



New Persistent Opioid Use After Outpatient Ureteroscopy for Upper Tract Stone Treatment

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| OBJECTIVE | To measure the incidence of persistent opioid use following ureteroscopy (URS). Over 100 Americans die every day from opioid overdose. Recent studies suggest that many opioid addictions surface after surgery. |
| METHODS | Using claims data, we identified adults who underwent outpatient URS for treatment of upper tract stones between January 2008 and December 2016 and filled an opioid prescription attributable to URS. We then measured the rate of new persistent opioid use—defined as continued use of opioids 91-180 days after URS among those who were previously opioid-naïve. Finally, we fit multivariable models to assess whether new persistent opioid use was associated with the amount of opioid prescribed at the time of URS. |
| RESULTS | In total, 27,740 patients underwent outpatient URS, 51.2% of whom were opioid-naïve. Nearly 1 in 16 (6.2%) opioid-naïve patients developed new persistent opioid use after URS. Six months following surgery, beneficiaries with new persistent opioid use continued to fill prescriptions with daily doses of 4.2 oral morphine equivalents. Adjusting for measured sociodemographic and clinical differences, patients in the highest tercile of opioids prescribed at the time of URS had 69% higher odds of new persistent opioid use compared to those in the lowest tercile (odds ratio, 1.69; 95% CI, 1.41-2.03). |
| CONCLUSION | Nearly 1 in 16 opioid-naïve patients develop new persistent opioid use after URS. New persistent opioid use is associated with the amount of opioid prescribed at the time of URS. Given these findings, urologists should re-evaluate their post-URS opioid prescribing patterns. <i>UROLOGY</i> 134: 103–108, 2019. © 2019 Elsevier Inc. |

While advancements in instrumentation and anesthetic technique have improved the tolerability of ureteroscopy (URS) for patients with urinary stone disease, many still experience pain following the procedure.¹ In fact, poorly managed pain is the most common reason for unplanned hospitalization after URS.² Taken together, pain management is an important part of patient-centric post-URS care. Although a variety of treatments have been shown to help alleviate post-URS pain,³ opioid analgesics are used the majority of the time in the US.⁴

However, emerging data from claims-based analyses of working-age adults reveal that rates of new persistent opioid use are high after surgery.⁵ Moreover, these rates do not differ between major and minor procedures, suggesting

that new persistent opioid use is not simply a consequence of poorly managed pain.⁵ Further, the amount of opioid prescribed at the time of surgery may predict subsequent persistence.⁶ To the extent that these findings also hold true for URS patients, urologists may need to re-evaluate their post-URS opioid prescribing patterns.

In this context, we performed a retrospective cohort study of privately-insured patients who underwent URS for upper tract stones. We sought to define the rate of new persistent opioid use in this population. We then examined the association between the amount of opioid prescribed at the time of URS and development of new persistent opioid use. Given that over 100 Americans die every day from an opioid overdose,⁷ findings from our study serve to inform urologists about a potentially modifiable source of patient harm.

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MATERIALS AND METHODS

Data Source and Study Population

For our study, we used Clinformatics Data Mart Database (OptumInsight, Eden Prairie, MN). This is a deidentified claims database from a single, large US insurance agency. It captures all

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inpatient, outpatient, emergency department, and pharmacy encounters for an estimated 73 million beneficiaries, including children and adults. Through relevant *Current Procedural Terminology* codes, we identified all beneficiaries in the database who were 18-64 years of age and underwent outpatient URS for upper tract stone disease between January 1, 2008 and December 31, 2016.

To assess perioperative opioid use, we excluded beneficiaries without continuous medical and prescription drug coverage and those enrolled in a Medicare Advantage plan during the year before and 6 months after their URS date. For inclusion, a beneficiary had to receive opioids that were attributable to his/her URS procedure. We defined this as a pharmacy fill of an opioid prescription (determined with appropriate National Drug Codes) either 30 days prior to or within 2 weeks after the URS date. We chose this window to account for beneficiaries who developed renal colic requiring opioids prior to surgery and for urologists who prescribe opioids preoperatively that are intended for postoperative use. To distinguish procedures performed on an outpatient basis, we only considered URS claims that were not associated with an inpatient confinement identifier. Additionally, we required that the first and last dates of service on a given URS claim had to be a day or less apart and fall outside of any inpatient stay. To minimize confounding, we excluded beneficiaries who underwent additional surgical procedures (determined using anesthesia *Current Procedural Terminology* codes) up to 6 months postoperatively. If a beneficiary underwent multiple URS procedures over the study period that met our inclusion criteria, we kept only his/her first procedure.

