

# Urologic Injury and Fistula After Hysterectomy for Benign Indications

Kai B. Dallas, MD, Lisa Rogo-Gupta, MD, and Christopher S. Elliott, MD, PhD

**OBJECTIVE:** To explore the rates and risk factors for sustaining a genitourinary injury during hysterectomy for benign indications.

**METHODS:** In this population-based cohort study, all women who underwent hysterectomy for benign indications were identified from the Office of Statewide Health Planning and Development databases in California (2005–2011). Genitourinary injuries were further classified as identified at the time of hysterectomy, identified after the date of hysterectomy; or unidentified until a fistula developed.

**RESULTS:** Of the 296,130 women undergoing hysterectomy for benign indications, there were 2,817 (1.0%) ureteral injuries, 2,058 (0.7%) bladder injuries and 834 (0.3%) genitourinary fistulas (80/834 of which developed after an injury repair). Diagnosis was delayed in 18.6% and 5.5% of ureteral and bladder injuries, respectively. Subsequent genitourinary fistula development was lower if the injury was identified immediately (compared with delayed) for both ureteral (0.7% vs 3.4% odds ratio [OR] 0.28; 95% CI 0.14–0.57) and bladder injuries (2.5% vs 6.5% OR 0.37; 95% CI 0.16–0.83). Indwelling ureteral stent placement alone was more successful in decreasing the risk of a second ureteral repair for immediately recognized ureteral injuries (99.0% vs 39.8% for delayed injuries). With multivariate adjustment, prolapse repair

(OR 1.44, 95% CI 1.30–1.58), an incontinence procedure (OR 1.40, 95% CI 1.21–1.61), mesh augmented prolapse repair (OR 1.55, 95% CI 1.31–1.83), diagnosis of endometriosis (OR 1.46, 95% CI 1.36–1.56), and surgery at a facility in the bottom quartile of hysterectomy volume (OR 1.37, 95% CI 1.01–1.89) were all associated with an increased likelihood of a genitourinary injury. An exclusively vaginal (OR 0.56, 95% CI 0.53–0.64) or laparoscopic (OR 0.80, 95% CI 0.75–0.86) approach was associated with lower risk of a genitourinary injury as compared with an abdominal approach.

**CONCLUSION:** Genitourinary injury occurs in 1.8% of hysterectomies for benign indications; immediate identification and repair is associated with a reduced risk of subsequent genitourinary fistula formation.

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From the Stanford University School of Medicine, Stanford, and Santa Clara Valley Medical Center, San Jose, California.

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Corresponding author: Kai B. Dallas, MD, Department of Urology, Stanford School of Medicine, Stanford, CA; email: kai.dallas@stanford.edu.

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Hysterectomy is a common operation, with approximately 600,000 performed annually in the United States.<sup>1</sup> Genitourinary injuries after hysterectomy are reported to occur at rates of 0.03–1.5% (ureteral), 0.2–1.8% (bladder) and 0.1–0.3% (fistula).<sup>2–16</sup> These injuries can be complicated by being unrecognized at the time of initial surgery in up to 87% of cases.<sup>2–13</sup> The morbidity of a genitourinary injury after hysterectomy often necessitates reoperation<sup>6,12,13</sup> and when compared with hysterectomy without urologic injury, the risk of permanent disability or litigious action has been shown to increase by 4 times and 10 times, respectively.<sup>7,13</sup> When considered in the context that up to one third of women in the United States will undergo a hysterectomy by age 60, the burden of posthysterectomy genitourinary complications is not trivial.<sup>14</sup>

Despite its importance, the data regarding genitourinary injury after hysterectomy is limited. Specifically, most studies focus on only one type of urologic injury, have short follow-up times that potentially underestimate the true risk of delayed injury presentation or are limited to small cohorts within a single



institution. In an effort to improve the existing literature, we aimed to explore our primary outcome of the combined urologic injury rates (ureteral, bladder and genitourinary fistula) identified at the time of, or in a delayed fashion, after hysterectomy performed for benign indications in a large contemporary population-based data set with long term follow-up. As a secondary outcome, we aimed to explore specific risk factors associated with the occurrence of a urologic injury in women undergoing hysterectomy for benign indications.

## METHODS

With approval from the California Protection of Human Subjects, data from the Office of Statewide Health Planning and Development for the state of California were used to retrospectively identify all women who underwent a hysterectomy for benign indications (Appendix 1, available online at <http://links.lww.com/AOG/B439>) during the years 2005–2011 (this study was institutional review board exempt because all patient information is deidentified in the databases). The Office of Statewide Health Planning and Development is a state office that collects, analyzes, and publishes data regarding health care with the aim to maintain quality. California-licensed hospitals are required to submit reports to Office of Statewide Health Planning and Development, and the data reported are screened for quality. Any record found to have an invalid entry or to contain incomplete or illogical data is deemed erroneous; a hospital's data must have an error rate of under 2.0% to be accepted.<sup>15</sup> We excluded those patients who had either a past or current medical history of malignancy (gynecologic, urologic, or gastroenterologic) (Appendix 2, available online at <http://links.lww.com/AOG/B439>).

