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Has the use of preoperative urodynamics for stress urinary incontinence surgery changed following the VALUE study?

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Abstract

Aims: To assess whether routine urodynamic testing (UDT) in women undergoing slings for uncomplicated stress urinary incontinence (SUI) has decreased following publication of the landmark VALUE study, which recommended against routine UDT in uncomplicated SUI.

Methods: We identified women in the Virginia All Payers Claims Database diagnosed with SUI between 2011 and 2016 using International Classification of Disease (ICD) codes (N39.3, 625.6). Appropriate ICD/CPT (current procedural terminology) codes were used to exclude non-index patients (prior anti-incontinence/prolapse surgery, urge incontinence, neurogenic bladder). Beta regression was used to assess for changes in the monthly proportion of urethral slings with preoperative UDT. Interventional ARIMA modeling was used to assess for a relationship between the date of VALUE (The Value of Urodynamic Evaluation) publication and the incidence of slings with preoperative UDT.

Results: Analysis identified 6740 women with SUI undergoing sling placement, with 343 non-index patients excluded. Of 6397 remaining women, 4026 (62.9%) underwent preoperative UDT. The annual number of slings with preoperative UDT declined from 748 to 402 between 2011 and 2016. Beta regression analysis demonstrated a decrease in the proportion of slings with preoperative UDT over the study (68%, 2011; 58%, 2016), with a statistically significant decrease in the proportion of slings with UDT after May 2012 (β coefficient, −.0093; $P < .001$). Interventional ARIMA models showed a trend toward decreasing slings with preoperative UDT after the VALUE trial ($P = .057$).

Conclusions: Our analysis demonstrated a decrease in the proportion of women undergoing preoperative UDT in uncomplicated SUI patients following the VALUE study. Further research is needed to examine factors underlying UDT utilization trends and promote value-driven care.

KEYWORDS

mid-urethral slings, perioperative evaluation, stress urinary incontinence, urodynamics

Abbreviations: DO, detrusor overactivity; MUI, mixed urinary incontinence; MUS, mid-urethral sling; SUI, stress urinary incontinence; UDT, urodynamic testing; UUI, urge urinary incontinence; VLPP, valsalva leak point pressure.

1 | INTRODUCTION

Historically, urodynamic testing (UDT) has been commonly used in the preoperative evaluation of stress urinary incontinence (SUI) in an effort to guide surgical decision-making and optimize patient counseling. Specific to surgical choice, this trend related in part to data supporting the use of specific anti-incontinence surgeries based on urodynamic factors. For example, a prior study supported the preferential use of retropubic rather than transobturator mid-urethral slings (MUSs) in patients with intrinsic sphincteric deficiency given superior long-term cure rates.[1] In addition to surgical choice, urodynamic variables have also been traditionally thought to provide predictive value. Accordingly, a lower valsalva leak point pressure (VLPP) or detrusor overactivity (DO) are findings that have been commonly associated with increased risk of surgical failure.[2,3] Further, a variety of urodynamic variables have been used in an attempt to predict postoperative voiding dysfunction, including detrusor contraction strength and flow rate.[4]

More recently, multiple studies have suggested that urodynamic findings fail to provide significant value in predicting surgical success or complications following sling placement.[5,6] In a secondary analysis of the notable SISTEr (Stress Incontinence Surgical Treatment Efficacy Trial), Nager et al[7] found that preoperative UDT predicted neither treatment success nor postoperative voiding dysfunction. Subsequently, the notable 2012 The Value of Urodynamic Evaluation (VALUE) study provided additional high-quality evidence demonstrating that the use of UDT fails to improve outcomes or reduce adverse events.[8] Similar findings were demonstrated in the 2013 Dutch Value of Urodynamics before Stress Urinary Incontinence Surgery (VUSIS 2) trial and 2015 meta-analysis by Rachenani et al.[9,10]