Exposure

Our exposure of interest was the amount of opioid prescribed that was attributable to the URS procedure. We quantified this using oral morphine equivalents (OMEs).

Outcome

Our primary outcome was new persistent opioid use among beneficiaries who were opioid-naïve prior to URS. We said that a beneficiary was opioid-naïve if she had no opioid prescriptions filled between 12 months and 31 days prior to his/her URS date. Consistent with prior work,⁵ we defined new persistent opioid use as a pharmacy fill for an opioid prescription between 91 and 180 days of the URS date. We chose this time period because we would expect normal surgical recovery to have occurred by then.

Statistical Analysis

For our initial analytic step, we used parametric and nonparametric tests, where appropriate, to compare opioid-naïve beneficiaries who developed new persistent use with those who did not. Specifically, we made comparisons over a variety of sociodemographic and clinical factors including beneficiary age, gender, race/ethnicity, education level, region of residence, level of comorbid illness (assessed with the modified Charlson comorbidity index⁸), the presence of concomitant mental illness and pain disorders (by searching claims in the 12 months prior to the URS procedure with the Clinical Classification System and relevant *International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification* diagnosis codes [Appendix Tables 1 and 2]), and whether an opioid prescription was filled in the 30 days prior to the URS date.

Next, we compared daily opioid doses during the 6 months after URS (by dividing the OMEs prescribed by the days supplied) among new persistent opioid users with those of chronic and intermittent opioid users. We defined chronic opioid users as beneficiaries who filled opioid prescriptions with at least 120 days' supply between 12 months and 31 days before their URS procedure, or filled at least 3 opioid prescriptions in the 3 consecutive months prior to their URS procedure. This level of use is associated with an increased risk of opioid-related mortality. We called beneficiaries who filled opioid prescriptions below this threshold intermittent users.

We then fit multivariable logistic regression models to evaluate the independent association between the development of new persistent opioid use among previously opioid-naïve beneficiaries and the amount of opioid prescribed that was attributable to the URS procedure. For modeling purposes, we sorted beneficiaries into terciles (low [$>0-213$ OMEs], medium [$>213-375$ OMEs], and high [>375 OMEs]) based on the amount of opioid prescribed. We included in our models the various sociodemographic and clinical factors described above. To account for the correlated nature of our data, we calculated robust standard errors using the Huber-White sandwich estimator.^{9,10}

Finally, we performed a series of sensitivity analyses to test the robustness of our findings. To disentangle new persistent opioid use following URS from an opioid prescription related to a recurrent stone episode, we reran our analysis after performing a wash-out in which beneficiaries, who had a claim for a diagnosis of stone disease filed on their behalf during the time window between 2 years and 6 weeks prior to their URS, were excluded. Second, we refit our models, excluding beneficiaries who had an emergency department visit or were hospitalized for a diagnosis of urinary stone disease during the first 6 months after their URS. For our third sensitivity analysis, we compared the amount of OMEs attributable to URS among beneficiaries who did and did not undergo ureteral stenting prior to surgery. We then assessed whether the odds of new persistent opioid use were moderated by preoperative stent placement up to 6 weeks prior to URS.

We performed all analyses using SAS Version 9.4 (Cary, NC). Tests were 2-tailed, and we set the probability of Type 1 error at 0.05. Our institution's Health Sciences Institutional Review Board deemed this study to be exempt from its oversight.

RESULTS

Over the study interval, a total of 27,740 beneficiaries underwent URS for upper tract stone disease who met our inclusion criteria. Of these, 14,196 (51.2%) were opioid-naïve, 9230 (33.3%) were intermittent users, and 4314 (15.6%) were chronic users. Among those who were opioid-naïve, 878 (6.2%) developed new persistent opioid use after URS.

