Validation of a Model Predicting De Novo Stress Urinary Incontinence in Women Undergoing Pelvic Organ Prolapse Surgery

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OBJECTIVE: To validate a previously developed prediction model for de novo stress urinary incontinence (SUI) after undergoing vaginal surgery for pelvic organ prolapse (POP).

METHODS: Model performance was determined using a cohort of women who participated in two, 14-center randomized trials in the Netherlands that evaluated whether postoperative SUI 1 year after surgery was reduced with or without concomitant midurethral sling at the time of surgery for symptomatic women who had at least stage 2 POP. Age, number of previous vaginal births, urine leakage associated with urgency, history of diabetes, body mass index, preoperative stress test result, and placement of a midurethral sling were used to calculate the predicted probability of an individual developing de novo SUI. Predicted probabilities were compared with outcomes and quantitated using the concordance index and calibration curves. Model accuracy was compared with and without the preoperative stress test, and net reclassification improvement was measured using probability cutoffs of 0.2, 0.3, and 0.4.

RESULTS: Of 239 participants who did not report preoperative SUI and underwent surgery, 152 were eligible for analysis with complete baseline and outcome data. Model discrimination was acceptable and consistent with performance in the original development cohort when the preoperative stress test result was included (concordance index 0.63; 95% CI 0.52–0.74) and had lower discrimination than when the stress test variable was not included (concordance index 0.57; 95% CI 0.46–0.67, P=.048). The model that included the stress test variable was most accurate when predicted probabilities of de novo SUI were between 0 and 50%, and it correctly reclassified upward 5.9% (95% CI −14.8 to 26.8) of participants with de novo SUI and correctly reclassified downward 16.9% (95% CI 6.6–27.7) of participants without de novo SUI.

CONCLUSION: On external validation, the model was predictive of de novo SUI after vaginal prolapse surgery and may facilitate decision making regarding concomitant sling placement.

CLINICAL TRIAL REGISTRATION: Nederlands Trial Register, NTRR 1197 en 1070.

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In women who do not report stress urinary incontinence (SUI) symptoms and are undergoing surgery for pelvic organ prolapse (POP), routinely performing a concomitant continence procedure reduces their risk of developing postoperative SUI symptoms, but also increases risk of complications such as bladder perforation, major bleeding and incomplete bladder emptying.[1–3] Thus, clinicians continue using a variety of strategies, such as office stress test and clinical risk stratification, to selectively choose when to perform the continence operation. However, providing a woman an accurate individual risk estimate remains challenging.

One common strategy uses the preoperative prolapse reduction stress test, which is performed by filling the bladder with sterile water to a prespecified amount, often 300 mL or to bladder capacity. The prolapsed organ is repositioned inside the vagina. The test is considered positive if the woman has leakage with coughing or straining in either the supine or standing position with her prolapse reduced. Routine use of the stress test in this context is supported in a US national guideline and supported by statistically significant associations between leaking visualized during a prolapse reduction stress test ("occult stress urinary incontinence") and developing de novo SUI after surgery.[4,5] Unfortunately, few studies have actually measured the stress test's predictive accuracy in this setting and one of the largest studies demonstrated that the stress test performs marginally better than chance (area under the curve 0.54).[6]

Between May 2007 and January 2011, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Pelvic Floor Disorders Network conducted the OPUS (Outcomes Following Vaginal Prolapse Repair and Midurethral Sling) trial comparing rates of de novo SUI for women who underwent concomitant vaginal prolapse surgery and a retropubic midurethral sling compared with a sham retropubic midurethral sling procedure.[2] Jelovsek et al[6] used participant data from this trial and developed and internally validated a statistical model to predict the probability of de novo SUI after vaginal prolapse surgery. Model accuracy (with or without the stress test) was significantly better than the stress test alone (area under the curve of 0.72 vs 0.54), and the model outperformed expert predictions.[6] Because a separate test cohort of women undergoing vaginal surgery for POP was not available at the time of model development, external validation was performed on stress-continent women undergoing abdominal sacral colpopexy surgery for POP with or without Burch cystourethropexy from the Colpopexy and Urinary Reduction Efforts trial.[1] However, no validation has been performed on patients outside of a NICHD Pelvic Floor Disorders Network trial. Additionally, the change in accuracy and clinical benefit of using the model with and without the stress test has not been thoroughly tested.