These studies have led to organized efforts to revise guideline recommendations regarding the use of UDT in the preoperative evaluation of SUI. Whereas some professional societies previously recommended routine UDT before anti-incontinence surgery, more recent guideline statements suggest that UDT in uncomplicated SUI patients is not beneficial.[7,11] Accordingly, the AUA/SUFU updated 2017 Guideline for the surgical treatment of female SUI supports the avoidance of UDT for the index patient.[12] Similarly, the European Urology Association 2018 Guidelines for urinary incontinence provides a "strong" recommendation against the use of routine urodynamics in the evaluation of uncomplicated SUI.[13]

Given this background, we sought to assess the rate of UDT in patients undergoing sling placement in a general population, with a focus on the comparison of utilization trends before and after the VALUE study publication.

2 | SUBJECTS AND METHODS

2.1 | Data and outcomes

After obtaining institutional review board approval (protocol #20794), we analyzed data from the Virginia All-Payer Claims Database (VAPCD) from 2011 through 2016. Established in 2011, the VAPCD includes medical claims from Virginia state residents insured through Medicare, Medicaid, and private commercial insurers. International Classification of Disease (ICD) 9th and 10th generation codes were used to identify adult female patients (age $\geq$ 21 years) diagnosed with SUI (codes N393 or 625.6). Current procedural terminology (CPT) codes were used to identify urodynamic procedures (codes 51726, 51727, 51728, 51729, 51797). Urethral sling procedures were identified via CPT code 57288.

Based on the VALUE trial and AUA/SUFU Guideline suggesting the limited value of preoperative UDT specifically in "index" and "uncomplicated" patients, respectively, we sought to exclude non-index patients from our analysis. Accordingly, given suggested criteria for non-index patients provided in these publications, we used appropriate CPT and ICD codes to exclude patients with a history of prior anti-incontinence or pelvic organ prolapse surgery and neurogenic bladder. In addition, we excluded patients with pre-existing ICD codes for overactive bladder and urge incontinence recorded before sling placement. Although the presence of mixed urinary incontinence (MUI) is not generally considered a strict criterion for non-index status, these publications forward that index patients should be stress-predominant. Given the limitations inherent to claims analyses, we were unable to determine incontinence subtype predominance in patients with MUI and, thus, excluded patients accordingly.

In patients undergoing multiple sling procedures during the study period, only the first procedure was used for our analysis. As a control, we also queried the number of patients undergoing hysterectomy (CPT 58541-58544, 58550-58554, 58570-57572) during the study period to demonstrate that a decrease in sling or UDT was not artifactually due to a decrease in the population captured in our data set. Accordingly, given publicly reported data demonstrating stability to the national rate of hysterectomy over the time period of our study, we sought to confirm a stable rate of hysterectomies performed in our cohort.

2.2 | Analysis

Descriptive analyses were performed to identify cumulative SUI diagnoses, urodynamic procedures, and urethral

slings over the study period. In addition, analysis of the number of slings with associated preoperative UDT was assessed, with sling procedures categorized as being associated with preoperative UDT based on the presence of UDT claim within the 6 months before sling placement. To assess for changes in the monthly proportion of urethral slings with preoperative urodynamic evaluation, a beta regression with a logit link was performed. To assess for a relationship between the date of VALUE study publication and the incidence of both slings with preoperative UDT and slings without preoperative UDT, we performed interventional ARIMA models with a step function evaluating for a significant change specifically at the time of study publication (May 2012). The R programming language version 3.4.1 (Vienna, Austria) was used for all analyses with a *P*-value (two-sided) less than .05 considered statistically significant.

3 | RESULTS

VACPD analysis identified 44 562 women with at least one diagnosis of SUI over the study period. Among these women, 11 204 (25.1%) and 7197 (16.2%) underwent UDT and urethral sling placement, respectively. Whereas the trends for SUI diagnoses remained stable across the study period, a sustained decline in UDT was seen (2919 [2011]; 1283 [2016]). At the same time, control analysis of the number of hysterectomies was constant throughout the study period, suggesting against a decrease in the at-risk population.