Table 1 compares opioid-naïve beneficiaries who developed persistent opioid use with those who did not. New persistent users were more likely to be women, white, less educated, have an anxiety or mood disorder, and have neck, arthritis, or other pain disorders ($P < .05$ for each comparison). New persistent opioid users were also more likely to have filled preoperative (ie, in the 30 days prior to the URS) opioid prescriptions (79.5% vs 75.4%; $P = .006$).

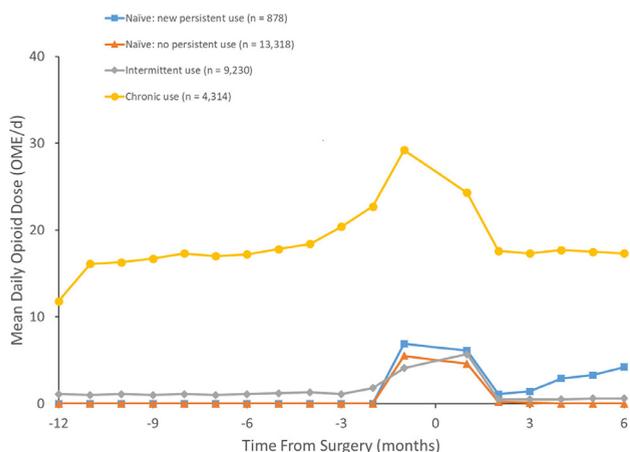
Figure 1 highlights the trajectory of mean daily opioid dose for beneficiaries stratified by their perioperative opioid use. Six months after URS, beneficiaries with new persistent opioid use

Table 1. Comparing opioid-naïve beneficiaries who develop new persistent opioid use with those who do not

| Characteristic | No Persistent Opioid Use (n = 13,318) | New Persistent Opioid Use (n = 878) | P Value |
|---------------------------------------|--|--|---------|
| Age in years (%) | | | .44 |
| 18-34 | 2,056 (15) | 153 (17) | |
| 35-44 | 3,055 (23) | 191 (22) | |
| 45-54 | 4,155 (31) | 268 (31) | |
| 55-64 | 4,052 (30) | 266 (30) | |
| Female gender (%) | 5,349 (40) | 384 (44) | .037 |
| Race/ethnicity (%) | | | .003 |
| White | 10,494 (79) | 726 (83) | |
| Black | 879 (7) | 64 (7) | |
| Other | 1,440 (11) | 66 (8) | |
| Unknown | 505 (4) | 22 (3) | |
| Education (%) | | | <.001 |
| High school or less | 3,446 (26) | 250 (28) | |
| Some college | 7,330 (55) | 508 (58) | |
| College or more | 2,542 (19) | 120 (14) | |
| Region of residence (%) | | | .025 |
| East North Central | 2,436 (18) | 154 (18) | |
| East South Central | 765 (6) | 64 (7) | |
| Middle Atlantic | 542 (4) | 25 (3) | |
| Mountain | 1,123 (8) | 69 (8) | |
| New England | 322 (2) | 14 (2) | |
| Pacific | 976 (7) | 53 (6) | |
| South Atlantic | 3,507 (26) | 220 (25) | |
| West North Central | 1,780 (13) | 136 (15) | |
| West South Central | 1,867 (14) | 143 (16) | |
| Charlson comorbidity index, mean (SD) | 0.4 (0.9) | 0.4 (1.0) | .035 |
| Mental health disorder (%) | | | |
| Adjustment | 271 (2) | 28 (3) | .021 |
| Anxiety | 1,094 (8) | 109 (12) | <.001 |
| Disruptive | 244 (2) | 20 (2) | .34 |
| Mood | 1,178 (9) | 128 (15) | <.001 |
| Alcohol or substance use disorder | 151 (1) | 12 (1) | .53 |
| Other psychiatric condition | 335 (3) | 29 (3) | .15 |
| Pain disorder (%) | | | |
| Back | 3,552 (27) | 250 (28) | .24 |
| Neck | 995 (7) | 94 (11) | <.001 |
| Arthritis | 4,199 (32) | 339 (39) | <.001 |
| Other pain disorder | 3,123 (23) | 263 (30) | <.001 |
| Preoperative opioid prescription (%) | 10,042 (75) | 698 (79) | .006 |

SD, standard deviation.