The primary aim of this study was to validate the de novo SUI model and test its accuracy in an international cohort independent from the NICHD Pelvic Floor Disorders Network. Secondary aims were to test the null hypothesis that there was no significant improvement in model discrimination when including the preoperative stress test result in the model and to determine the net reclassification improvement of participants when including the stress test as a predictor in the model.

METHODS

This study used methods of reporting set forth in the TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis) Statement.[7] The study population consisted of participants in the CUPIDO (Concomitant surgery and Urodynamic investigation in genital Prolapse and stress Incontinence. A Diagnostic study including Outcome evaluation) trials.[8] The CUPIDO trials were conducted in 14 centers in the Netherlands. The studies were performed between November 2007 and April 2011. The CUPIDO-1 trial was a multicenter, randomized trial that evaluated whether concomitant midurethral sling at the time of vaginal surgery for women who had at least stage 2 POP resulted in fewer patients with postoperative SUI in women who preoperatively reported one or more SUI episodes, or who did not preoperatively report SUI but had a positive office stress test without prolapse reduction.[8,9]

The CUPIDO-2 trial evaluated women who did not report preoperative SUI episodes and had a negative office stress test without prolapse reduction.[8,10] Participants who demonstrated leaking with reduction of POP were randomized at the time of vaginal POP surgery to receive or not to receive a concomitant midurethral sling. Participants who did not leak with the prolapse reduction stress test underwent only POP surgery without midurethral sling and were followed in a longitudinal cohort. Transobturator and retropubic midurethral slings were allowed in both studies.

In both studies, preoperative and postoperative SUI was defined as a positive response to the question relating to SUI in the Dutch version of the Urogenital Distress Inventory.[11] Stress urinary incontinence had to be present more than once a week and dominant over urgency urinary incontinence (ie, more episodes of SUI than urgency urinary incontinence on the Urogenital Distress Inventory). All participants in CUPIDO-1 and CUPIDO-2 were eligible for inclusion in this analysis if they did not report preoperative SUI using this definition. Study details of both trials have been previously published and participant characteristics are summarized in Tables 1 and 2. The trials were registered in a national trial registry (http://www.trialregister.nl NTRR 1197 and 1070), all participating centers obtained approval of their local Medical Ethical Committees, and informed consent was obtained on all study participants.[8–10]

The primary outcome evaluated was dichotomous and was defined as the participant reporting bothersome SUI at the 6 weeks, 6 months or 12 months visit

Table 1. Study Characteristics Between the Original Model Build Cohort From the OPUS Trial[2] and the CUPIDO Trials

	OPUS Trial (n=457)	CUPIDO Trials (n=152*)
Data collection period	May 2007–January 2011	CUPIDO-1: November 2007–April 2011 CUPIDO-2: November 2007–April 2014
Study design	Randomized, single-blind, sham-controlled trial	Randomized, nonblind trials CUPIDO-2 included a parallel cohort
Setting†	7 academic centers across the United States	CUPIDO-1: 14 centers across the Netherlands CUPIDO-2: 13 centers across the Netherlands
Inclusion criteria	Women planning to undergo vaginal prolapse surgery who reported the symptom of feeling or seeing a vaginal bulge but reported no symptoms of SUI	Women planning to undergo vaginal prolapse surgery who had at least stage 2 prolapse CUPIDO-1 included those who reported a history of SUI at least once/wk or a positive stress test without reduction of prolapse. CUPIDO-2 included those who did not report a history of SUI at least once/wk. If reduction stress test or urodynamics demonstrated leaking, they were randomized. Otherwise, they were followed in a parallel cohort without sling placement.
Outcome‡	Pelvic Floor Distress Inventory—Do you usually experience urine leakage related to: cough, sneezing, or laughing; physical exercise, such as walking, running, aerobics, or tennis; or lifting or bending over? Yes was a response of somewhat, moderately, or quite a bit at any time up to and including 12 mo after surgery	Urinary Distress Inventory—How much are you bothered by leakage related to activity, coughing or sneezing? Yes was a response of slightly, moderately, or greatly anytime up to and including 12 mo after surgery
Prevalence of de novo SUI [n (%)]	115 (25.2)	34 (22.4)