The Office of Statewide Health Planning and Development databases include the Patient Discharge and Ambulatory Surgery data sets, which together cover every inpatient (Patient Discharge) and outpatient (Ambulatory Surgery) surgical encounter within the entire state of California (with the exception of Veterans Affairs facilities). Each encounter includes up to 20 surgical procedure codes (the Patient Discharge data set uses International Classification of Diseases, 9th Revision [ICD-9] procedure codes, and the Ambulatory Surgery data set uses Current Procedure Terminology codes). The databases also include up to 25 associated diagnosis codes (ICD-9) pertaining to the admission diagnoses, procedure diagnoses, and the patient's past medical history. Finally, the databases include a unique patient

identifier, which allows longitudinal follow-up between encounters.

For each study participant, we identified the hysterectomy approach (vaginal, abdominal, laparoscopic, and laparoscopic-assisted vaginal) as well as the presence of concomitant surgeries including incontinence operations and pelvic organ prolapse repairs with or without the use of mesh (Appendix 1, <http://links.lww.com/AOG/B439>). We identified cases that were converted to open with the ICD-9 diagnosis code V64.41, because we wanted to control for the fact that these types of cases have potentially higher injury rates and thus could falsely inflate the injury rate of an open approach. Demographic information including age, race, payer status, and comorbid conditions known to be associated with surgical complications (diabetes mellitus, obesity, hypertension, and vascular disease) were also identified. In addition, we also classified the indication for hysterectomy into three diagnosis groups based on diagnosis codes including leiomyoma disease, abnormal uterine bleeding, and endometriosis (Appendix 3, available online at <http://links.lww.com/AOG/B439>). These groups were not considered to be mutually exclusive. We identified cases of obstetric hysterectomy by identifying those patients whose diagnosis for hysterectomy was specifically related to an obstetric complication (ie, 641.0–641.9, 635.1, 666.0–666.3). Additionally, we ranked facilities by the quartile of total hysterectomy volume over the study period to explore for its associations with urologic injury (fewer than 9, 9–64, 65–160, and more than 161 hysterectomies per year). Finally, because we were interested in exploring the association of cystoscopy with the identification of genitourinary injury, we identified cases where cystoscopy was performed using procedure codes (573.2, 52000). Specifically, we explored the frequency of cystoscopy by surgical approach and rates of injury whether a cystoscopy was coded or not.

Participants were categorized as having a genitourinary injury if they had a procedure code for a genitourinary repair intraoperatively or postoperatively (Appendix 3, <http://links.lww.com/AOG/B439>). Injuries were classified as either “identified-immediate” (repaired the day of hysterectomy), “identified-delayed” (repaired after the day of hysterectomy) or “unidentified.” An “unidentified” injury was defined as a genitourinary fistula repair after hysterectomy with no coding of a prior urologic injury repair. In women with identified injuries (identified-immediate or identified-delayed), we further noted those who developed a subsequent genitourinary fistula.



We performed univariate and multivariate analysis of the demographic and surgical characteristics of our cohort to measure associations with the occurrence of genitourinary injury during hysterectomy. We additionally examined women who were more likely to have injuries that were not identified-immediate. For univariate comparisons, we used the  $\chi^2$  test and univariate logistic regression for categorical variables and the student's *t*-test for continuous variables. Multivariate analysis was performed using multivariable logistic regression models for the occurrence of a genitourinary injury. Independent variables included individual demographics, past medical history, surgical approach, reason for hysterectomy, presence of concomitant surgery and the surgical volume of the facility where hysterectomy was performed.

Because ureteral stenting was the most common repair performed after a hysterectomy, we analyzed the proportion of women who went on to have a formal ureteral repair operation owing to failure of endoscopic management and subcategorized these based on the timing of stent placement (identified-immediate compared with identified-delayed). To account for the possibility that an indwelling ureteral stent was placed merely due to a high index of suspicion of injury and not due to a true injury, we further performed a sensitivity analysis based on the presence or absence of a diagnosis code that might suggest ureteral injury (Appendix 4, available online at <http://links.lww.com/AOG/B439>). Because there were many possible diagnosis codes that suggest a ureteral injury (ie, E878.8- "Accidental cut, puncture, perforation during surgery"), we included a broad list of possible codes.

All statistical analysis was performed with R 3.5.0 (<https://www.R-project.org/>). A two-sided  $P < .05$  was taken to indicate statistical significance.

## RESULTS

A total of 296,130 women underwent a hysterectomy procedure for benign indications during the study period. Most hysterectomies were performed as an inpatient procedure (92.5%,  $n=274,065$ ). The mean age of the cohort was 47.4 years and the study group varied in terms of race and payer status (Table 1). Most women had their surgical approach detailed (96.5%), with an open abdominal surgery being the most common (36.9%), followed by pure laparoscopic (26.1%), pure vaginal (21.2%), and a laparoscopic-assisted vaginal approach (12.3%). When examining the indication for hysterectomy, 159,907 (54.0%) were for leiomyomas, 55,683 (18.8%) were for endometri-

osis, and 86,661 (29.3%) were for uterine bleeding diagnoses with many women (24%) having multiple diagnoses (Table 1). In addition to hysterectomy, a total of 49,552 women (16.7%) underwent a concomitant pelvic organ prolapse repair and 8,734 (2.9%) underwent a concomitant incontinence procedure.

