### **Original Article - Female Urology**

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# The evolution of incontinence into resolved, refractory and *de novo* urgency urinary incontinence following sling placement at time of prolapse repair in a large urodynamic cohort

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**Purpose:** To improve counseling in women at risk of refractory and/or *de novo* urgency urinary incontinence (UUI) following sling placement at time of prolapse repair, we created an outcome model to characterize changes in storage dysfunction.

**Materials and Methods:** We identified 139 women who underwent urodynamics followed by sling or no sling placement at the time of prolapse repair over a 6-year period. Our primary outcome was the presence of UUI following sling placement. Data were analyzed in SAS using chi-square, Fisher's exact, Student's t-test, and Kaplan–Meier methods.

**Results:** At baseline, the sling group had significantly higher subjective (62/81 [76.5%] vs. 18/58 [31.0%]; p<0.001), objective (62/81 [76.5%] vs. 6/58 [10.3%]; p<0.001), and occult (41/81 [50.6%] vs. 6/58 [10.3%]; p<0.001) stress urinary incontinence (SUI); and rates of subjective and objective UUI were similar to the no sling group prior to surgery. After surgery (mean follow-up 859 days) there was no difference with or without sling, in the rate of SUI (subjective, objective) and further SUI treatments (bulking agent, repeat sling). Higher rates of *de novo* (13/81 [16.0%] vs. 6/58 [10.3%]; p=0.454) and refractory (31/81 [38.3%] vs. 14/58 [24.1%]; p=0.048) UUI were noted in the sling group following surgery. On Kaplan–Meier analysis, a greater proportion of women in the no sling group did not report UUI at longest follow-up (hazard ratio 0.63; 95% confidence interval 0.37–1.06; p=0.081).

**Conclusions:** Women should be counseled on the risk of *de novo* and refractory UUI following sling placement at time of prolapse repair.

Keywords: Female; Urinary incontinence; Urodynamics; Urologic surgical procedures

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## **INTRODUCTION**

The International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint report on terminology for female pelvic floor dysfunction [1] defines the subjective symptoms of urgency urinary incontinence (UUI) as the "complaint of involuntary loss of urine associated with urgency", and the objective finding on physical exam the "observation of involuntary leakage from the urethra synchronous with the sensation of a sudden, compelling desire

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### to void that is difficult to defer."

New onset de novo UUI is a frustrating outcome following sling placement and the debate of several published reviews over the past 10 years [2-6]. In a recent review by Marcelissen and Van Kerrebroeck [2], the authors found the incidence of de novo urgency and UUI to be around 15%. They also found a time dependent increase in symptoms over time, with 30% of women reporting urgency and UUI at long term follow-up. Clinical risk factors for de novo UUI after sling surgery included women with mixed incontinence and elevated age. Urodynamic risk factors included detrusor overactivity, low bladder capacity, and elevated detrusor pressure implying obstruction. In the recent systematic review of 32 studies by Pergialiotis et al. [3], the authors found an overall incidence of de novo overactive bladder of 11.5% in nonrandomized studies (280 women) and 6.4% in randomized studies (50 women).

What is poorly reported in the published literature is the time course for the evolution of resolved, refractory and *de novo* UUI following sling placement. Recognizing this weakness, Shin and Choo [7] classified postoperative UUI into *de novo*, persistent and disappearance; with sling comparison groups stratified by SUI predominant, equivalent and UUI predominant. In addition to limited reports on the evolution in SUI and UUI over time, there is a paucity of an adequate no sling control group in many of the clinical studies on *de novo* UUI following sling placement published in the past 5 years [7-17].

Herein our primary aim was to characterize changes in objective and subjective UUI and SUI with or without sling placement in women undergoing prolapse repair. Using a systematic classification system, rates of never UUI, *de novo* UUI, resolved UUI and refractory UUI are quantified.

### **MATERIALS AND METHODS**

After obtaining Institutional Review Board approval (Stanford University IRB protocol number: 35034), we identified 139 women who underwent urodynamics followed by sling or no sling placement at the time of prolapse repair at our institution from 2009 to 2015 using Current Procedural Terminology (CPT) codes. Surgeries were performed by multiple surgeons. Inclusion criteria included the presence of a Pelvic Organ Prolapse Quantification System (POP-Q) stage II or greater cystocele. Patients with a primary diagnosis of neurogenic bladder, including spinal cord injury, Parkinson disease, and multiple sclerosis were excluded from this study. Following a 2 reviewer chart review (XZ, ADD), data were manually recorded into REDCap (Research Electronic Data

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Capture) [18,19]. Recorded variables included demographics, prolapse stage, preoperative SUI/UUI classification, preoperative urodynamic findings, surgery date, prolapse repair, presence or absence of sling placement, and postoperative SUI/UUI classification.