OPUS, Outcomes Following Vaginal Prolapse Repair and Midurethral Sling; CUPIDO, Concomitant surgery and Urodynamic investigation in genital Prolapse and stress Incontinence. A Diagnostic study including Outcome evaluation[8–10]; SUI, stress urinary incontinence.
* Sample size is 198, which includes all eligible participants with complete data.
† All participants who received a midurethral sling in OPUS received a retropubic sling, whereas CUPIDO participants may have received either a retropubic or transobturator sling.
‡ Outcomes listed are those used in the model development and validation process.

to the question, "Do you experience urine leakage related to physical activity, coughing or sneezing?"[11] Bothersome SUI was defined as a response of "slightly," "moderately," or "greatly" bothersome on the Urogenital Distress Inventory question.[11]

Baseline predictors used in the model included: age at the time of surgery (continuous); number of previous vaginal births (continuous); urine leakage associated with urgency defined using the Urogenital Distress Inventory question 9a ("Do you experience urine leakage related to the feeling of urgency?" yes/no);[11] history of diabetes mellitus (yes/no); body mass index (BMI [calculated as weight in kilograms divided by height in meters squared] continuous); preoperative prolapse reduction stress test result (leak/no leak); and concomitant continence procedure performed (yes/no) at the time of vaginal prolapse surgery.

An individual's predicted probability of de novo SUI was calculated by entering the values of each baseline predictor into the published model.[6] This model is available at riskcalc.org. Model accuracy was measured using the concordance index and Brier score (zero equals a perfect model) (Rufibach K. Use of Brier score to assess binary predictions [letter]. J Clin Epidemiol 2010;63:938–9). The concordance index ranges from 0.5 to 1, where 0.5 indicated that the model is no better than chance at making a prediction and 1 indicates that the model perfectly discriminates between those who experienced the event and those who did not. The incremental prognostic value of the stress test when added to the model was assessed using comparison of area under the receiver operator characteristic curve using the bootstrap test for two correlated receiver operating characteristic curves.[12]

Table 2. Participant Characteristics Between Women Who Developed De Novo Stress Urinary Incontinence After Vaginal Surgery for Pelvic Organ Prolapse and Women Who Did Not in the Original Model Build Cohort From the OPUS Trial[2] and the External Validation Cohort From the CUPIDO Trials

	OPUS Trial (n=457)				CUPIDO Trials (n=152*)			
	Positive SUI		Negative SUI		Positive SUI		Negative SUI	
	n	Value	n	Value	n	Value	n	Value
Age at surgery (y)	115	62±9.8	341	64±10	34	65±10	118	63±10
Parity	114	3.1±2.0	336	2.9±1.8	34	2.5±1.3[†]	118	2.4±1.1[†]
BMI (kg/m^2)	115	28±5.2	342	28±5.2	34	26±4.2	118	26±3.5
Preoperative stress test								
Positive	111	44 (40)	327	112 (34)	34	12 (35)	118	34 (29)
Negative		67 (60)		215 (66)		22 (65)		84 (71)
Midurethral sling[‡]	115	24 (21)	342	199 (58)	34	2 (6)	118	24 (20)
No midurethral sling[‡]		91 (79)		143 (42)		32 (94)		94 (80)
Leakage with a feeling of urgency	110	46 (42)	322	110 (34)	34	6 (18)	118	13 (11)
No leakage with a feeling of urgency		64 (58)		212 (66)		28 (82)		105 (89)
Diabetes	113	20 (18)	334	38 (11)	34	1 (3)	118	7 (6)
No Diabetes		93 (82)		296 (89)		33 (97)		111 (94)

OPUS, Outcomes Following Vaginal Prolapse Repair and Midurethral Sling; CUPIDO, Concomitant surgery and Urodynamic investigation in genital Prolapse and stress Incontinence. A Diagnostic study including Outcome evaluation[8–10]; SUI, stress urinary incontinence; BMI, body mass index.