Of the 296,130 women who underwent hysterectomy, 5,455 (1.8%) suffered at least one genitourinary injury including 2,817 (1.0%) ureteral injuries (2,042 treated with an indwelling ureteral stent alone), 2,058 (0.70%) bladder injuries and 834 resultant fistulas (0.28%) (Fig. 1). Of women with a genitourinary injury, 174 (3.2%) sustained concomitant bladder and ureteral injuries. Overall, 4,701 of genitourinary injuries during a hysterectomy (86.2%) were identified with the other 754 (13.8%) unidentified (patient presented with a delayed fistula). Of the 4,701 patients who sustained an identified injury before fistula formation, 536 (11.4%) were identified in a delayed fashion (not at the time of hysterectomy). Overall, 18.6% of ureteral injuries and 5.5% of bladder injuries were of the identified-delayed type (including combined bladder and ureteral injuries). The rate of subsequent genitourinary fistula formation was lower if the injury repair was identified-immediate compared with identified-delayed for both ureteral (0.7% vs 3.4% odds ratio [OR] 0.28; 95% CI 0.14–0.57) and bladder injuries (2.5% vs 6.5% OR 0.37; 95% CI 0.16–0.83) (Fig. 1). The rate of fistula formation was also higher in cases of combined bladder and ureteral injury (as compared with single injuries) for both immediately identified (1.4% vs 3.7% OR 2.65; 95% CI 1.12–6.23) and delayed identified injuries (2.7% vs 25.0% OR 12.26; 95% CI 2.99–50.24). In cases of delayed repair of any urologic injury, the median time to repair was 84 days (interquartile range: 21–274); the time to fistula repair in cases in which no prior bladder or ureteral repair was performed was 106 days (interquartile range: 48–305 days).

Indwelling stent placement as the sole means to treat a ureteral injury was more successful in decreasing the rate of subsequent ureteral repair surgery when it was identified immediately (99.0% did not require a future formal operative repair) as opposed to being of the identified-delayed type (60.2% required subsequent ureteral repair, OR 144.15, 95% CI 82.27–252.58). When considering the 1,778 patients who had an indwelling ureteral stent placed at the time of hysterectomy (ie, identified-immediate injuries managed with an indwelling ureteral stent alone) a diagnosis code of a ureteral injury was only present in 332 cases (18.7%). There was a higher rate of subsequent formal repair of the ureter in patients



**Table 1. Baseline Characteristics of Women Undergoing Hysterectomy for Benign Indications at Nonfederal Facilities in the State of California (2005–2011) and Overall Rate of a Genitourinary Injury**

| Total Cohort (N=296,130)                          | Injury (n=5,455 [1.8]) | OR (95% CI)      | P     |
|---|------------------------|------------------|-------|
| Age (y, mean=47.43)                               | 47.42                  | NA               | .66   |
| Approach*   |                        |                  |       |
| Abdominal (n=109,188)                             | 2,219 (2.0)            | Ref              | Ref   |
| Laparoscopic (n=77,415)                           | 1,281 (1.7)            | 0.82 (0.76–0.87) | <.001 |
| Vaginal (n=62,860)                                | 924 (1.5)              | 0.72 (0.67–0.78) | <.001 |
| LAVH (n=36,348)                                   | 607 (1.7)              | 0.82 (0.75–0.90) | <.001 |
| Race  |                        |                  |       |
| White (n=160,857)                                 | 2,964 (1.8)            | Ref              | Ref   |
| Black (n=27,602)                                  | 438 (1.6)              | 0.86 (0.78–0.94) | .003  |
| Hispanic (n=72,589)                               | 1,290 (1.8)            | 0.96 (0.90–1.03) | .270  |
| Asian (n=23,135)                                  | 549 (2.4)              | 1.29 (1.18–1.42) | .001  |
| Other (n=11,947)                                  | 214 (1.8)              | 0.97 (0.84–1.11) | .690  |
| Payer   |                        |                  |       |
| Private (n=220,270)                               | 3,991 (1.8)            | Ref              | Ref   |
| Medicare (n=25,317)                               | 491 (1.9)              | 1.09 (0.99–1.20) | .070  |
| Medicaid (n=39,893)                               | 828 (2.1)              | 1.17 (1.08–1.26) | <.001 |
| Other (n=6,659)                                   | 145 (2.2)              | 1.23 (1.03–1.45) | .016  |
| POP repair (n=49,552)                             | 1,017 (2.1)            | 1.14 (1.06–1.22) | <.001 |
| Diagnosis <sup>†</sup>                            |                        |                  |       |
| Endometriosis (n=55,683)                          | 1,301 (2.3)            | Ref              | Ref   |
| Leiomyomas (n=159,907)                            | 2,890 (1.8)            | 0.77 (0.72–0.82) | <.001 |
| Bleeding (n=86,661)                               | 1,482 (1.7)            | 0.73 (0.67–0.78) | <.001 |
| Incontinence procedure (n=8,734)                  | 238 (2.7)              | 1.54 (1.34–1.76) | <.001 |
| Mesh augmentation (prolapse) (n=5,741)            | 177 (3.1)              | 1.72 (1.48–2.00) | <.001 |
| Comorbidity                                       |                        |                  |       |
| Diabetes mellitus (n=23,478)                      | 456 (1.9)              | 1.06 (0.96–1.17) | .23   |
| Hypertension (n=75,763)                           | 1,454 (1.9)            | 1.06 (1.00–1.12) | .07   |
| Obesity (n=14,614)                                | 295 (2.0)              | 1.10 (0.98–1.24) | .10   |
| Vascular disease (n=6,507)                        | 152 (2.3)              | 1.28 (1.08–1.51) | .003  |
| Bottom 25% facility volume <sup>‡</sup> (n=1,562) | 40 (2.6)               | 1.40 (1.01–1.90) | .03   |

