

IS TESTING FOR OCCULT STRESS URINARY INCONTINENCE PREDICTIVE OF POST-OPERATIVE STRESS URINARY INCONTINENCE IN PATIENTS WITH PELVIC ORGAN PROLAPSE? A PRAGMATIC STUDY

Hypothesis / aims of study

Pelvic organ prolapse (POP) surgery may unmask occult stress urinary incontinence (OSUI) in previously asymptomatic patients. Preoperative urodynamic studies (UDS) with prolapse reduction may, by potentially unmasking OSUI, assist surgical decision-making, and has been used in practice. This study aims to investigate the post-operative rate of SUI, according to presence or absence of OSUI on preoperative UDS, from 2 clinically relevant perspectives: 1st based on presence or absence of OSUI preoperatively and subsequent outcomes based on surgical choice and 2nd, based on the surgical decision (POP or POP-SUI surgery) and subsequent outcomes based on OSUI status

Study design, materials and methods

A retrospective cohort study of all stress-continent women presenting at KGH from 2003-2013 for prolapse surgery was conducted, along with a cross-sectional survey of these patients, now remote from surgery. Charts were reviewed to obtain demographic characteristics, preoperative UDS, surgical information and symptoms at the 1 year visit. All patients were counselled similarly taking into consideration baseline surgical risks factors, personal preferences and UDS results. Inclusion criteria were: continent women undergoing any prolapse surgery, with or without anti-incontinence procedure, and pre-operative UDS studies available. Preoperative continence was defined as "very rare" or "occasional" stress incontinence on the standardized intake form on initial visit. OSUI(+) refer to women who had a positive leakage on valsalva at bladder volume of 300 ml or cystometric capacity, during reduction phase of UDS, and OSUI(-) to those without leakage following prolapse reduction during UDS. Reduction was done with a vaginal pessary, typically a ring, but in some case a Gelhorn or a Gehrund.

All eligible patients were offered to participate in a survey using validated questionnaires to assess longer-term outcomes. Primary outcome was presence of long-term SUI as defined as a score $>$ or $=$ 1 on the SUI-specific question of the Urinary Distress Inventory (UDI-6). Secondary outcomes included subjective SUI at 1-year follow-up (defined as patient's self-report of SUI as noted on postop visit), and overall scores from 3 validated short form questionnaires: the International Conference on Incontinence Modular Questionnaire, the UDI-6, and the Incontinence Impact Questionnaire. As we were surveying all patients, a sample size was not obtained.

Results

568 patients presented for POP surgery at our hospital, of which 455 were ineligible (no UDS: 187, pre op SUI: 239, deceased: 14, chart not available: 13, mailing address unavailable: 2), resulting in 113 enrolled women, of whom 54 were OSUI(+) and 59 were OSUI(-). Demographic data and types of surgeries performed were similar regardless of OSUI status, except for the rate of concomitant SUI surgery: 42 (78%) in the OSUI(+) group versus 9 (15.3%) in OSUI(-) patients underwent SUI surgery. The response rate to the questionnaires forming the basis for long-term outcomes was 58.4%. In particular, median time since surgery for the whole group who returned questionnaires was 7 years [IQR 4.3-9] and similar between OSUI(+) (6.5 years [4.0-9.0]) and OSUI(-) (8.0 years [4.0-10.0]). Mean age (SD) was 63.0 (11.4) in OSUI(+) and 59.5 (11.6) in OSUI(-) (non-significant). Overall, the rate of long term post op SUI was 24% (16/66), of which 75% (12/16) had 'no' or 'slight' bother, and the rate of subjective 1yr SUI was 11.1% (10/90).

Amongst OSUI(+) patients who responded to the survey (n=31), the rate of objective long-term SUI was 12.5% vs 42.9% comparing women with and without an SUI procedure (p=0.11). For those with available data on the secondary outcome of subjective SUI at 1-year (n=45), the rates of were 8.8% vs 18.2%, respectively (p=0.58). Amongst OSUI(-) patients who responded to the survey (n=35), the rate of objective long-term SUI was 40% vs 26.7% comparing women with and without an SUI procedure (p=0.61). For those with available data on the secondary outcome of subjective SUI at 1-year (n=45), the rates of were 0% vs 12.8%, respectively (p=1). When looking only at "severe" SUI on long-term objective (score of 2 or 3 on SUI question of UDI-6), women with preoperative OSUI(+) had a significantly greater rate of post op SUI if they did not have concomitant SUI surgery: 0% versus 42.9% (p=0.045). Overall mean questionnaires scores (SD) were similar between women with pre op OSUI(+) and those with OSUI(-): ICIQ (out of 21) 3 (0-7) vs 5 (0-9), UDI6 (out of 100) 12.5 (4.2-4.8) vs 16.7 (4.2-29.2) and IIQ7 (out of 100) 0 (0-4.8) vs 0 (0-14.3).

