of the 95% CI were identical for data analysis according to intention to treat and the per-protocol analysis, both based on all valid observations.

In the surgery group, subjective cure was 43 of 58 (74%) and in the individual treated group 42 of 56 (75%) (relative risk 0.99, 95% CI 0.80–1.23). Objectively cured were 37 of 38 women (97%) in the surgery group and 33 of 34 women (97%) in the individual treated group (relative risk 1.00, 95% CI 0.93–1.09).

In women with mixed UI who underwent a midurethral sling operation (n=341, follow-up available n=292), the urgency component was subjectively cured in 203 of 292 (70%) and the SUI component in 227 of 292 women (78%) after surgery. Improvement was indicated by 265 of 292 women (91%).

Detrusor overactivity was the only urodynamic parameter that was independently associated with the risk for postoperative persistence of incontinence. Detrusor overactivity was present on urodynamics

Table 3. Treatment Received

	Randomized Patients		Nonrandomized Patients	
	Surgery (n=64)	Individually Tailored Treatment (n=62)	Urodynamics Concordant (n=310)	Urodynamics Discordant (n=142)
Initial treatment				
Surgery	61 (95)	57 (92)	280 (90)	122 (86)
Conservative treatment based on urodynamic findings	1 (2)*	4 (6)†	NA	6 (4)‡
Other	2 (3)§	1(2)‖	29 (9)¶	14 (10)**
Treatment after 1 y				
Surgery	62 (97)	61 (98)	282 (91)	125 (88)
Retropubic tape	18 (28)	15 (24)		
Transobturator tape	44 (72)	46 (74)		
Conservative treatment based on urodynamic findings	0	0	NA	3 (2)
Other	2 (3)§	1 (2)‖	28 (8)††	14 (10)**

NA, not applicable.
Data are n (%).
* Detrusor overactivity.
† Detrusor overactivity (n=2), dysfunctional voiding (n=1), mild symptoms in combination with the absence of urodynamic stress urinary incontinence (n=1).
‡ Detrusor overactivity (n=4), dysfunctional voiding (n=2).
§ Patient request.
‖ Postvoid residual, not confirmed during urodynamics.
¶ Comorbidity (n=3), patient request (n=26).
** Patient's request (n=13), comorbidity (n=1).
†† Comorbidity (n=3), patient request (n=25).

Table 4. Outcome After 1 Year of Follow-Up

	Randomized Patients*			Nonrandomized Patients*	
	Immediate Surgery (n=64)	Individually Tailored Treatment (n=62)		Urodynamics Concordant (n=282)	Urodynamics Discordant (n=125)
Questionnaire					
Mean improvement Urogenital Distress Inventory score–UI	44±24	39±25	95% CI (−∞ to 5)	48±26	41±27
Urogenital Distress Inventory score UI	10±18	10±18	*P*=.99	11±19	13±21
Urogenital Distress Inventory score overactive bladder	11±17	9±13	*P*=.57	9±14	10±17
Urogenital Distress Inventory score obstructive symptoms	11±22	14±22	*P*=.45	9±15	10±16
			RR (95% CI)		
Global impression of improvement scale					
Improvement	50/55 (91)	52/57 (91)	1.00 (0.89–1.12)	207/222 (93)	92/103 (89)
Equal	2/55 (4)	2/57 (4)		12/222 (5)	8/103 (8)
Impairment	3/55 (6)	3/57 (5)		3/222 (1)	3/103 (3)
No presence of SUI	43/58 (74)	42/56 (75)	0.99 (0.80–1.23)	171/230 (74)	71/105 (68)
No presence of UI	41/58 (71)	37/55 (68)	1.05 (0.82–1.35)	161/230 (70)	64/105 (61)
Bladder diary (48 h)					
No leakage	45/53 (85)	41/50 (82)	1.04 (0.87–1.23)		
Stress test					
Negative	37/38 (97)	33/34 (97)	1.00 (0.93–1.09)		

UI, urinary incontinence; CI, confidence interval; RR, relative risk; SUI, stress urinary incontinence.
Data are mean±standard deviation or n/N (%) unless otherwise specified.
* Results are reported according to the number of valid observations.

in 34 of 578 women (6%). In women with detrusor overactivity, 27 of 34 women (79%) had symptoms of mixed UI. Of all women with detrusor overactivity who were treated surgically, 23 of 28 women (82%) indicated that the UI had improved compared with 367 of 396 (93%) of women without detrusor overactivity (odds ratio [OR] 0.36, 95% CI 0.13–1.03). Bothersome postoperative SUI was present in nine of 28 (32%) women with detrusor overactivity compared with 69 of 409 (17%) women without detrusor overactivity (OR 2.3, 95% CI 1.01–5.4).

In five women, within the first days postoperatively, a reintervention was performed to surgically release the sling. Clean intermittent catheterization for a period longer than 6 weeks after surgery was indicated in eight of 453 women (2%); in two patients, a reoperation was indicated because of large postvoid residuals. Of the women who underwent a reoperation, three of seven had received retropubic tape and four of seven patients had received transobturator tape.

Reoperation occurred in one of 64 women in the immediate surgery group (release of the sling), in zero of 62 women of the individually tailored group, and in 13 of 452 women in the observational cohort. Indications for reoperation were tape exposure (n=3), a large postvoid residual (n=7), or persistence or recurrence of SUI (n=4).