Preoperative and postoperative SUI/UUI classifications were made by direct chart review of the entire medical record for each patient and application of the IUGA/ICS joint report on the terminology for female pelvic floor dysfunction [1]. SUI was classified as subjective, objective, and occult. UUI was classified as subjective and objective. Subjective SUI was defined as the patient "complaint of involuntary loss of urine on effort or physical exertion (e.g., sporting activities), or on sneezing or coughing" [1]. Objective SUI during pelvic exam was defined as "observation of involuntary leakage from the urethra synchronous with effort or physical exertion, or on sneezing or coughing" [1]. Occult SUI was defined as absence of subjective incontinence but presence of urine leakage with prolapse reduced on pelvic exam. Subjective UUI was defined as the "complaint of involuntary loss of urine associated with urgency" [1]. Objective UUI was defined as the presence of detrusor overactivity on urodynamics in accordance with the IUGA/ICS definition of objective UUI as the "observation of involuntary leakage from the urethra synchronous with the sensation of a sudden, compelling desire to void that is difficult to defer" [1]. Subcategories of SUI or UUI were not mutually exclusive for the purpose of the applied SUI/UUI classification system.

Our primary outcome was the presence of UUI following sling placement. Patients were classified into never UUI, de novo UUI, resolved UUI, or refractory UUI, when compared to their preoperative state. Data were analyzed in Statistical Analysis System software (SAS Institute, Cary, NC, USA) using chi-square and Fisher's exact test (categorical variables), Student's t-test (continuous variables), and Kaplan-Meier methods. Tabulated data are presented as mean±standard deviation. A p-value <0.05 was defined as significant. Kaplan-Meier analysis with the Cox proportional hazard ratio (HR) was performed to look at the association between time and the proportion of women free of UUI and SUI at longest follow-up, stratified by sling placement. We powered our study to identify a 20% difference in de novo UUI between the sling (p=0.3) and no sling group  $(p_0=0.1)$ . A study with a power of 80% would require a total sample of 131 subjects with a control to experimental ratio of 0.7 to test the association at the 5% level using the two proportion independent chi-square test ( $\alpha$ =0.05, power=0.8, m=0.7). Power calculation was carried out using PS Power (Version 3.1.6; Vanderbilt University, Nashville, TN, USA).

#### Table 1. Preoperative characteristics stratified by sling placement (n=139)

# **ICUROLOGY**

Variable	Overall (n=139) –	Sling placement		n velve
		Yes (n=81)	No (n=58)	p-value
Baseline characteristic				
Age (y)	62.6±11.4	60.4±11.9	65.6±10.1	0.006
BMI (kg/m²)	27.0±5.3	27.2±5.5	26.8±5.2	0.786
POP-Q stage				
II	55 (39.6)	32 (39.5)	23 (39.7)	0.989
111	77 (55.4)	46 (56.8)	31 (53.4)	0.794
IV	7 (5.0)	3 (3.7)	4 (6.9)	0.408
Preoperative incontinence				
SUI, subjective	80 (57.6)	62 (76.5)	18 (31.0)	<0.001
SUI, objective	68 (48.9)	62 (76.5)	6 (10.3)	<0.001
SUI, occult	47 (33.8)	41 (50.6)	6 (10.3)	<0.001
UUI, subjective	75 (54.0)	46 (56.8)	29 (50.0)	0.428
UUI, objective	24 (17.3)	15 (18.5)	9 (15.5)	0.644
Preoperative urodynamics				
Capacity (mL)	528.7±218.2	531.8±222.6	524.4±213.9	0.843
Pdet@Qmax (cmH <sub>2</sub> O)	20.5±13.7	17.6±10.9	24.6±16.1	0.005
Qmax (mL/s)	17.7±10.0	19.4±10.0	15.3±9.6	0.014
PVR (mL)	117.1±182.3	86.8±163.9	159.4±199.1	0.025
BOOI (Pdet@Qmax-2*Qmax)	4.5±9.6	2.1±5.9	7.9±12.4	0.002
BCI, K=5 (Pdet@Qmax+5*Qmax)	108.2±47.9	114.7±47.9	100.9±47.2	0.093
BCI, K=1 (Pdet@Qmax+1*Qmax)	38.2±14.4	37.0±12.3	39.8±16.9	0.283

Values are presented as mean±standard deviation or number (%).