Note: Preoperative opioid prescription refers to opioid-naïve beneficiaries who filled opioid prescriptions in the 30 days before surgery.

**Figure 1.** Trajectory of daily opioid dose after URS, stratified by perioperative opioid use. Intended for color reproduction.

continued to fill prescriptions with daily doses of 4.2 OMEs (or nearly 1 tablet per day of 5-mg hydrocodone). When compared to other groups, new persistent opioid users had daily doses that were higher than intermittent users but lower than chronic users.

Figure 2 displays the relationship between new persistent opioid use among previously opioid-naïve beneficiaries and the amount of opioid prescribed that was attributable to the URS procedure. Compared to beneficiaries in the lowest tercile of opioid prescribed, significantly more in the highest tercile went on to new persistent opioid use (8.1% vs 4.8%; $P < .001$). This difference persisted after adjusting for measured sociodemographic and clinical differences (7.5% vs 4.6%; $P < .001$). Put differently, beneficiaries in the highest tercile of opioid prescribed at the time of URS had 69% higher odds of new persistent opioid use compared to those in the lowest tercile (odds ratio [OR], 1.69; 95% confidence interval [CI], 1.41-2.03). Mood disorder, neck disorder, arthritis disorder, and other pain disorders were also associated with odds of developing new persistent use (Table 2).

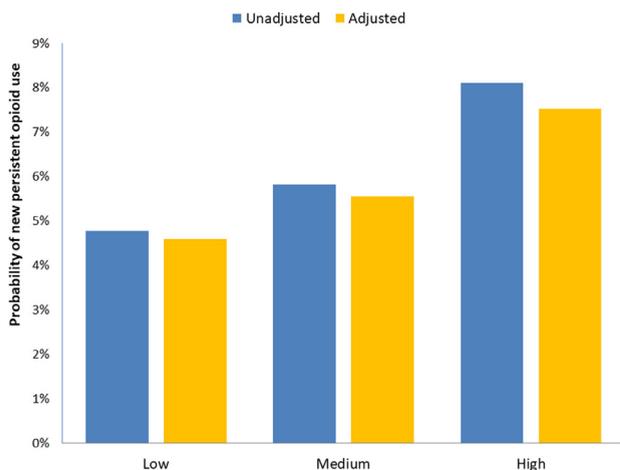


Figure 2. Probability of new persistent use after URS, stratified by the amount of opioid prescribed at the time of surgery. Intended for color reproduction.

After excluding beneficiaries who had a medical claim filed on their behalf for a diagnosis of urinary stone disease during the time window between 2 years and 6 weeks before surgery, those in the highest tertile of opioids prescribed still had 77% higher odds of new persistent opioid use compared to those in the lowest tertile (OR, 1.77; 95% CI, 1.42-2.22). When we excluded beneficiaries who had an emergency department visit or were hospitalized for a diagnosis of urinary stone disease during the first 6 months after their URS, those in the highest tertile of opioids prescribed still had 69% higher odds of new persistent opioid use compared to those in the lowest tertile (OR, 1.69; 95% CI 1.39-2.06).

Finally, compared to beneficiaries without preoperative ureteral stenting, we found that those with a stent were prescribed higher amounts of OMEs at the time of URS (median, 315 vs 263, respectively; $P < .001$ using the Wilcoxon rank-sum test). However, after controlling for preoperative ureteral stenting in our multivariable regression models, beneficiaries in the highest tertile of opioids prescribed still had higher odds of new persistent opioid use compared to those in the lowest tertile (OR, 1.69; 95% CI, 1.40-2.03).

DISCUSSION

Our study has 2 principal findings. First, we found that nearly one in 16 opioid-naïve beneficiaries undergoing outpatient URS for upper tract stone treatment develop new persistent opioid use. Moreover, they continued filling prescriptions with doses equivalent to nearly 1 tablet per day of 5-mg hydrocodone even 6 months after surgery—a daily rate which is higher than that of intermittent narcotic users. Second, we found that the amount of opioid prescribed at the time of URS was strongly associated with the development of new persistent opioid use. To provide context, nearly 6300 URS procedures are performed annually in Michigan.¹¹ Assuming 51.2% are opioid-naïve, we would expect 200 new persistent users after URS in that state alone each year. Given these findings, urologists should re-evaluate their post-URS opioid prescribing patterns.