OR, odds ratio; NA, not applicable; Ref, reference; LAVH, laparoscopic-assisted vaginal hysterectomy; POP, pelvic organ prolapse.

Data are n (%) unless otherwise specified.

\* A total of 11,000 patients (3.7%) did not have surgical approach detailed.

<sup>†</sup> Diagnosis groups were not mutually exclusive. Overall, 73,641 patients had none of these coded, 151,345 had one, 62,526 had two, and 8,618 had all three diagnoses coded.

<sup>‡</sup> Fewer than 61 procedures over the study period.

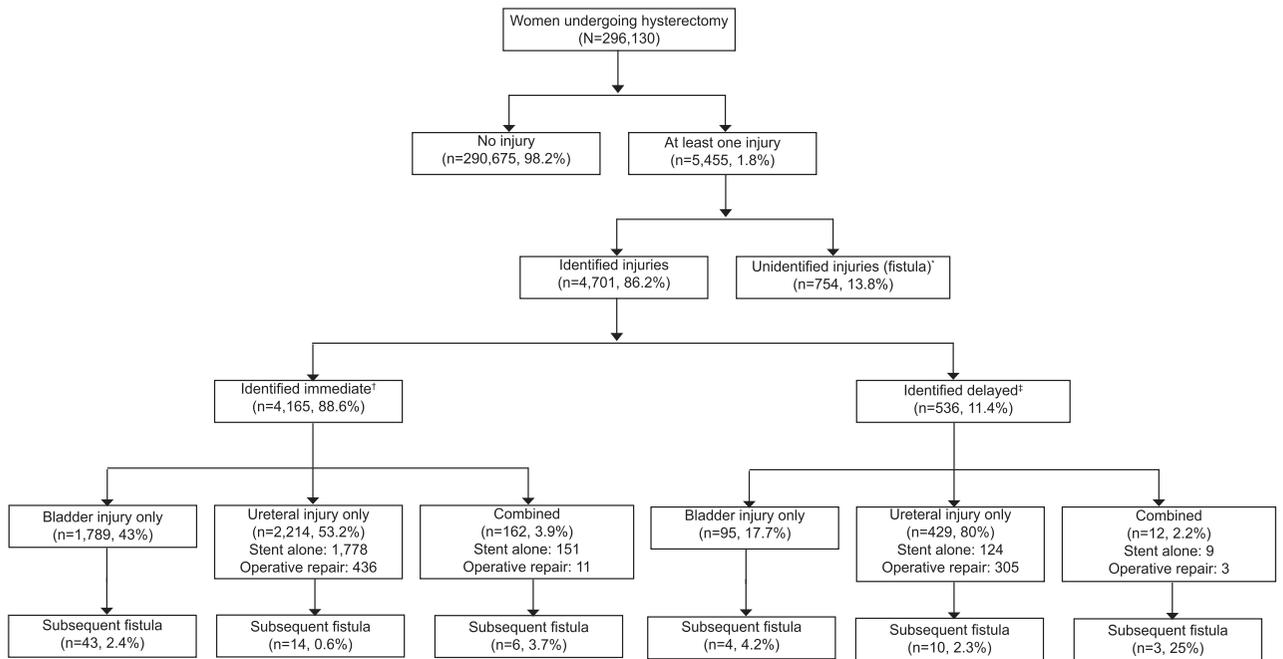
managed with indwelling ureteral stent placement if there was a diagnosis of ureteral injury present (3.3% vs 0.8% OR 2.55; 95% CI 1.36–4.78).

Genitourinary injuries at the time of hysterectomy were slightly more common in those undergoing an open abdominal approach (2.0%) compared with a vaginal (1.5%) or laparoscopic (1.7%) approach (OR 1.39; 95% CI 1.29–1.50 and OR 1.23; 95% CI 1.15–1.32, respectively). Injuries were also more common in cases with concomitant pelvic organ prolapse repair (2.1% vs 1.8%, OR 1.14; 95% CI 1.06–1.22), concomitant incontinence procedure (2.7% vs 1.8%, OR 1.54; 95% CI 1.34–1.76), or mesh use for prolapse repair (3.1% vs 1.8%, OR 1.72; 95% CI 1.48–2.00) (Table 1). There were a total of 3,823 cases in which there was a conversion to laparotomy, and the rate of injury was higher in these women (5.2% vs 1.8%, OR 3.04; 95% CI 2.68–

3.46). However, even when considering these patients as being in the laparoscopic group (ie, intention to treat), the injury rate in the open surgery cohort was still significantly higher (2.0% vs 1.8%,  $P=.014$ ).