Data are n, mean±SD, or n (%) with sample sizes.

* Sample size is 198, which includes all eligible participants with complete data.

† Median (interquartile range) for parity was 2 (2–3) for women with positive stress urinary incontinence and 2 (2–3) for participants with negative stress urinary incontinence.

‡ All participants who received a midurethral sling in OPUS received a retropubic sling, whereas CUPIDO participants may have received either a retropubic or transobturator sling.

Model accuracy was also measured using calibration plots. Calibration curves along with distributions of predicted probabilities of those with and without each outcome were generated to visually observe how close model predictions were to actual predictions. A perfect relationship followed a straight 45-degree line.

To assess whether the addition of the stress test to the model would influence clinical practice, we assessed whether the newly predicted risk crossed clinically meaningful thresholds for an individual. These subsequent changes in risk classification were quantified by the net reclassification improvement.[13–15] Categorical net reclassification improvements define upward and downward reclassification only if predicted risks move from one category to another.[13–15] However, in the absence of clinical guidelines for risk categories when using a preoperative prolapse reduction stress test, we separately reported the event, nonevent, and total net reclassification improvement based on the event rate in the current study and using ±10% using prespecified risk thresholds of 20%, 30%, and 40%. All analyses were performed using R version 3.4.3 (2017-11-30).

RESULTS

Of the 239 participants who did not report preoperative SUI and underwent surgery, 152 were eligible for analysis, with complete baseline and outcome data from the two trials. The CUPIDO-1 study randomized 138 participants, and 134 underwent surgery for POP with or without midurethral sling. Eleven of these participants were eligible for this

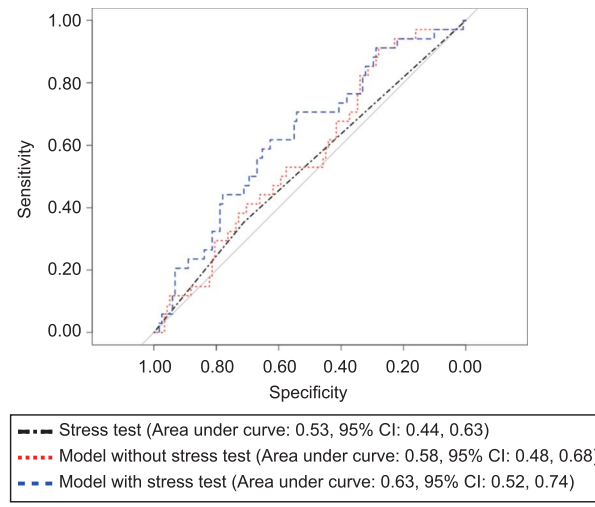

Fig. 1. Comparison of model discrimination using the area under the curve between the model with and without the stress test variable and the stress test alone.

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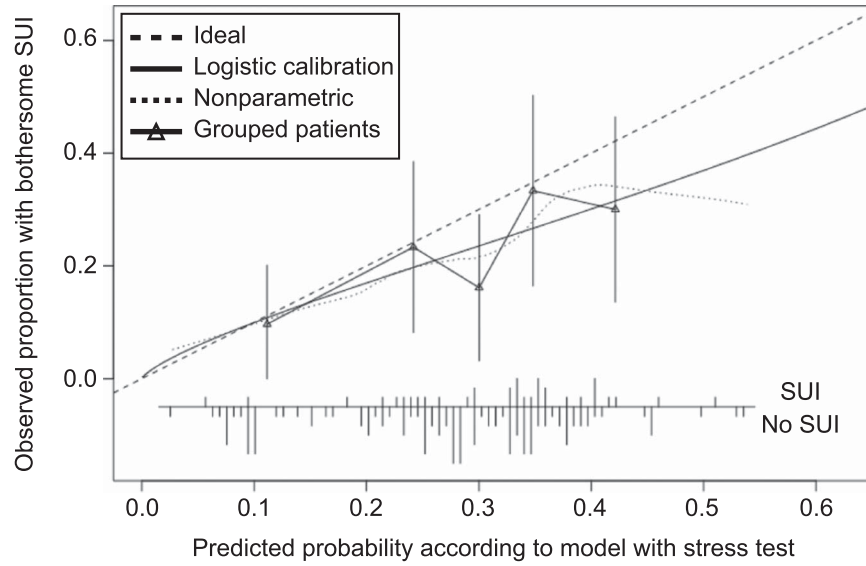