BMI, body mass index; POP-Q, Pelvic Organ Prolapse Quantification System; SUI, stress urinary incontinence; UUI, urgency urinary incontinence; Pdet@Qmax, detrusor pressure at maximum flow; Qmax, maximum flow rate; PVR, post void residual; BOOI, bladder outlet obstruction index; BCI, bladder contractility index.

## RESULTS

One hundred and thirty-nine women (mean age, 62.6±11.4 years) met inclusion criteria, underwent urodynamics and were included for analysis (Table 1). Baseline POP-Q stage was well matched between the sling and no sling groups (stage II, p=0.989; stage III, p=0.794; stage IV, p=0.408). The sling group had a significantly higher subjective SUI (62/81 [76.5%] vs. 18/58 [31.0%]; p<0.001], objective SUI (62/81 [76.5%] vs. 6/58 [10.3%]; p<0.001], and occult SUI (41/81 [50.6%] vs. 6/58 [10.3%]; p<0.001) compared to the no sling group. Most importantly the sling and no sling groups were matched for the presence of preoperative UUI, with no significant different in rates of baseline subjective (46/81 [56.8%] vs. 29/58 [50.0%]; p=0.428) and objective (15/81 [18.5%] vs. 9/58 [15.5%]; p=0.644) UUI prior to surgery. Preoperative urodynamics (sling vs. no sling) demonstrated statistically significant differences in Pdet@Qmax (17.6 cmH2O vs. 24.6 cmH2O; p=0.005), Qmax (19.4 mL/s vs. 15.3 mL/s; p=0.014), post void residual (86.8 mL vs. 159.4 mL; p=0.025), and bladder outlet obstruction index (BOOI=Pdet@Qmax-2\*Qmax; 2.1 vs. 7.9; p=0.002). Otherwise, urodynamic capacity and bladder contractility index (BCI=Pdet@Qmax+K\*Qmax) were similar in each group. BOOI and BCI were originally derived by Abrams [20] who found K=5 cmH<sub>2</sub>O/mL/s in men. Subsequently Griffiths [21] found K=1 cmH<sub>2</sub>O/mL/s to be more accurate for women. BOOI and BCI are frequently reported for women using both K-values, and we herein report for comparison to prior studies.

Following surgery, women were followed for a mean follow-up of 859 days (Table 2). Postoperatively, rates of subjective SUI, objective SUI, and further surgical treatments for SUI (bulking agent, repeat sling) were not statistically different between groups. In the sling group following surgery, a significantly greater proportion of women had subjective UUI compared to the no sling group (44/81 [54.3%] vs. 19/58 [32.8%]; p<0.001). Accordingly, a highly proportion of women in the sling group underwent further pharmacologic UUI treatments (anticholinergics, beta-3 agonist), although not statistically significant. Additional treatments required for postoperative incomplete bladder emptying were characterized (alpha blocker, any requirement for intermittent catheterization, any requirement for indwelling catheterization, sling incision, and sling excision). There was a similar