A total of 209, 131, and 3 patients were excluded due to prior anti-incontinence or pelvic organ prolapse surgery, overactive bladder/mixed incontinence, and neurogenic bladder, respectively. Accordingly, 6397 women with SUI undergoing sling placement remained for analysis and had a mean age of 53.5 years (95% confidence interval, 53.2-53.8). Of these women, preoperative UDT was performed in 62.9% (4026/6397).

The trends in urethral slings performed both with and without UDT are illustrated in Figure 1. Accordingly, the number of slings with preoperative UDT decreased from 748 to 402 in comparison of annuals totals in 2011 vs 2016. However, the number of slings without preoperative UDT also decreased throughout the study period (358 [2011] vs 299 [2016]), indicating a general decrease in sling placements overall.

While both those slings with and without preoperative UDT were decreasing, beta regression analysis demonstrated a greater rate of decline in subset of women with preoperative UDT as compared to those without. Accordingly, a statistically significant decrease in the proportion of slings with UDT after May 2012 was observed (β coefficient, −.0093; $P < .001$) (Figure 2). Therefore, our model estimates that the ratio of those with vs without preoperative UDT has decreased by a mean of 0.0093 per month. For instance, if the proportion began at 0.5 (50% undergoing UDT), in 1 year the proportion would expect to decrease to 0.47 (47% undergoing UDT) according to our model.

Interventional ARIMA modeling to assess for a significant change, specifically at the time of study publication is illustrated in Figure 3. This evaluates whether there is a significant difference in the time series model before, compared to after the specified date (publication of the VALUE study in this study). Accordingly, a trend toward a decrease in slings with preoperative UDT occurring at the May 2012 publication of the VALUE

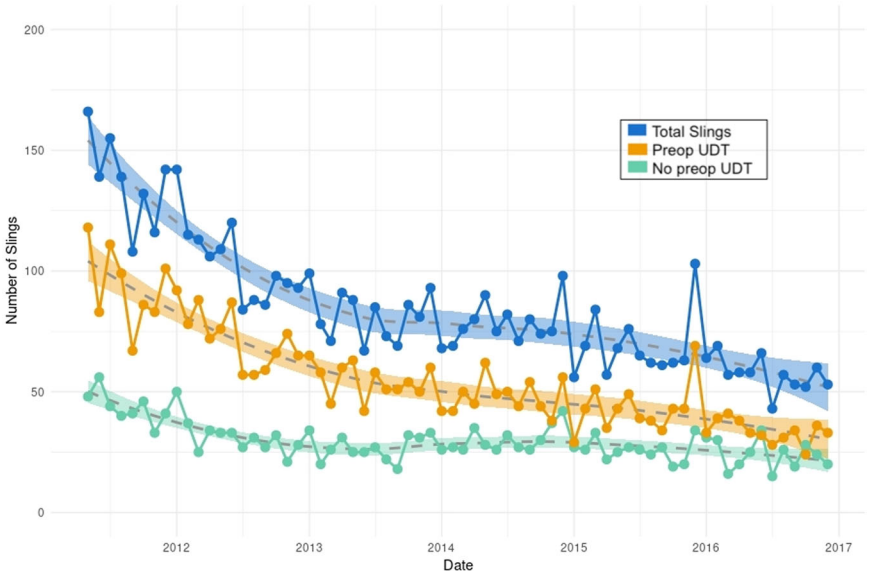

FIGURE 1 Trends in the urethral sling placements with and without preoperative urodynamic testing