Fig. 2. Calibration curve of de novo stress urinary incontinence (SUI) model that includes stress test as a predictor and its performance in Concomitant surgery and Urodynamic investigation in genital Prolapse and stress Incontinence participants. Distribution of predicted probabilities shown separately below the plot for patients with and without de novo SUI. Validation concordance index: 0.63 (95% CI 0.52–0.74). *Triangles* indicate observed proportion of disease by 20th percentiles of the predicted probability.

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analysis because they did not report preoperative SUI. The CUPIDO-2 study randomized 231 participants, and 228 underwent surgery. Of the 228 participants, 145 (63.6%) were eligible for this analysis because they did not report preoperative SUI, leaving a total of 156 participants eligible for analysis. Four of the eligible 156 participants did not have outcome data available at any point during the follow-up period, leaving 152 participants from both trials with complete data.

Tables 1 and 2 demonstrate the characteristics of the CUPIDO participants compared with those included in the original model development cohort.[6] The Dutch cohort was clinically similar in age, parity, and rate of positive stress test results compared with the model development cohort. However, the Dutch cohort had clinically lower average BMI and lower rates of diabetes and less women reported leaking with a feeling of urgency. Among patients who developed de novo SUI, CUPIDO participants had fewer midurethral slings placed per the trial design compared with the development cohort (Tables 1 and 2: CUPIDO, 6% vs OPUS, 21%). The overall prevalence of de novo SUI in the CUPIDO participants