#### Table 2. Postoperative characteristics stratified by sling placement (n=139)

Variable	Quorall (n=120)	Sling placement		n value
Vallable	Overall (II=159)	Yes (n=81)	No (n=58)	p-value
Follow-up (day)	859±956	860±944	859±975	0.995
Postoperative SUI				
Subjective	25 (18.0)	14 (17.3)	11 (19.0)	0.758
Objective	4 (2.9)	2 (2.5)	2 (3.4)	0.733
Further treatment for SUI				
None	132 (95.0)	78 (96.3)	54 (93.1)	0.842
Bulking	3 (2.2)	2 (2.5)	1 (1.7)	0.766
Sling	4 (2.9)	1 (1.2)	3 (5.2)	0.171
Postoperative UUI				
Subjective	63 (45.3)	44 (54.3)	19 (32.8)	<0.001
Objective	5 (3.6)	4 (4.9)	1 (1.7)	0.316
Further treatment for UUI				
None	107 (77.0)	59 (72.8)	48 (82.8)	0.336
Anticholinergics	25 (18.0)	17 (21.0)	8 (13.8)	0.276
Beta-3 agonist	11 (7.9)	8 (9.9)	3 (5.2)	0.311
Botox injection	2 (1.4)	1 (1.2)	1 (1.7)	0.811
Sacral stimulation	4 (2.9)	2 (2.5)	2 (3.4)	0.733
Posterior tibial nerve stimulation	3 (2.2)	2 (2.5)	1 (1.7)	0.766
Further treatment for incomplete emptying				
None	110 (79.1)	60 (74.1)	50 (86.2)	0.189
Alpha blocker	6 (4.3)	3 (3.7)	3 (5.2)	0.674
Intermittent catheterization	13 (9.4)	10 (12.3)	3 (5.2)	0.152
Indwelling catheterization	16 (11.5)	13 (16.0)	3 (5.2)	0.048
Sling incision	1 (0.7)	1 (1.2)	0 (0.0)	0.396
Sling removal	0 (0.0)	0 (0.0)	0 (0.0)	N/A

Values are presented as mean±standard deviation or number (%).

SUI, stress urinary incontinence; UUI, urgency urinary incontinence; N/A, not available.

 Table 3. Urgency urinary incontinence (UUI) classification following

 sling placement at time of pelvic organ prolapse repair

UUI	Overall	Sling placement		n value
classification	(n=139)	Yes (n=81)	No (n=58)	p-value
Never UUI	39 (28.1)	20 (24.7)	19 (32.8)	0.341
<i>De novo</i> UUI	19 (13.7)	13 (16.0)	6 (10.3)	0.454
Resolved UUI	36 (25.9)	17 (21.0)	19 (32.8)	0.169
Refractory UUI	45 (32.3)	31 (38.3)	14 (24.1)	0.048

Values are presented as number (%).

proportion of these treatments utilized after surgery, with the exception a greater requirement for indwelling catheterization following surgery in the sling group (13/81 [16.0%] vs. 3/58 [5.2%]; p=0.048).

Women were stratified by type of UUI after surgery (never UUI, *de novo* UUI, resolved UUI, and refractory UUI) with respect to the presence of UUI prior to surgery (Table 3). There was a similar proportion of women who never experienced UUI before or after surgery who underwent sling placement (20/81 [24.7%]) when compared to those who did not undergo sling placement (19/58 [32.8%]; p=0.341). In those who underwent sling placement, incidence of *de novo* (13/81 [16.0%] vs. 6/58 [10.3%]; p=0.454) and resolved (17/81 [21.0%] vs. 19/58 [32.8%]; p=0.169) UUI occurred at a similar rate when compared to those women who did not undergo sling placement. Refractory UUI was identified in a greater proportion of women following sling placement when compared to those who did not undergo sling placement (31/81 [38.3%] vs. 14/58 [24.1%]; p=0.048]. In the subgroup analysis of women with preoperative objective UUI, there was a greater proportion of refractory UUI in women following sling placement when compared to those who did not undergo sling (11/15 [73.3%] vs. 4/9 [44.4%]; p=0.212), though this did not reach statistical significance.

On Kaplan–Meier analysis, there was overlap of both curves at all time points, with no difference in the proportion of women not reporting SUI at the time of longest follow-up when stratified by sling placement (HR 0.98; 95%



Fig. 1. Kaplan–Meier curve for proportion of women not reporting stress urinary incontinence (SUI) at the time of longest follow-up. HR, hazard ratio; CI, confidence interval.

Fig. 2. Kaplan–Meier curve for proportion of women not reporting urgency urinary incontinence (UUI) at the time of longest follow-up. HR, hazard ratio; CI, confidence interval.

confidence interval [CI] 0.43–2.23; p=0.969) (Fig. 1). For the outcome UUI at longest follow-up, there was a trend towards a greater proportion of women in the no sling group who were free of UUI at longest follow-up (HR 0.63; 95% CI 0.37–1.06; p=0.081), however despite separation of the curves at all time points, this difference in proportion hazard did not achieve statistical significance (Fig. 2).