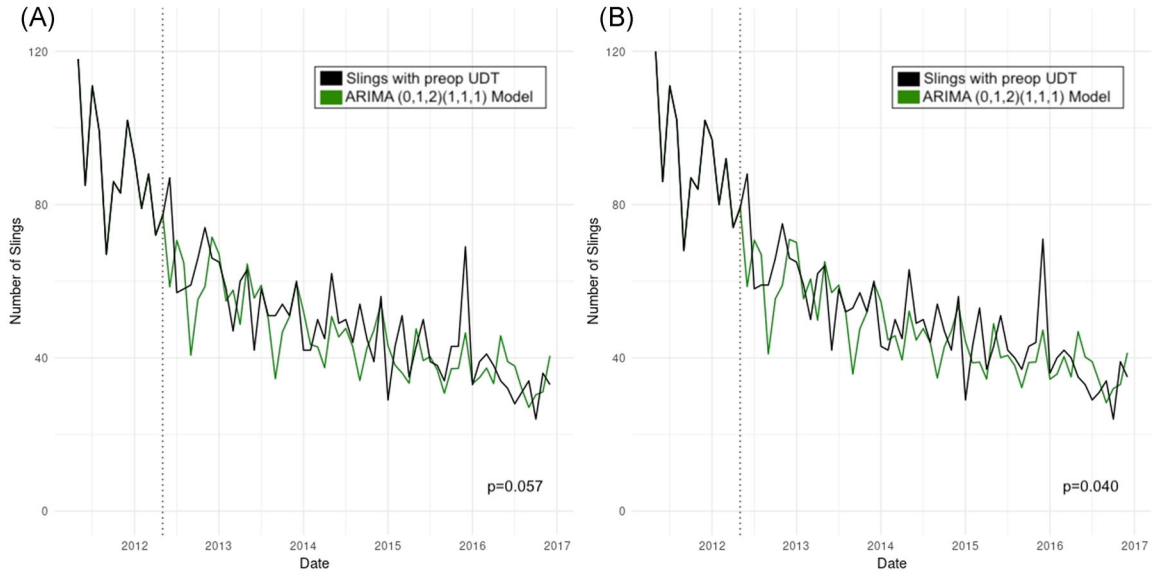

FIGURE 2 Monthly slings with preoperative urodynamic testing in relation to publication of VALUE study (vertical line). Analyses performed with (A) and without (B) exclusion criteria

study was seen ($P = .057$). Sensitivity analysis was then performed by removing non-index exclusion criteria. This analysis also revealed a significant decrease in the number of slings with preoperative UDT ($P = .040$).

4 | DISCUSSION

To our knowledge, this study represents the first directed assessment of preoperative UDT trends for uncomplicated SUI in a generalized patient population following publication of the VALUE study. Our data reveal several important findings. Foremost, we observed a 10 percentage point decline to the proportion of sling patients undergoing UDT preoperatively (68% to 58%). Further, our analysis demonstrated a change in the rate of preoperative UDT occurring specifically around the time of VALUE publication and a persistent reduction through 2016 ($P < .001$).

These findings are seen within the context of a sustained decline in sling placements observed in our study despite a stable number of women diagnosed with SUI. This decline is most likely related to the effects of the 2008 FDA Public Health Notification regarding complications associated with transvaginal placement of mesh in the treatment of pelvic organ