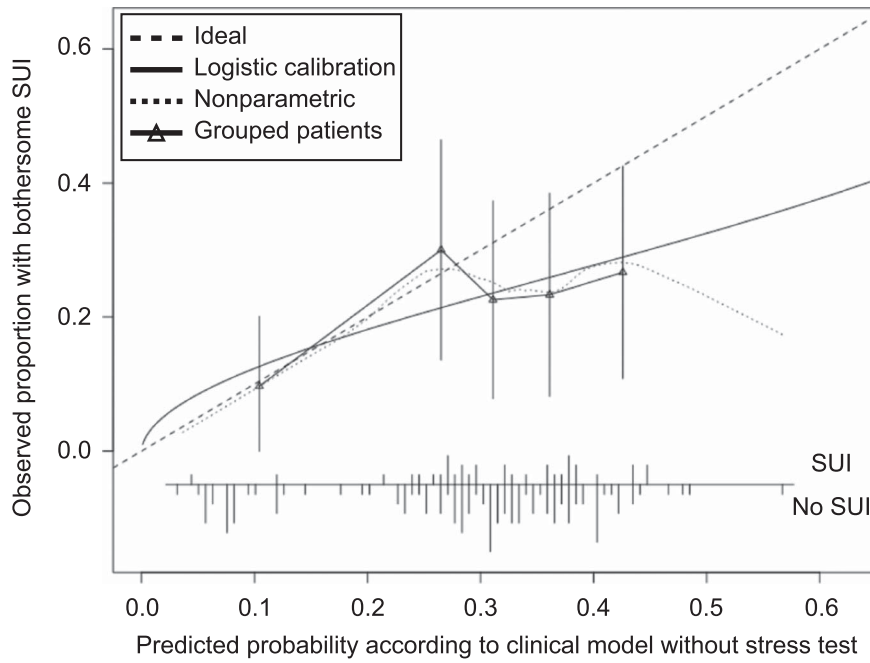

Fig. 3. Calibration curve of de novo stress urinary incontinence (SUI) model that does not include the stress test as a predictor and its performance in Concomitant surgery and Urodynamic investigation in genital Prolapse and stress Incontinence participants. Distribution of predicted probabilities shown separately below the plot for patients with and without de novo SUI. Validation concordance index: 0.57 (95% CI 0.46–0.67). *Triangles* indicate observed proportion of disease by 20th percentiles of the predicted probability.

Jelovsek. Validation of De Novo Stress Incontinence Model. Obstet Gynecol 2019.

Table 3. Reclassification Table for the de Novo Stress Urinary Incontinence Model With and Without the Stress Test and Using Three Probability Thresholds*

	Model With Stress Test					
Model Without Stress Test	0–19%	20–29%	30–39%	More than 40%	Total	% Reclassified
De novo SUI: no (n=118)						
0–19%	25	0†	0†	0†	25	0
20–29%	2‡	23	5†	0†	30	23
30–39%	0‡	15‡	26	4†	45	42
More than 40%	0‡	0‡	12‡	6	18	67
Total	27	38	43	10	118	
De novo SUI: yes (n=34)						
0–19%	2	0‡	0‡	0‡	2	0
20–29%	1†	7	4‡	0‡	12	42
30–39%	0†	3†	9	3‡	15	40
More than 40%	0†	0†	1†	4	5	20
Total	3	10	14	7	34	

SUI, stress urinary incontinence.

* The net reclassification improvement for addition of the prolapse reduction stress test to the de novo SUI prediction model results with the use of the numbers shown in the table was: † the number of individuals incorrectly reclassified when the model with the stress test was used vs the model without the stress test; ‡ the number of individuals correctly reclassified when the model with the stress test was used vs the model without the stress test.

was similar to the OPUS development cohort (CUPIDO, 34/152 [22%] vs original, 115/457 [25%]).

When the preoperative stress test result was included, model discrimination was similar in performance to the original published model (concordance index 0.63; 95% CI 0.52–0.74, Brier 0.173 vs original concordance index 0.73; 95% CI 0.65–0.80).[6] When the stress test variable was not included, model discrimination dropped (concordance index 0.57; 95% CI 0.46–0.67, P=.048, Brier 0.179) although performance remained within the original model's CIs. The model including the preoperative stress test had significantly better discrimination than the model without the stress test (area under the receiver operator characteristic curve 0.63 vs 0.57; P=.038, Fig. 1).

Calibration curves demonstrated that the model with the stress test accurately predicted actual probabilities of de novo SUI from 0 to 50% (Fig. 2). The predicted probabilities from the model without the stress test over-predicted actual risk when the probability was greater than 40% (Fig. 3). Although the CIs demonstrated that the predicted probabilities were overall similar to actual rates and the model had statistically significant utility in predicting SUI, considerable individual variability remained, as seen by the CIs for each quintile and for the absence of a monotonic increase in observed probability compared with predicted probability.

The reclassification table indicated the number of individuals who moved to another risk category or remained in the same risk category as a result of adding

Table 4. Summary of Net Reclassification Improvement Calculations for the de Novo Stress Urinary Incontinence Model With and Without the Stress Test and Using Three Probability Thresholds*

	Estimate	SE	95% CI, Lower	95% CI, Upper
NRI	0.228	0.120	−0.013	0.468
NRI event	0.059	0.105	−0.148	0.268
NRI nonevent	0.169	0.052	0.066	0.277
Pr (Up|event)	0.206	0.071	0.071	0.353
Pr (Down|event)	0.147	0.061	0.035	0.269
Pr (Down|nonevent)	0.246	0.041	0.169	0.331
Pr (Up|nonevent)	0.076	0.025	0.033	0.128

SE, standard error; NRI, net reclassification improvement; event, participant who developed de novo stress urinary incontinence; nonevent, participant who did not develop de novo stress urinary incontinence; Pr, probability.