Table 2. Factors associated with the development of new persistent opioid use after surgery

| Characteristic | Odds Ratio | 95% Confidence Interval |
|---|------------|-------------------------|
| Amount of opioid prescribed (reference: low) | | |
| Medium | 1.22 | 1.02-1.46 |
| High | 1.69 | 1.41-2.03 |
| Age (reference: 18 to 34) | | |
| 35 to 44 | 0.83 | 0.66-1.04 |
| 45 to 54 | 0.86 | 0.70-1.07 |
| 55 to 64 | 0.88 | 0.71-1.09 |
| Female gender | 1.09 | 0.94-1.26 |
| Race/ethnicity (reference: White) | | |
| Black | 1.00 | 0.76-1.31 |
| Other | 0.71 | 0.55-0.93 |
| Unknown | 0.66 | 0.43-1.01 |
| Education (reference: high school or less) | | |
| Some college | 0.96 | 0.81-1.12 |
| College or more | 0.68 | 0.54-0.86 |
| Region of residence (reference: East North Central) | | |
| East South Central | 1.23 | 0.90-1.67 |
| Middle Atlantic | 0.8 | 0.52-1.24 |
| Mountain | 0.97 | 0.72-1.30 |
| New England | 0.68 | 0.38-1.20 |
| Pacific | 1.00 | 0.71-1.39 |
| South Atlantic | 0.96 | 0.77-1.19 |
| West North Central | 1.2 | 0.95-1.53 |
| West South Central | 1.25 | 0.98-1.59 |
| Charlson comorbidity index | 1.06 | 0.99-1.14 |
| Mental health disorder | | |
| Adjustment | 1.35 | 0.89-2.04 |
| Anxiety | 1.24 | 0.98-1.57 |
| Disruptive | 0.93 | 0.57-1.49 |
| Mood | 1.43 | 1.15-1.79 |
| Alcohol or substance use disorder | 0.85 | 0.47-1.52 |
| Other psychiatric condition | 1.00 | 0.67-1.50 |
| Pain disorder | | |
| Back | 0.91 | 0.77-1.07 |
| Neck | 1.30 | 1.02-1.67 |
| Arthritis | 1.24 | 1.06-1.45 |
| Other pain disorder | 1.21 | 1.04-1.42 |
| Preoperative opioid prescription | 1.05 | 0.87-1.25 |

Note: Preoperative opioid prescription refers to opioid-naïve beneficiaries who filled opioid prescriptions in the 30 days before surgery.

To date, but a single institutional study involving just 200 patients has examined new persistent opioid use after URS. Ours is the first national study to tackle this timely topic.¹² The rate that we observed (6.2%) is comparable to what has been published for other common surgical procedures, including varicose vein removal, hemorrhoidectomy, carpal tunnel repair, ventral incisional hernia

repair, reflux surgery, and bariatric surgery.⁵ The observed association between the amount of opioid prescribed at the time of URS and the development of new persistent opioid use has been shown with orthopedic surgery, as well. In particular, Gossett et al found that among the greatest modifiable risk factors for the development of new persistent opioid use after several common foot and ankle procedures was the total prescribed initial opioid dose in the perioperative period.¹³

Our study must be considered in the context of several limitations. First, although we had data on the number of opioid pills prescribed each beneficiary after URS, we do not know the exact quantity taken. Second, our claims-based analysis misses any opioid prescription fills that were paid out-of-pocket, as well as those prescriptions prescribed but never filled. Third, our study population was drawn from a large cohort of commercially-insured, working-age adults, and their dependents. While the prevalence of urinary stone disease is high in this group,¹⁴ our findings may not be generalizable to the uninsured, underinsured, and those 65 years and older. Fourth, the amount of OMEs prescribed at the time of URS can be affected by a variety of things, including some patient factors that are difficult to measure in medical claims.