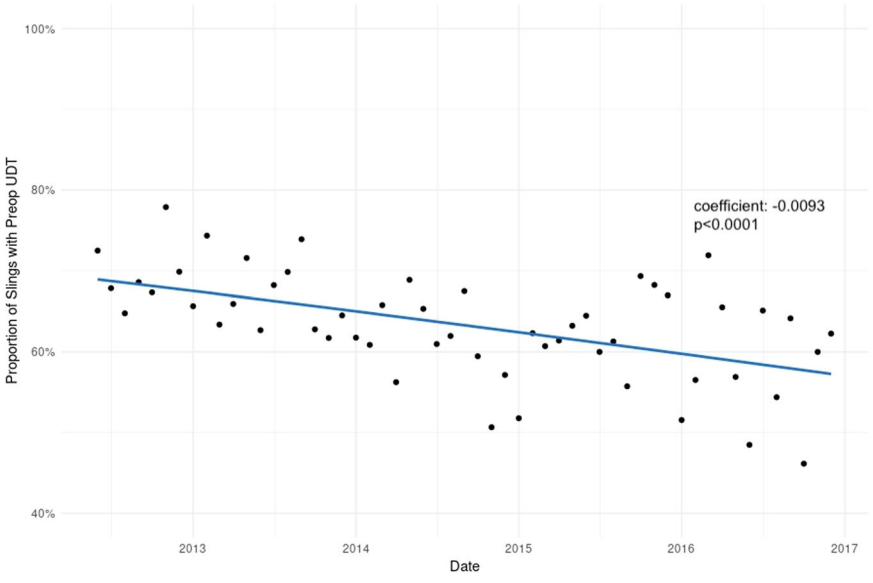

FIGURE 3 Proportion of slings with preoperative urodynamic testing from date of VALUE study publication through end of study period. VALUE, The Value of Urodynamic Evaluation

prolapse and SUI.[14] Previous study evaluating trends following the Food and Drug Administration (FDA) notification has demonstrated a decrease in the use of synthetic MUS. Accordingly, Rac et al[15] reported a trend toward a decrease in mesh slings between 2007 and 2013. In addition, Palmerola et al[16] recently reported an initial decline in sling placement after the 2011 FDA notification, with a subsequent increase following the 2014 AUGS/SUFU position statement. Our data suggest a continued decline in MUS use through at least 2016. Nonetheless, even in the setting of fewer sling placements, our analysis demonstrates a sustained reduction in the proportion of surgical patients undergoing preoperative UDT.

Prior investigation has assessed UDT trends following the VALUE study in a more narrow patient population. In a Southern California managed care population of 15 711 women undergoing sling placement, Lippmann et al[17] demonstrated a decrease of 19 percentage points (39% to 20%) in preoperative UDT. Similarly, Lloyd et al[18] reported a preoperative UDT decrease of 29 percentage points in the analysis of 387 women undergoing MUS at the Cleveland Clinic. Finally, in a recent survey-based study assessing the impact of the Dutch VUSIS 2 trial on UDT use in the Netherlands, just 17% of Dutch providers reported use of preoperative UDT for uncomplicated SUI as compared to the previously reported 34% rate.[19]

Our investigation adds to the literature in several important ways. First, we used interventional ARIMA models, which are less susceptible to typical confounding as they model an underlying long-term trend.[20] Prior cohort studies with simple pre vs post comparisons that do not account for this are more susceptible to unmeasured confounding. We paired this with a beta regression that allowed for estimation of the rate of decrease in the proportion of slings with preoperative UDT and also has greater power for hypothesis testing than simple pre vs post comparison.[20]

Second, this study captures a heterogeneous combination of practice settings and payers. Accordingly, our analysis reflects a variety of providers (eg, urologist, gynecologist) and practice (eg, academic, private) characteristics that are important to our understanding of UDT practice patterns. Prior investigation has demonstrated a larger decrease in UDT use when comparing urologists with gynecologists and hypothesized that differences in training and clinical practices are likely contributors.[18] Similarly, practice setting is important, and it is possible that the decline observed by Lippmann et al in the analysis of Kaiser Permanente UDT trends may not be observed across different care delivery systems or in fee-for-service payment models. Finally, the introduction of clinical practice changes may be facilitated in single-institution academic settings, as reported by Lloyd et al. Indeed, that study's primary investigator also practiced at a site for the VALUE study, which could suggest a comprehensive understanding of related guidelines and support for their implementation. Indeed, these factors likely underscore the more modest reduction in UDT seen in our investigation compared to prior study, highlighting the importance of a wider analysis and strength of the patient population in our study.