Genitourinary injuries were also more common in cases in which there was a diagnosis of endometriosis (2.3%) as compared with a diagnosis of leiomyomas (1.8%, OR 0.77; 95% CI 0.72–0.82) or abnormal uterine bleeding (1.7%, OR 0.73; 95% CI 0.67–0.78). The genitourinary injury rate was also significantly higher in the 2,077 women identified who underwent an obstetric hysterectomy (7.0%) as compared with the rest of the cohort (OR 4.08; 95% CI 3.44–4.84). Finally, injuries were more common at facilities in the bottom quartile of overall hysterectomy surgical volume (2.6%) compared the rest of the cohort (1.8%) (OR 1.40; 95% CI 1.01–1.90).





**Fig. 1.** Injury and timing of presentation after hysterectomy for benign indications. \*Defined as subsequent repair of genitourinary fistula without any repair of the bladder or ureter prior. †Defined as a repair of the bladder or ureter on the same day hysterectomy was performed. ‡Defined as repair of the bladder or ureter more than 1 day after the hysterectomy. If a patient had only an indwelling stent placed at the time of hysterectomy, 17 would go on to have a formal operative repair in the future (1.0%) and 42 (2.4%) would have another stent placed in the future. There were 78 percutaneous nephrostomies placed at the time of the index surgery, and of these, 38 (48.7%) had another type of urologic repair at the same time. An additional 11 had a delayed repair and 29 (37.2%) had no definitive repair over the study period.

Dallas. *Urologic Injury After Hysterectomy*. *Obstet Gynecol* 2019.

Of the 5,455 women who sustained a genitourinary injury of some form, a total of 1,290 (23.6%) did not have their injuries identified immediately. An injury, if one occurred, was least likely to be of the delayed type in women undergoing an open approach (17.5%) as compared with those who had a vaginal (24.0%, OR 1.49; 95% CI 1.23–1.79) or laparoscopic approach (31.7% OR 2.18; 95% CI 1.86–2.56). The laparoscopic-assisted vaginal approach was associated with the lowest rate of immediate recognition of an injury, if one occurred (65.7%, OR 2.45; 95% CI 2.00–2.99). Injuries were also less likely to be identified if a concomitant pelvic organ prolapse repair was performed (OR 1.29; 95% CI 1.10–1.50) (Table 2).

Multivariate modeling revealed that concomitant prolapse repair (OR 1.44; 95% CI 1.30–1.58), an incontinence procedure (OR 1.40; 95% CI: 1.21–1.61), mesh augmented prolapse repair of a prolapse repair (OR 1.55; 95% CI 1.31–1.83), a diagnosis of endometriosis (OR 1.46; 95% CI 1.36–1.56), and surgery at a facility in the bottom quartile of hysterectomy volume (OR 1.37; 95% CI 1.01–1.89) were all associated with an increased likelihood of a genitourinary injury occurring. A purely vaginal (OR 0.56; 95% CI

0.53–0.64), laparoscopic (OR 0.80; 95% CI 0.75–0.86) or laparoscopic-assisted vaginal approach to hysterectomy (OR 0.77; 95% CI 0.70–0.84) were all associated with a lower risk of a genitourinary injury as compared with an abdominal approach (Table 3).

A concomitant cystoscopy was only coded in 18,013 cases of hysterectomy (6.4%). Cystoscopy was coded in 11.3% of exclusively vaginal hysterectomies, 8.7% of laparoscopic-assisted vaginal hysterectomies, 4.9% of exclusively laparoscopic hysterectomies, and 2.9% of abdominal hysterectomies. It was also more likely to be coded in cases where immediately identified injury occurred (Appendix 5, available online at <http://links.lww.com/AOG/B439>).

## DISCUSSION

In this population-based study of nearly 300,000 women undergoing a hysterectomy for benign indications, we found a combined genitourinary injury incidence of 18 per 1,000 patients (1.8%). Our study contributes to the current literature by not only completely assessing all types of genitourinary injury after hysterectomy, but also by examining the risk factors for sustaining or failing to recognize such