### DISCUSSION

In our present investigation, we systematically applied a methodical classification system grounded in IUGA/ICS terminology [1] in order to define the presence of SUI and UUI, before and after sling surgery. Using this system, we found that our two groups of women, with or without sling placement, were well matched for preoperative UUI prior to surgery. Following surgery, we found no difference in the proportion of women with subjective and objective SUI, which is consistent with appropriate surgeon selection of women who underwent sling versus no sling, and indicative of successful sling placement after surgery. The sling group in our study had a higher rate of indwelling catheter use limited to the immediate postoperative period, with no women requiring long term indwelling catheterization or sling removal.

Our study builds upon the existing literature on *de novo* UUI. We found a *de novo* UUI incidence of 16.0% after sling placement, compared to 10.3% of women in the no sling group, however this difference failed to achieve significance (p=0.454). Regarding refractory UUI, we found that this was significantly more common after sling, with 38.3% of women

reporting this bothersome complaint, compared to just 24.1% in the no sling group (p=0.048), which is higher than reported in the literature [16]. Interestingly, only 21.0% of women reported resolution of their UUI following sling placement, compared to 32.8% of women in the no sling group (p=0.169), which failed to achieve statistical significance, however is lower than the rates of resolved UUI reported in published literature [7,13].

On Kaplan-Meier analysis we found no significance in the proportion of women without SUI at longest follow-up (Fig. 1). Limitations of applying Kaplan-Meier methodology for the assessment of incontinence [11] include several assumptions which must be acknowledged when generalizing the findings of our study, and include selection bias, information bias and follow-up bias, as not all women followed up at equal durations after surgery. Overlap of the Kaplan-Meier SUI curves at all time points indicates, the women who followed up were well matched between the sling and no sling groups for the presence of SUI after surgery. Strengths of this approach include our ability to characterize changes over time. Strengths of our cohort include the large number of women for a urodynamic study (n=139) and a relatively large number of women with at least 1 to 5 years of follow-up from 500 to 2,000 days. Regarding our findings on the presence of UUI at longest follow-up over time (Fig. 2), separation of the Kaplan-Meier UUI curves is noted at all time points following surgery, with the no sling group reporting less UUI when compared to our sling group at each time point. The limitations of applying Kaplan-Meier methodology to our patient population, include the acknowledgment that censoring a woman for an event, in this case the presence of UUI, does not capture the magnitude of incontinence or bother score specifically attributed to the UUI. Acknowledging this, we found no significant difference in second- or third-line overactive bladder treatments in either group after surgery. These findings suggest that even though UUI was present in proportionally more women who underwent sling surgery, SUI success in each group was similar. To our knowledge, our study is the first to report Kaplan-Meier SUI and UUI outcomes with respect to time to longest follow-up, for sling placement at time of prolapse repair [11].

It must be accounted for that our cohort is a highly select group of women who underwent preoperative urodynamic pressure flow evaluation of the bladder prior to surgery. Urodynamic evaluation is typically reserved for situations "when it is important to determine if urodynamic obstruction is present and particularly when invasive, potentially morbid or irreversible treatments are considered" [22] For women with mixed incontinence, the approach to SUI treatment is typically individualized, and based on degree of bother from UUI, SUI, and prolapse. Sling placement is a highly effective first line surgical option for SUI. On the other hand, the etiology of UUI is complex. In women with mixed incontinence, including components of SUI, the etiology of urinary urgency could include pre-existing intrinsic detrusor overactivity, partial bladder outlet obstruction as a result of prolapse kinking at the bladder neck, or a combination of each. In our study, the presence of preoperative objective UUI (urodynamic detrusor overactivity) was associated with a non-significant greater proportion of women with refractory UUI in the sling group, however small number of events limits generalization of this subgroup.