Notwithstanding these limitations, our study has important clinical implications. Specifically, urologists need to ask themselves whether opioids are always required after URS. Consider prior empirical work from Fujii et al. Among 330 patients who underwent minor surgical procedures at their academic medical center, including cystoscopy with ureteral stent placement, 92% were prescribed an opioid for postoperative analgesia. Yet, only two-thirds ever filled their prescription.¹⁵ What is more, a retrospective chart review from Indiana University showed that rates of postoperative pain issues and the need for additional medical care because of inadequate pain control did not differ between patients who were prescribed opioids and those on an opioid-free pathway after URS.¹⁶ Collectively, these data suggest a substantial number of post-URS patients could be managed without opioids.

However, if opioids are needed, urologists should reflect on the amount that they prescribe. An analysis of data from the Veterans Health Administration drives this message home. Among 1976 patients who underwent surgical treatment for urinary stone disease, a wide opioid dosing distribution (interquartile range, 140-300 OMEs) was observed. Such variation highlights an opportunity for standardizing postoperative opioid prescribing.¹⁷ To this end, investigators at the University of Michigan recently developed evidence-based postoperative opioid prescribing guidelines for laparoscopic cholecystectomy. Following implementation of these guidelines at their institution, opioid prescription sizes decreased by 63% without increasing the need for medication refills.¹⁸ Leading professional

societies could use this approach as a template for reducing the amount of opioids prescribed at the time of URS.

CONCLUSION

Nearly 1 in 16 opioid-naive patients develop new persistent opioid use after URS. New persistent opioid use is associated with the amount of opioid prescribed at the time of URS. Given the growing opioid epidemic in the US and large volume of URS procedures performed each year, our findings are timely. In light of them, urologists should re-evaluate their post-URS opioid prescribing patterns.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2019.08.042>.

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EDITORIAL COMMENT



The opioid epidemic claimed the lives of 70,237 Americans in 2017.¹ To put that in perspective, it is more than twice as many Americans who died from prostate cancer in 2016.¹ Urolithiasis is also a common condition affecting 1 out of every 11 people in the United States and is often treated with opioids.² In 2009, the National Inpatient Sample showed that 15,409 inpatient ureteroscopies were performed.³ In the United States, it is commonplace for urologists to prescribe opioids after ureteroscopy. Yet, data show that that between 40% and 60% of the prescribed opioids are not used by patients and that the majority of patients have excess opioids regardless of the type of surgery.⁴

Recognizing these issues, the authors of this work present data analyzing claims data to determine the number of opioid prescriptions related to outpatient ureteroscopy. The authors then evaluated these patients for any new opioid prescriptions between 91 and 180 days after their ureteroscopy to define new persistent opioid use. The data set is quite large, including almost 28,000 patients. Of those patients, 51% were opioid-naïve. Six percent of those opioid-naïve patients developed new persistent opioid use. It is also important to note that according to their data, one-third of patients were intermittent users and just over 15% became chronic users. The data also show that patients who received more opioids had a significantly higher risk of becoming new persistent opioid users. The authors noted that new persistent opioid use was more common in patients who were female, white, less educated, have an anxiety or mood disorder or have pain disorders.

The primary outcome mentioned is the amount of opioids prescribed, therefore, the data presented is unable to answer how many opioids were consumed by the patients. Nonetheless, the rate of new opioid prescriptions still serves as a reasonable surrogate for new persistent opioid use. In addition, unconsumed opioids can certainly result in abuse either by the patient or by someone else. The data set used only pertains to insured patients who filled prescriptions through their insurer. Therefore, we also do not know how the data extrapolates to uninsured patients, or those who did not pay for opioids through their insurance.

Renal colic can be a debilitating situation. Historically, opioids have been viewed as the gold standard of pain control with few serious side effects. Furthermore, NSAIDs are not recommended for patients with renal insufficiency which further limits the nonopioid options in these patients. Others have reported on the feasibility of performing ureteroscopy without prescribing opioids with success.⁵ This study adds to growing data that even small exposures can cause patients to become persistent users.⁴ While opioids may be needed in some patients after ureteroscopy, urologists should discuss the risks of opioids compared to the benefits with patients.

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