**Table 2. Rates of Nonimmediate Repairs\* of Genitourinary Injury After Hysterectomy for Benign Indications Performed at Nonfederal Facilities in the State of California (2005–2011)**

| Overall Injuries (n=5,455)                     | Nonimmediate Repair (n=1,290 [23.6]) | OR (95% CI)      | P     |
|--|--------------------------------------|------------------|-------|
| Age (y, mean=47.42)                            | 46.36                                | NA               | <.001 |
| Approach <sup>†</sup>                          |                                      |                  |       |
| Abdominal (n=2,219)                            | 389 (17.5)                           | Ref              | Ref   |
| Laparoscopic (n=1,281)                         | 406 (31.7)                           | 2.18 (1.86–2.56) | .001  |
| Vaginal (n=924)                                | 222 (24.0)                           | 1.46 (1.23–1.79) | .001  |
| LAVH (n=607)                                   | 208 (34.3)                           | 2.45 (2.00–2.99) | .001  |
| Race   |                                      |                  |       |
| White (n=2,964)                                | 729 (24.6)                           | Ref              | Ref   |
| Black (n=438)                                  | 99 (22.6)                            | 0.90 (0.30–1.13) | .365  |
| Hispanic (n=1,290)                             | 317 (24.6)                           | 1.00 (0.70–1.16) | .988  |
| Asian (n=549)                                  | 105 (19.1)                           | 0.73 (0.57–0.91) | .006  |
| Other (n=214)                                  | 40 (18.7)                            | 0.70 (0.49–0.99) | .053  |
| Payer  |                                      |                  |       |
| Private (n=3,991)                              | 983 (24.6)                           | Ref              | Ref   |
| Medicare (n=491)                               | 111 (22.6)                           | 0.89 (0.71–1.11) | .325  |
| Medicaid (n=828)                               | 157 (19.0)                           | 0.72 (0.59–0.86) | <.001 |
| Other (n=145)                                  | 39 (26.9)                            | 1.13 (0.77–1.62) | .535  |
| POP repair (n=1,017)                           | 280 (27.5)                           | 1.29 (1.10–1.50) | .001  |
| Diagnosis <sup>‡</sup>                         |                                      |                  |       |
| Endometriosis (n=1,301)                        | 268 (20.6)                           | 0.80 (0.68–0.92) | .003  |
| Leiomyomas (n=2,890)                           | 636 (22.0)                           | 0.82 (0.72–0.92) | .002  |
| Bleeding (n=1,482)                             | 379 (25.6)                           | 1.15 (1.01–1.33) | .041  |
| Incontinence procedure (n=238)                 | 50 (21.0)                            | 0.85 (0.61–1.16) | .328  |
| Mesh augmentation (prolapse) (n=177)           | 44 (24.9)                            | 1.07 (0.75–1.50) | .700  |
| Comorbidity                                    |                                      |                  |       |
| Diabetes mellitus (n=456)                      | 121 (26.5)                           | 1.18 (0.85–1.47) | .130  |
| Hypertension (n=1,454)                         | 388 (26.7)                           | 1.25 (1.09–1.43) | .002  |
| Obesity (n=295)                                | 80 (27.1)                            | 1.21 (0.93–1.58) | .150  |
| Vascular disease (n=152)                       | 43 (28.3)                            | 1.28 (0.89–1.82) | .173  |
| Bottom 25% facility volume <sup>§</sup> (n=40) | 12 (30.0)                            | 1.39 (0.68–2.67) | .345  |

OR, odds ratio; NA, not applicable; Ref, reference; LAVH, laparoscopic-assisted vaginal hysterectomy; POP, pelvic organ prolapse. Data are n (%) unless otherwise specified.

\* Defined as a repair of the bladder or ureter more than 1 day after the hysterectomy or subsequent fistula repair if no repair of bladder or ureter.

<sup>†</sup> A total of 424 patients (7.8%) did not have surgical approach detailed.

<sup>‡</sup> Diagnosis groups were not mutually exclusive. Overall 1,517 patients had none of these coded, 2,444 had one, 1,253 had two, and 241 had all three diagnoses coded.

<sup>§</sup> Less than 61 procedures over the study period.

injuries. Further, we also explore the effect of timing on repair. We observed that most injuries (76.4%) were identified at the time of surgery and immediately repaired. Overall, 18.6% of ureteral injuries and 5.5% of bladder injuries were of the identified-delayed type. Although the majority of fistulas occurred without a history of any repair, at a rate of 2.5 per 1,000 patients, there was an increased risk of fistula formation if the injury was repaired in a delayed fashion for both ureteral (0.7% vs 3.4%) and bladder injuries (2.5% vs 6.5%) compared with those that were of the identified-immediate type. Our results highlight that particular attention should be paid to those who sustain a ureteral and bladder injury combined, because the rate of fistula formation was twice as high for identified-immediate injuries and more than nine

times higher for identified-delayed injuries of this type (2.7% vs 25.0%). We found a high success rate of indwelling ureteral stent placement in decreasing the rate of future ureteral repair surgery for ureteral injuries if the injury was recognized immediately (99.0% success rate in the cohort overall and 96.7% success rate in the subcohort with a confirming diagnosis of ureteral injury). Conversely, indwelling stent placement performed in a delayed fashion was only effective in 39.8% of cases.

