

A MODEL FOR PREDICTING THE RISK OF DE NOVO STRESS URINARY INCONTINENCE IN WOMEN UNDERGOING PELVIC ORGAN PROLAPSE SURGERY

Hypothesis / aims of study

Women without baseline SUI symptoms who undergo vaginal prolapse surgery or a sacrocolpopexy for pelvic organ prolapse (POP) may also undergo a concomitant continence surgery such as a midurethral sling or Burch cystourethropexy to minimize the risk of *de novo* post-operative stress urinary incontinence (SUI). Some surgeons do not routinely recommend a concomitant continence operation. Instead, they selectively recommend a continence procedure using the patient's unique risk factors and/or pre-operative stress testing. Additionally, an individual patient may have a preference regarding the value of a concomitant continence operation after weighing the risks and benefits. We hypothesized that: 1) a prediction model could refine the likelihood of developing *de novo* SUI within 12 months of POP surgery using baseline patient and testing characteristics in women participating in 2 large POP surgery trials and 2) the prediction model would perform better than experts. Such a prediction model could be a useful adjunct when discussing the risks and benefits of a concomitant continence procedure at the time of POP surgery.

Our study aims were to construct and validate a prediction model for the probability of developing *de novo* SUI 12 months after surgery for POP and to compare the ability of the prediction model to expert estimates.

Study design, materials and methods

A prediction model was developed using the dataset (n = 465) from the randomized trial "Outcomes Following Vaginal Prolapse Repair and Midurethral Sling (OPUS)" that estimated the prevalence of *de novo* SUI after vaginal POP surgery with or without TVT.[1] Experts identified 12 possible pre-operative predictors of post-operative SUI available in the trial including: age, race, parity, BMI, smoking, diabetes, strenuous physical activity, baseline urgency urinary incontinence symptoms, pre-operative POPQ stage, POPQ point Aa, a positive pre-operative prolapse reduction stress test and performance of a concomitant TVT. The outcome of the model was *de novo* SUI as determined by 'somewhat,' 'moderately,' or 'quite a bit' responses on the Pelvic Floor Distress Inventory regarding leaking urine at or any time up to 12 months after surgery using the questions-"Do you usually experience urine leakage related to: coughing, sneezing, or laughing; physical exercise such as walking, running, aerobics, or tennis; or lifting or bending over?" A multivariable logistic regression model was fit and stepdown procedures were used to find the best reduced model. The model was internally validated using 1000 bootstrap samples to obtain the bias-corrected accuracy using the concordance index. Model reliability was assessed using bias-corrected calibration plots. Twenty two experts predicted post-operative SUI using the same predictors including stress test results from a random sample of OPUS trial subjects (n=32). The area under the curve (AUC) from the prediction model was compared with 1) expert's predictions; 2) pre-operative prolapse reduction stress test alone; and 3) the dataset (N=322) from the "Colpopexy and Urinary Reduction Efforts (CARE)" randomized trial that estimated rates of *de novo* SUI after open abdominal sacral colpopexy with or without Burch urethropexy.[2] AUC values closer to 1 indicate better predictions.

Results

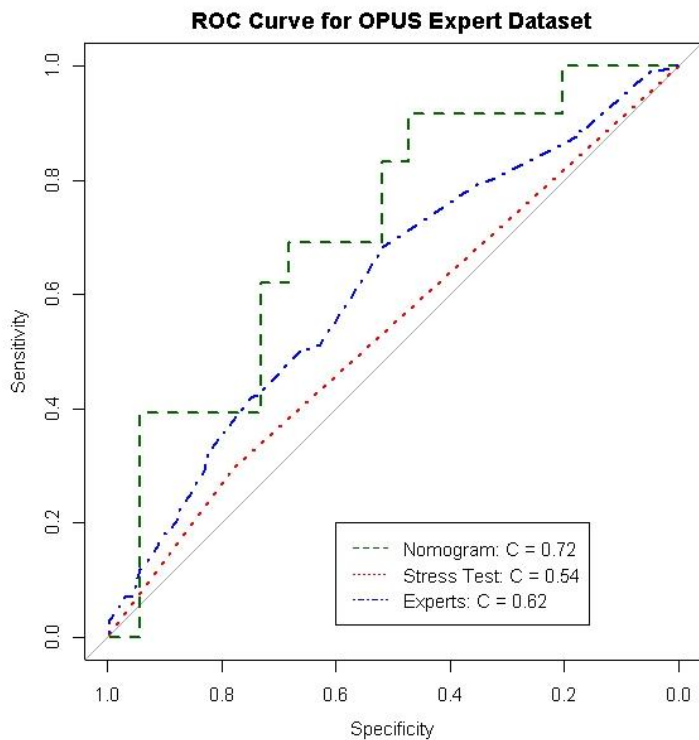
465 OPUS participants had SUI data available up to 12 months after surgery. The prediction model was useful for discriminating between women who did and did not develop *de novo* SUI after POP surgery (concordance index = 0.73, 95% CI 0.67, 0.80). The model was better at predicting risk of *de novo* SUI than experts when applied to the test data set of 32 patients (model AUC = 0.72 vs. expert AUC = 0.62, P<.001). The model was also better at predicting post-operative *de novo* SUI than pre-operative prolapse reduction stress test alone (AUC = 0.72 vs 0.54, P <0.001) (Figure). When the model was applied to the CARE dataset, a concordance index of 0.62 (95% CI 0.56, 0.69) was noted.

Interpretation of results

The CARE and OPUS trials demonstrated that 'on average' performing either a Burch or midurethral sling at the time of POP surgery reduces the probability of *de novo* SUI although individual patient risks may vary.[1,2] In practice, many surgeons and patients continue to use this information along with specific patient or testing characteristics to make decisions about performing concomitant continence surgery at the time of POP surgery based on an individual's risk. We constructed a prediction model using data available preoperatively that combines specific patient characteristics and the results from pre-operative prolapse reduction stress test. This model is accurate at predicting which women will and will not develop SUI after POP surgery and performs better at predicting an individual's risk than expert clinicians. This model can potentially improve the accuracy of predicting *de novo* SUI in patients undergoing POP surgery and reduce variability in predicting risk and subsequent counseling between clinicians and patients.

Concluding message

The prediction model provides a valid individualized risk estimate for developing *de novo* SUI following vaginal surgery for POP and acceptable prediction of SUI following abdominal surgery. The model significantly outperforms a pre-operative prolapse reduction stress test and clinical experts using all available predictors.



References

1. Wei JT, Nygaard I, Richter HE, et al. A midurethral sling to reduce incontinence after vaginal prolapse repair. *N Engl J Med* 2012; 366:2358-67.
2. Brubaker L, Cundiff GW, Fine P, et al. Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. *N Engl J Med* 2006; 354:1557-66.

Disclosures

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