The modest decline in preoperative UDT observed in our investigation highlights the difficult nature of guideline adherence. Indeed, even with this reduction, our analysis revealed that more than half of patients continue to undergo UDT before sling placement. Within the urologic community, numerous evidence-based guidelines and best practice statements exist in an effort to support consistency and quality of patient care. Even so, multiple investigations demonstrate poor adherence to established urologic guidelines.[21-23] A related study has identified barriers to physician adherence with guidelines and include a lack of physician familiarity with guidelines and costs related to guideline implementation.[24] Further, physicians may consider guidelines as factors that can impede autonomy and flexibility, thereby deleteriously affecting their relationship with patients.[24]

In addition to promoting high-quality care, guideline implementation can also play a significant role in reducing the cost of care. Indeed, the cost of routine preoperative UDT in SUI patients is significant. Accordingly, secondary cost-effectiveness analysis of the VALUE study projected an annual savings of $13 to 34 million (in 2014 dollars) given a 30% decrease in urodynamics use.[25] Similarly, Lippmann et al estimated a cost savings of at least $400 000 in comparing UDT volume at Kaiser Permanente Southern California in the periods before and after the VALUE publication. Given the widespread movement within the healthcare system toward value-based care, placing focus on avoiding unnecessary UDT is important to the urologic and gynecologic communities.

The limitations of this study include those inherent to health claims database analyses such as coding inconsistencies and lack of clinical detail. Accordingly, given the absence of clinical records, we were unable to identify patients with stress-predominant MUI and thus excluded patients with MUI. Future evaluation of UDT trends in this subset of patients is valuable. Further, we were unable to capture clinical information such as active prolapse and post-void residual. Criteria such as active high-grade prolapse or elevated post-void residual are suggested as criteria to define non-index/complicated patients, and such clinical information may be important

to guiding choice for preoperative UDT. Finally, information on the type of provider (urologist or general medicine practitioner) is not available in our data set for subgroup analysis. Despite these limitations, our study is strengthened by the variety of patients across different providers and care settings captured through a claims analysis. In addition, the statistical methods used in our analysis allowed for assessment of this larger group of patients while inherently accounting for confounding and strengthening related conclusions.

In conclusion, a sustained modest decrease in the proportion of slings with preoperative UDT was seen from 2011 through 2016. A trend toward a greater decline in slings with preoperative UDT was seen at the time of VALUE study publication. Nonetheless, the proportion of women undergoing UDT before sling placement remains significant. Future research is needed to identify reasons underlying the continued use of UDT in uncomplicated patients. In addition, future efforts are needed to promote guideline implementation and facilitate value-driven care.