A major strength of our study is that it corroborates, on a population level, the findings of several smaller studies while additionally describing risk factors for sustaining an injury or failing to recognize an injury, if one occurred. We found similar overall rates of ureteric injury to previous studies of



**Table 3. Multivariate Model for Risk of Urologic Injury During Hysterectomy for Benign Indications Performed at Nonfederal Facilities in the State of California (2005–2011)**

|   | OR (95% CI)      | P     |
|---|------------------|-------|
| Age                                     | 1.00 (0.99–1.00) | .56   |
| Approach                                |                  |       |
| Abdominal                               | Ref              | Ref   |
| Vaginal                                 | 0.59 (0.53–0.64) | <.001 |
| Laparoscopic                            | 0.80 (0.75–0.86) | <.001 |
| LAVH                                    | 0.77 (0.70–0.84) | <.001 |
| Race                                    |                  |       |
| White                                   | Ref.             | Ref.  |
| Black                                   | 0.81 (0.73–0.90) | .001  |
| Hispanic                                | 0.92 (0.86–0.98) | .016  |
| Asian                                   | 1.22 (1.11–1.35) | <.001 |
| Other                                   | 0.88 (0.75–1.02) | .085  |
| Payer                                   |                  |       |
| Private                                 | Ref              | Ref   |
| Medicare                                | 1.04 (0.92–1.17) | .508  |
| Medicaid                                | 1.14 (1.05–1.24) | .002  |
| Other                                   | 1.27 (1.07–1.51) | .006  |
| POP repair                              | 1.44 (1.30–1.58) | <.001 |
| Incontinence procedure                  | 1.40 (1.21–1.61) | <.001 |
| Mesh augmentation (prolapse)            | 1.55 (1.31–1.83) | <.001 |
| Comorbidity*                            | 1.06 (1.02–1.10) | .006  |
| Diagnosis                               |                  |       |
| Leiomyomas                              | 1.05 (0.99–1.12) | .117  |
| Endometriosis                           | 1.46 (1.36–1.56) | <.001 |
| Bleeding                                | 0.98 (0.92–1.04) | .441  |
| Facility volume (quartile) <sup>†</sup> |                  |       |
| 4th                                     | Ref              | Ref   |
| 3rd                                     | 0.99 (0.93–1.05) | .688  |
| 2nd                                     | 0.99 (0.89–1.10) | .800  |
| 1st                                     | 1.37 (1.01–1.89) | .049  |

OR, odds ratio; Ref, reference; LAVH, laparoscopic-assisted vaginal hysterectomy; POP, pelvic organ prolapse.

\* For each additional comorbidity (of hypertension, diabetes mellitus, obesity, and vascular disease), the odds of an injury occurring increases by 1.06.

<sup>†</sup> 1st: fewer than nine hysterectomies over the study period; 2nd: 9–64 hysterectomies over the study period; 3rd: 65–160 hysterectomies over the study period; 4th: more than 161 hysterectomies over the study period.

hysterectomy for benign indications and lower rates of ureteral injuries identified in a delayed fashion compared with studies that included hysterectomy for malignancy.<sup>5</sup> We found that time to repair of a genitourinary injury that was missed was prolonged (median 84 days; interquartile range: 21–274 days), which is consistent with existing literature.<sup>5,16</sup> Our overall bladder injury rate is similar to the rate of 0.8% found in a meta-analysis of 79 studies<sup>6</sup> with a similar incidence of delayed identification. Our finding of a 0.3% fistula occurrence was identical to that of a nationwide cohort study from Sweden that included

182,641 women.<sup>16</sup> Analogous to other studies, we found an increased risk of fistula formation after any urologic injury, with a further increase in risk if the injury is repaired in a delayed fashion.<sup>5,17</sup> Our finding of a high success rate for ureteral injuries managed with an indwelling stent alone when identified immediately and a large decrease in effectiveness if stenting is performed in a delayed fashion is akin to the rates observed in smaller studies.<sup>18,19</sup>

We identified several patient factors associated with a small increased risk of an injury occurring including concomitant procedures (prolapse repair: 0.3% increased risk; incontinence procedure: 0.9% increased risk), surgical approach (open approach 0.5% increased risk), facility surgical volume, and diagnostic indication for hysterectomy (risk of injury was 0.5% greater in cases of endometriosis). These associations all remained significant with multivariate adjustment. One interesting finding is the highest rate of injury occurring in Asian women, whereas black race was protective from injury. One possible explanation for this finding might be the association of race with hysterectomy indication. Specifically, Asian women have the highest rates of endometriosis (the diagnosis associated with the highest risk of injury in our cohort) as the indication for hysterectomy,<sup>20</sup> whereas black women are more likely to undergo hysterectomy for leiomyoma disease (the diagnosis associated with a lower risk of injury in our cohort).<sup>20</sup>

It is not surprising that we find a significantly higher rate of genitourinary injury in the special case of women who underwent obstetric hysterectomy, where the risk of injury is four times higher in those with a gravid uterus (which would increase the technical challenge of the operation). Given that there are approximately 500,000 births in California per year,<sup>21</sup> and the incidence of obstetric hysterectomy in developed countries is estimated to be 0.05%<sup>22</sup> our identification of 2,077 obstetric hysterectomies over the 7-year study period (0.05%) is expected.