De novo UUI following sling placement is challenging to predict on urodynamics. In our study, objective UUI was defined as the presence of detrusor overactivity on urodynamics. In the context of the urodynamic risk factors cited by Marcelissen and Van Kerrebroeck [2], we found no difference in detrusor overactivity (objective UUI) and bladder capacity between the sling and no sling groups. This is contrary to what was previously cited as an important urodynamic risk factor for de novo UUI [2]. Additionally, increased preoperative Qmax (26.7 mL/s vs. 19.1 mL/s) has been associated with resolved UUI after sling placement [14]. In our study, women undergoing sling had a mean Qmax of 19.4 mL/s, which could potentially account for only 21.0% rate of resolved UUI in our study. With regards to detrusor pressure, elevated detrusor pressure implying obstruction has been associated with de novo UUI after sling [2]. In our study, women undergoing sling had a Pdet@Qmax of 17.6 cmH<sub>2</sub>O, which was lower than the no sling group which demonstrated a Pdet@Qmax of 24.6 cmH<sub>2</sub>O. Contrary to the literature, we found a 16.0% rate of de novo UUI in the lower pressure sling group. In thinking of the pathophysiology of stress incontinence, it makes sense that women who underwent sling had lower voiding pressure on baseline urodynamics, as SUI is the result of low outflow resistance and likely reflects the need for sling placement in our sling group.

It is important to recognize that any voiding dysfunction after sling placement should raise concern about the possibility of an obstruction created by the sling. In our analysis, the rate of additional treatment for incomplete emptying did not differ significantly between groups, except the need for indwelling catheterization (sling 13/81 [16.0%] vs. no sling 3/58 [5.2%]; p=0.048). The timing of urethrolysis vary widely in the literature, ranging on average 4 to 36 months after sling placement [23-25]. Postoperative urodynamics may be helpful

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to compare voiding pressure before versus after sling placement in this group to confirm diagnosis of obstruction. If obstruction is suspected, sling incision or urethrolysis should be considered.

The mechanical stop test is an easy way to measure isovolumetric detrusor contractile pressure and detrusor contractile reserve [26] in men considering sling placement. For women, the effect of a sling can be simulated with the Marshall–Marchetti test. In 1987 Bergman and Bhatia [27] performed this test during urodynamics and leak point pressure was increased from 38.1 cmH<sub>2</sub>O at baseline, up to 207.2 cmH<sub>2</sub>O with varying degrees of elevation of the urethrovesical junction. Isovolumetric strength has been shown to improve selection of men considering anti-incontinence surgery [28] Given the low pressures at which women void [29], the application of the Marshall–Marchetti test to simulate outlet resistance at time of urodynamics could represent a future research opportunity.

Important considerations with regards to our research methodology include the selection of a suitable control group of women without sling who underwent prolapse repair. Given that both of our groups had similar prolapse stage and underwent similar prolapse repairs, we directed our analysis on the additive effect of the independent variable (sling placement) on the dependent variable postoperative UUI. As such we included a control group to delineate the impact of sling placement on postoperative UUI, and powered our study to include a sufficiently large sample size. With this approach, degree of prolapse repair success could potentially confound the association between UUI and sling placement if kinking of the bladder neck was present from a residual cystocele following surgery. For future research, preoperative and postoperative incontinence would be best evaluated using psychometrically validated questionnaires along with objective measures. As such, the dominance of stress versus urgency predominant symptoms in mixed incontinence would be quantified. Additional prospective research is needed, and should standardize patient enrollment criteria and follow-up measures in order to accurately capture not only changes in SUI following sling placement, but also quantify the risks of never UUI, de novo UUI, resolved UUI, and refractory UUI after surgery.

### CONCLUSIONS

Counseling and expectation management is a critical element of shared decision making when selecting incontinence treatment. Our study provides guidance for counseling women on the risks of never UUI, *de novo* UUI, resolved UUI, and refractory UUI, following sling placement at time of prolapse repair.

### **CONFLICTS OF INTEREST**

The authors have nothing to disclose.

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### **AUTHORS' CONTRIBUTIONS**

Research conception and design: Xinyuan Zhang and Amy D. Dobberfuhl. Data acquisition: Xinyuan Zhang, Robyn K. Shaffer, and Amy D. Dobberfuhl. Statistical analysis: Xinyuan Zhang. Data analysis and interpretation: Xinyuan Zhang and Amy D. Dobberfuhl. Drafting of the manuscript: Xinyuan Zhang and Amy D. Dobberfuhl. Critical revision of the manuscript: Xinyuan Zhang, Robyn K. Shaffer, and Amy D. Dobberfuhl. Obtaining funding: Amy D. Dobberfuhl. Administrative, technical, or material support: Xinyuan Zhang, Robyn K. Shaffer, and Amy D. Dobberfuhl. Supervision: Amy D. Dobberfuhl. Approval of the final manuscript: Amy D. Dobberfuhl.

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