When looking at the other vintage point, women who had concomitant continence surgery tended to have lower rate of long-term SUI if preop UDS was positive for OSUI: 12.5% vs 40% if OSUI(-) (p=0.19). Women who chose not to have a concomitant SUI surgery tended to have more post op SUI if preop UDS was positive for OSUI: 42.9% vs 26.7% if OSUI(-) (p=0.4). Similar trends were noted for the secondary outcome of subjective 1 year SUI. Overall, mean questionnaires scores (SD) were similar between women with or without concomitant SUI surgery.

These outcome rates were consistent when stratified by time since surgery (<5/≥5 years).

Interpretation of results

Published data comparing outcomes based on addition of SUI surgery alone shows that the addition of an SUI procedure reduces the risk of postoperative SUI.^(1,2) Nevertheless, this is a procedure which increases operating time and has associated risks to the bladder, ureters, and surrounding pelvic structures. Therefore this procedure should be included only for the appropriate patient population.

Our results demonstrate that OSUI(+) patients appear to stand to benefit most from SUI surgery. For this patient population, the addition of SUI surgery results in a reduction in post-operative SUI, both in terms of subjective short-term and objective long-term outcome measures. The difference was greatest when limited to moderate to severe symptoms. While not statistically significant,

the differences in outcomes are of similar magnitude to previous studies. Our data did not show a statistically significant difference in these outcomes when stratified by follow-up of <5 or ≥5 years, although this analysis is limited by the small number of patients. Although OSUI(-) patients had a lower rate of post-operative SUI, these women with post oop SUI but initially asymptomatic patients should be considered to have had a false negative result on UDS testing. This suggests that the UDS methods currently in use are not effectively capturing all patients who should be considered for a concomitant SUI procedure. This result is limited to UDS testing with prolapse reduction conducted by insertion of pessary, the standard for the authors' center. Although this study cannot calculate this value, one could say that preop UDS may have a more significant meaning if positive than if negative: its positive predictive value might be better than its negative predictive value.

Concluding message

This study offers a unique pragmatic view of real-world reality, taking into account patient preferences and UDS results. Our rate of SUI following POP with or without SUI surgery is similar to that reported in the literature in the long term. Although limited by its small size, our results demonstrate that, for OSUI-positive patients, the rate of subjective short-term and objective long-term SUI tended to be less if an anti-incontinence surgery was added, in agreement with published literature.^(1,2)

Given that patients in the OSUI-negative group nonetheless presented with postoperative SUI, it is evident that UDS testing is not conclusively predictive of postoperative outcomes. This outcome suggests the need for further studies comparing methods of prolapse reduction for UDS, which include pessary, speculum, and manual reduction. One study has shown that a half speculum was the most effective method and pessary the least.⁽³⁾

Representing up to 10 years of patient's objective and validated outcomes, these results demonstrate the importance of discussing the continued risk of postoperative SUI, even with negative UDS testing, when discussing surgical planning with patients.

References

1. Brubaker L; Cundiff GW; Fine P; Nygaard I; Richter HE; Visco AG; Zyczynski H; Brown MB; Weber AM; Pelvic Floor Disorders Network. Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. *N Engl J Med*. 2006;354(15):1557-66.
2. Wei JT; Nygaard I; Richter HE; Nager CW; Barber MD; Kenton K; Amundsen CL; Schaffer J; Meikle SF; Spino C; Pelvic Floor Disorders Network. A midurethral sling to reduce incontinence after vaginal prolapse repair. *N Engl J Med* 2012;366(25):2358-67
3. Visco, A.G., Brubaker, L., Nygaard, I., Richter, H.E., Cundiff, G., Fine, P., Zyczynski, H., Brown, M.B., Weber, A.M. from the Pelvic Floor, Disorders Network. The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy: the Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial. *Int Urogynecol J*. 2008;19(5):607-14.

Disclosures

Funding: William Samuel Thomas Connell Memorial Studentship Fund **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Queen's University Health Sciences Research Ethics Board **Helsinki:** Yes **Informed Consent:** Yes