The association of genitourinary injury with route of hysterectomy is worthy of discussion—the American College of Obstetricians and Gynecologists Committee Opinion recommends consideration of minimally invasive hysterectomy when appropriate.<sup>23</sup> In their guidelines, they recommend offering a vaginal approach when technically feasible and medically appropriate with the caveat that the potential benefits of a combined laparoscopic and vaginal approach must be weighed against the potentially increased risk and expense of two distinct operative approaches. Our data reflects that the addition of laparoscopy to a vaginal approach is significantly associated with an increased genitourinary injury rate. Along



similar lines, we find that the open abdominal approach was associated with the highest rate of genitourinary injury. This is particularly relevant given the recent rise of abdominal hysterectomy over laparoscopic in the setting of controversy surrounding uterine morcellation.<sup>24</sup> Although other studies have shown minimally invasive hysterectomy to be associated with higher rates of genitourinary injury,<sup>25–27</sup> we believe our findings can be explained by the exclusion of gynecologic malignancy, which would be associated with more challenging surgery with higher risk of injury, similar to that seen with endometriosis. Additionally, analyzing approach in an intention-to-treat manner (conversion to open analyzed in the laparoscopic groups) balances injury rate by approach (although the injury rate in the open surgery cohort was still significantly higher than the other groups).

Our results are also of particular importance when considering whether or not universal cystoscopy at the time of hysterectomy is warranted. Although the AAGL acknowledges existing literature regarding the effectiveness of cystoscopy in the identification of genitourinary injury in their 2012 practice guidelines, they ultimately conclude that the level of evidence and the limited data currently available preclude recommendation for making cystoscopy an integral component of laparoscopic hysterectomy.<sup>28</sup> Our finding that the immediate identification and repair of an injury improves outcomes (both reducing fistula formation and increasing the likelihood of successful management of a ureteral injury with stenting alone) supports the recommendation of considering cystoscopy a critical component of the hysterectomy procedure, if one accepts that universal cystoscopy increases the detection rate for such injuries.<sup>29</sup> At the same time, however, it is important to recognize that cystoscopy itself is likely not 100% sensitive (especially in cases of thermal injury) and thus if there is a high clinical suspicion of injury, the suspicion should remain even if cystoscopy is negative for lower thresholds for stent placement. This concept is supported by our finding that separately coded cystoscopy does not eliminate the possibility of a delayed presentation injury. Further, our findings that separately coded cystoscopy is associated with higher rates of immediately identified injuries should be viewed cautiously given the fact that cystoscopy appears to be more likely coded when there is a genitourinary injury or a clinical suspicion of an injury and appears to not be coded in situations of routine surveillance (only 6% of all hysterectomies). The reason for this likely is associated with the fact that cystoscopy charges are bundled with hysterectomy procedures

and not routinely coded in an administrative data set.<sup>30</sup> As a result, we are unable to unequivocally answer if universal surveillance cystoscopy at the time of hysterectomy is a worthwhile endeavor.

Our study has other limitations common to all studies using administrative data sets. First, our results are entirely dependent on data set coding reliability, though, the Office of Statewide Health Planning and Development has previously reported a low error tolerance level of less than 2%.<sup>15</sup> Another limitation is that only complications that were addressed surgically would be included; however, we feel that significant urologic injury is rarely amenable to conservative therapy short of a surgical procedure. Another potential limitation of our study is that any woman who had her complication managed outside of California would be missed. Finally, we are aware that interventions, such as indwelling stent placement, may have been performed for other indications aside from a genitourinary injury such as suspicion of an injury. We attempted to address this limitation by performing a sensitivity analysis where stent placement and a confirming diagnosis both needed to be present, however this was limited by the fact that only 18.7% of instances of indwelling ureteral stent insertion included a diagnosis code of a ureteral injury. Nevertheless, even when only considering these cases with a diagnosis of a ureteral injury present, immediate stenting of injuries was still effective more than 96% of the time. Finally, it is important to highlight that most of the effect sizes of the statistically significant associations reported in this article fall in the range of potential bias (ie, OR greater than 1.00 and less than 2.00 or less than 1 and greater than 0.3)<sup>31</sup> and conclusions based on these results need to be tempered.

Despite the limitations discussed above, our study has many notable strengths. It is a large population-based study including every hysterectomy performed for benign indications (aside from Veterans Affairs) in the entire state of California and captures all subsequent procedures even if a woman changes facility (as long as she remained in the state of California). Because California is home to 14% of the entire U.S. population and our data represents a wide range of facilities, surgeons, racial, and payer types, our results are highly generalizable. This study also benefits from having a long follow-up of up to 7 years (mean follow up 3.5 years) allowing us to capture delayed presentations. More importantly, our investigation, unlike most existing literature, is not limited to one specific type of urologic injury and we further defined those who are at the highest risk for injury (identifying those for whom a higher index of suspicion should be held). We detail the importance of identifying urologic injuries at the time



of hysterectomy as it is not only protective against future fistula formation but also increases the chance of successful management of ureteral injuries with an indwelling stent alone (avoiding future surgeries). Finally, given our data show the benefits of early detection of injuries, this study can be referenced to support liberal use of cystoscopy at the time of hysterectomy with a low threshold for stent placement to reduce the morbidity of unrecognized genitourinary injury.

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