DISCUSSION

This study evaluated the value of urodynamics in the preoperative workup in women with complaints of SUI. We found that in women with SUI and urodynamics discordant with clinical assessment, outcome of an immediate midurethral sling operation was not inferior to outcome of individually tailored treatment based on urodynamic findings.

All patients in whom surgery was considered after history-taking were included. This allowed us to determine the effect of urodynamic findings on deviation of the intended surgery and to determine whether alternative treatment enhanced positive outcomes or avoided complications. Alternative treatments, eg, drugs, a pessary, and prolongation of pelvic floor muscle training, are aimed at controlling a certain discordant condition. Alternative treatment may therefore reduce the occurrence of postoperative adverse events like overactive bladder complaints or voiding dysfunction. However, alternative treatment also has an obvious risk of delaying an effective treatment for SUI. In our study, the effect on

treatment selection of discordant urodynamic findings was very limited. Detrusor overactivity (n=7) and dysfunctional voiding (n=2) were the findings that led us to initially abandon surgical treatment; however, after 1 year, only three women (0.5%) did not undergo surgery based on discordant urodynamic findings.

Our results are in line with the findings of the VALUE trial, which showed that preoperative office evaluation alone was not inferior to evaluation with urodynamic testing.[22] That RCT randomly allocated women with SUI to a workup with or without urodynamics; we have randomized only the women with a discordant result from urodynamics and the medical history, because these women might benefit from urodynamics. By selecting such a design, we kept the group of women with concordant findings out of the randomized comparison, thus reducing random error.[30] This study showed, complementary to the results of the VALUE trial, that even in women in whom the urodynamics had showed discordant findings, an individualized treatment did not improve the outcome as compared with immediate surgery despite the urodynamic finding(s).[22]

In patients in whom urodynamics do not contribute to treatment selection, they can be used for counseling about the perspectives on postoperative outcome. One study showed higher, albeit not significant, overall success after surgery in women with urodynamic demonstrable stress incontinence compared with no urodynamic stress incontinence.[17] In one underpowered RCT and in one retrospective study, cure rates were comparable in patients with and without urodynamic SUI.[16,29] In this study, we also have not found any effect of urodynamic findings with regard to SUI on clinical outcomes.

The need for preoperative urodynamics is often justified by the consideration that pre-existing detrusor overactivity may be either a contraindication for surgery or at least carries the risk for a worse prognosis.[31–33] It is known that the subjective cure rate is lower in cases of preoperative detrusor overactivity.[32,34] In the present study, detrusor overactivity was the only urodynamic parameter that was associated with a compromised cure of symptoms of SUI. In another study, detrusor overactivity has also been identified as the only independent risk factor for lower cure rates of SUI after surgery (OR 2.9, 95% CI 1.3–6.7).[20] Because complaints of UI in women with detrusor overactivity improved in 81% of the women, it seems justified that the detection of detrusor overactivity preoperatively does not naturally lead to deviation of the intended surgery. Moreover, it is questionable also whether counseling on the postoperative perspectives in patients with detrusor overactivity does counterbalance the disadvantages of urodynamics. The difference in improvement between women with and without detrusor overactivity was approximately 11%. Detrusor overactivity was found in 6% of women, which implies that in 152 women, urodynamics need to be performed to predict no improvement of complaints in one extra woman correctly.

Strengths of this study were the adequate randomization and allocation concealment and the prospective evaluation of a large number of women with predominant SUI who underwent quality-controlled urodynamics in a nationwide study at academic and nonacademic centers. This makes our results applicable to patients in secondary or tertiary care centers. The recommendation to perform urodynamics before invasive treatment for SUI is advocated by several national and international professional organizations and authorities. Therefore, the management of women with SUI opting for surgical treatment will be similar throughout countries, and our findings seem therefore applicable to international practice.

This study has also some limitations. The attending specialist was not blinded to the allocated arm and to the urodynamic results. As a result of this, treatment selection could be influenced by urodynamic findings, which led to one protocol violation and bias in objective outcome measurement could not be excluded. Also urodynamic results like a low maximum urethral closure pressure could influence the type of sling selection in the surgery group; however, only one woman in the surgery arm had a maximum urethral closure pressure below 20 cm H_2O. Furthermore, for the primary (subjective) outcomes, the data collectors were blinded to the allocated arm, which avoided detection bias.

Treatment was not standardized for those women who were allocated to individually tailored treatment based on urodynamics findings. In this study, choices as made in clinical daily practice were followed and most women underwent an operation within 1 year regardless of discordant urodynamic finding(s). Thus, this study does not answer further questions regarding the long-lasting effects of alternative treatment in this group.

Surgery for SUI can lead to postoperative voiding dysfunction including urinary retention; this occurs in 7–36% depending on the definition used.[35–39] A high preoperative postvoid residual and a low maximum flow velocity have been correlated to voiding dysfunction postoperatively in some studies,[38,40,41] although other studies contradict that voiding dysfunction could be predicted by urodynamics.[39,42] We excluded women with a large postvoid residual as well as

women with previous incontinence surgery or advanced pelvic organ prolapse. The results of this study are therefore not applicable to those women with "complicated" SUI; the relevance of preoperative urodynamics in these patients needs further evaluation.

In women with uncomplicated SUI, an immediate midurethral sling operation is not inferior to individually tailored treatment based on urodynamic findings; therefore, urodynamics should no longer be advised routinely before primary surgery in these women. Although detrusor overactivity was associated with an impaired postoperative cure, women with detrusor overactivity improved significantly.

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