NRI=[Pr (up|event)−Pr (down|event)]+[Pr (down|nonevent)−Pr (up|nonevent)]=event NRI+nonevent NRI.

The sum of the net percentages of correctly reclassified persons with and without the event of interest; this statistic is implicitly weighted for the event rate and cannot be interpreted as a percentage. Theoretical range is −2 to 2.[15]

* Categorical NRIs (cutoffs of 0.2, 0.3, and 0.4).

the stress test result as a predictor in the model (Table 3). The addition of the stress test in the model improved down-classification of patients without de novo SUI into a lower decile of risk to a greater extent than it did up-classifying patient with de novo SUI into a higher decile of risk (Table 3). The net percentage of participants with de novo SUI correctly classified upward using the model with the stress test was 5.9% (event net reclassification improvement 0.059, 95% CI −0.148 to 0.268, Table 3). The net percentage of participants without de novo SUI correctly classified downward was 16.9% (nonevent net reclassification improvement 0.169, 95% CI 0.066–0.277, Table 4). The sum of the net percentages (overall net reclassification improvement) of correctly reclassified participants with and without de novo SUI was 0.228 (95% CI −0.013 to 0.468).

DISCUSSION

We succeeded in externally validating the de novo SUI model using an international cohort independent from the NICHD Pelvic Floor Disorders Network. The prediction model that included the preoperative stress test performed better than the model without the stress test in this cohort. Based on these findings, we recommend including the prolapse reduction stress test with the prediction model into the standard workup of a woman planned for vaginal prolapse repair who does not report preoperative SUI. Based on this study and our previous study, the stress test alone did not accurately discriminate between women who develop de novo SUI and women who do not. However, adding the stress test information to the clinical prediction model increased predictive accuracy and successfully down-classified women by providing lower predicted probabilities of de novo SUI in women who did not develop de novo SUI.

Because there is no single measure that is able to assess all contributions of an additional risk factor in a prediction model, we tested this through different methods: 1) reporting the accuracy of the stress test and 2) reporting the accuracy of the addition of the stress test with regard to calibration and reclassification. The concordance index is frequently insensitive to change, so it was surprising to find that inclusion of the stress test improved predictive discrimination.[16] Reclassification statistics provide more relevant information for clinical decisions than the concordance index.[16] The addition of the stress test improved the correct reclassification of persons without de novo SUI but did not improve the correct reclassification of persons with de novo SUI resulting in no overall net improvement. However, this should be considered as a limitation in light of the low sample size of patients with de novo SUI in the CUPIDO participants. Unfortunately, there are no generally accepted approaches to estimate the sample size requirements for validation studies of prediction models.[7]

Many clinicians perform urodynamics in patients before POP surgery. Urodynamics is a constellation of studies, including cystometry and a pressure-flow study that includes a bladder stress test. Cystometry may be used to detect detrusor overactivity and urethral function. However, there is no evidence that these advantages improve the outcome in women who report preoperative SUI undergoing vaginal prolapse repair with or without midurethral sling.[17,18] Urodynamics are of limited value in women with SUI[19,20] and urodynamics cause discomfort, are time consuming and costly.[21] Therefore, a prolapse reduction stress test performed during basic office evaluation is in our opinion sufficient.[22]

An important strength of this study is that the model was externally validated with a comparable cohort with different risk profiles and situated in another country with differences in race, culture and health system. The added value of a prolapse reduction stress test was tested by comparing a model with and without the stress test using multiple measures. The model is still moderately predictive, and it is possible that additional markers or tests could improve this. Future studies that identify additional markers or predictors of de novo SUI could be incorporated into the model and potentially improve prediction.

In women undergoing vaginal prolapse repair this externally validated prediction model may facilitate preoperative counselling of women without SUI symptoms considering combining the prolapse repair with a midurethral sling. Incorporating results from the stress test into the model provides the most optimal predictions of de novo SUI after surgery.

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