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REFERENCES

1. Schierlitz L, Dwyer PL, Rosamilia A, et al. Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. *Obstet Gynecol*. 2012;119:321-327.
2. O'Connor RC, Nanigian DK, Lyon MB, Ellison LM, Bales GT, Stone AR. Early outcomes of mid-urethal slings for female stress urinary incontinence stratified by valsalva leak point pressure. *Neurourol Urodyn*. 2006;25:685-688.
3. Paick JS, Oh SJ, Kim SW, Ku JH. Tension-free vaginal tape, suprapubic arc sling, and transobturator tape in the treatment of mixed urinary incontinence in women. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19:123-129.
4. Wang A, Chen M. The correlation between preoperative voiding mechanism and surgical outcome of the tension-free vaginal tape procedure, with reference to quality of life. *BJU Int*. 2003;91:502-506.
5. Rodríguez LV, de Almeida F, Dorey F, Raz S. Does valsalva leak point pressure predict outcome after the distal urethral polypropylene sling? Role of urodynamics in the sling era. *J Urol*. 2004;172:210-214.
6. Bai SW, Jung YH, Jeon MJ, Jung DJ, Kim SK, Kim JW. Treatment outcome of tension-free vaginal tape in stress urinary incontinence: comparison of instrinsic sphincter deficiency and noninstrinsic sphincter deficiency patients. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007;18:1431-1434.
7. Nager CW, FitzGerald M, Kraus SR, et al. Urodynamic measures do not predict stress continence outcomes after surgery for stress urinary incontinence in selected women. *J Urol*. 2008;179:1470-1474.
8. Nager CW, Brubaker L, Litman HJ, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med*. 2012;366(21):1987-1997.
9. Van Leijsen SA, Kluivers KB, Mol BW, et al. Value of urodynamics before stress urinary incontinence surgery: a randomized controlled trial. *Obstet Gynecol*. 2013;12:999-1008.
10. Rachaneni S, Latthe P. Does preoperative urodynamics improve outcomes for women undergoing surgery for stress urinary incontinence? A systematic review and meta-analysis. *BJOG*. 2015;122:8-16.
11. Ghoniem G, Stanford E, Kenton K, et al. Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19:5-33.
12. Kobashi KC, Albo ME, Dmochowski RR, et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. *J Urol*. 2017;198:875-883.
13. Burkhard FC, Bosch JLHR, Cruz F, et al. *EAU Guidelines on Urinary Incontinence in Adults*. European Association of Urology, 2018. https://uroweb.org/wp-content/uploads/EAU-Guidelines-on-Urinary-Incontinence-2018-large-text.pdf. Accessed 21 September 2019.
14. Food and Drug Administration. FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. http://wayback.archive-it.org/7993/20170111190506/, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm. Accessed 24 September 2019.
15. Rac G, Younger A, Clemens JQ, et al. Stress urinary incontinence surgery trends in academic female pelvic medicine and reconstructive surgery urology practice in the setting of the food and drug administration public health notifications. *Neurourol Urodyn*. 2017;36:1155-1160.
16. Palmerola R, Peyronnet B, Rebolos M, et al. Trends in stress urinary incontinence surgery at a tertiary center: midurethral sling use following the AUGS/SUFU position statement. *Urology*. 2019;131:71-76.
17. Lippmann QK, Diwadkar GB, Zhou H, Menefee SA. Trends in urodynamics study utilization in a Southern California managed care population. *Am J Obstet Gynecol*. 2015;213(5):724 (e1-e6).
18. Lloyd J, Dielubanza E, Goldman H. Trends in urodynamic testing prior to midurethral sling placement—what was the value of the VALUE trial? *Neurourol Urodyn*. 2017;37:1046-1052.
19. Mengerink BB, Nelen W, van Leijsen S, Heesakkers J, Kluivers KB. De-implementation of urodynamics in The Netherlands after the VALUE/VUSIS-2 results: a nationwide survey. *Int Urogynecol J*. 2018;29:1261-1267.
20. Bernal J, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial. *Int J Epidemiol*. 2017;46:348-355.
21. Tobert CM, Nepple KG, McDowell BD, et al. Compliance with American Urological Association guidelines for nonmuscle invasive bladder cancer remains poor: assessing factors

associated with noncompliance and survival in a rural state. *Urology*. 2019;132:150-155. [Epub ahead of print].
22. Shapiro D, Kamnetz S, Le B. Vasectomy practice patterns among family medicine physicians and compliance with the American Urological Association 2012 vasectomy guidelines. *Urology*. 2017;109:115-120.
23. Strope SA, Elliott SP, Saigal CS, et al. Urologist compliance with AUA best practice guidelines for benign prostatic hyperplasia in Medicare population. *Urology*. 2011;78:3-9.
24. Baiardini I, Braido F, Bonini M, Compalati E, Canonica GW. Why do doctors and patients not follow guidelines? *Curr Opin Allergy Clin Immunol*. 2009;9:228-233.
25. Norton PA, Nager CW, Brubaker L, et al. The cost of preoperative urodynamics: a secondary analysis of the VALUE trial. *Neurourol Urodyn*. 2016;35:81-84.

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