



Assessing the safety of ureteral stent placement for obstructive urolithiasis in patients during the COVID-19 pandemic

Ankur U. Choksi, Soum D. Lokeshwar, Mursal Gardezi, Christopher S. Hayden, Amir I. Khan, Timothy Tran, Dinesh Singh, Piruz Motamedinia, Thomas V. Martin

Department of Urology, Yale School of Medicine, Yale University, New Haven, CT, USA

Contributions: (I) Conception and design: AU Choksi, SD Lokeshwar, TV Martin; (II) Administrative support: TV Martin, P Motamedinia, D Singh, T Tran; (III) Provision of study materials or patients: TV Martin, P Motamedinia, D Singh, T Tran; (IV) Collection and assembly of data: AU Choksi, SD Lokeshwar, M Gardezi, CS Hayden, AI Khan; (V) Data analysis and interpretation: AU Choksi, SD Lokeshwar, M Gardezi, CS Hayden, AI Khan; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Thomas V. Martin, MD. Department of Urology, Yale School of Medicine, Yale University, 333 Cedar Street, P.O. Box 208058, New Haven, CT 06520-8058, USA. Email: thomas.v.martin@yale.edu.

Background: Patients with an active severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [coronavirus disease 2019 (COVID-19)] infection are at a higher risk of post-operative mortality. In this retrospective case-control study, we analyzed the post-operative safety of patients undergoing cystoscopy with ureteral stent placement for obstructing ureteral calculi who tested positive for COVID-19.

Methods: We retrospectively identified patients who underwent cystoscopy and ureteral stent placement between June 5, 2020 and December 31, 2022 as an add-on case. Patients were stratified by whether they had a positive COVID-19 test on admission. Baseline characteristics were compared using Student's *t*-test for continuous variables and Pearson chi-square test for categorical variables. Univariate and multivariate logistic regression analysis was performed to identify predictors of postoperative 30-day mortality.

Results: A total of 1,408 patients underwent add-on cystoscopy with ureteral stent placement for an obstructing calculus, of which 55 (3.9%) patients had a positive COVID-19 test. When stratified by COVID-19 status, both groups were similar with regards to age, sex, race, co-morbidities, indications, procedure duration, and type of anesthesia administered. Of the 137 patients that were admitted to the intensive care unit (ICU), 9 patients were COVID-19 positive (16.4% *vs.* 9.5%, $P=0.09$). On multivariate logistic regression, patients with COVID-19 had a higher odds of 30-day mortality [odds ratio (OR) =7.06; 95% confidence interval (CI): 2.03–24.47; $P=0.002$] when controlling for age, co-morbidities, vaccination status, anesthesia type, and indication for the stent.

Conclusions: Patients that underwent cystoscopy and ureteral stent placement for an obstructing ureteral stone with a concurrent COVID-19 diagnosis had an increased risk of perioperative 30-day mortality.

Keywords: Urolithiasis; coronavirus disease 2019 (COVID-19); ureteral stent; mortality

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Introduction

Background

With regards to the triage of patients with diseases generally treated with surgical intervention, healthcare providers were tasked at balancing the risk of peri-operative complications

associated with infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus [coronavirus disease 2019 (COVID-19)] with the progression of disease while not operating (1). For patients who had surgery in the setting of a peri-operative diagnosis of COVID-19 infection, pulmonary complications were noted to occur in

almost half of patients and mortality was noted in almost one-fourth of patients (2,3). Post-operative cardiovascular complications were minimized as the delay from time of COVID-19 infection was increased (4). Post-operative mortality for patients undergoing elective non-cardiac surgeries was noted to be approximately 4% when performed within 7 weeks of initial COVID-19 diagnosis as compared to 1.5% when performed after 7 weeks, similar to that of someone not diagnosed with COVID-19 (5). The findings from these studies established the recommendations that elective surgeries be postponed by 7 weeks following initial diagnosis of the SARS-CoV-2 virus.

For the approximately 1.3 million patients within the United States that present to the emergency department each year with symptoms secondary to an obstructing ureteral stone, surgical intervention may need to be performed in a non-elective manner regardless of whether the patient has COVID-19 infection (6,7). Changes in practice patterns for nephrolithiasis were noted as the rate of non-operative management increased, the rate of shockwave lithotripsy and nephrostomy tube placement without general anesthesia increased, and the delay between renal decompression and definitive stone surgery increase (8). These trends were noted to be consistent with early recommendations based on expert opinion for the triage of the urologic surgical patient (9,10).

Highlight box

Key findings

- Patients with concurrent severe acute respiratory syndrome coronavirus 2 [coronavirus disease 2019 (COVID-19)] illness have a seven-fold greater odds of mortality following cystoscopy and ureteral stent placement for an obstructing ureteral stone.

What is known and what is new?

- Initial studies during the COVID-19 pandemic has suggested that there is an increased risk of cardiopulmonary complications for surgical patients that are infected with COVID-19 virus.
- This manuscript provides a retrospective review of mortality outcomes for patients that underwent cystoscopy and ureteral stent placement.

What is the implication, and what should change now?

- Providers should be aware of the potential mortality risks associated with cystoscopy and ureteral stent placement in a patient with COVID-19.

Rationale and knowledge gap

There are minimal data regarding the safety and peri-operative risks of patients undergoing cystoscopy and ureteral stent placement in the operating room for obstructive urolithiasis in a non-elective manner with a concurrent diagnosis of SARS-CoV-2 infection.

Objective

In this retrospective analysis, we examine the peri-operative safety of patients who underwent cystoscopy and ureteral stent placement during the COVID-19 pandemic, after presenting to the emergency department and were diagnosed with an obstructing ureteral calculus. We present this article in accordance with the STROBE reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-24-57/rc>).

Methods

Patient selection

Within our health system, the first patient that underwent cystoscopy with ureteral stent placement [Current Procedural Terminology (CPT) 52332] for a ureteral calculus with COVID-19 was on June 05, 2020. After Institutional Review Board approval was obtained, we retrospectively identified all patients that presented to the emergency department and were diagnosed with a ureteral calculus within our health system between June 05, 2020 and December 31, 2022. Within this set of patients, we identified patients that were evaluated by urologists and added on for cystoscopy with ureteral stent placement. Decision to pursue definitive stone surgery at the initial presentation was per surgeon discretion and clinical judgement.

Outcome measures

We assessed the safety of cystoscopy and ureteral stent placement by assessing the rate and predictors of post-operative intensive care unit (ICU) admission and 30-day mortality. Additional post-operative outcomes were assessed in the form of length of stay, 30- and 90-day readmission rates and 90-day mortality.

Variables

We abstracted the patient's name, age, sex, date of presentation, COVID-19 status, history of prior COVID-19 vaccination, procedure CPT code, procedure duration, surgeon, indication for ureteral stent placement and type of anesthesia from the electronic medical health record. Because many patients had multiple indications for ureteral stent placement, for those patients that had presence of fever $>100.4^{\circ}\text{F}$, provider concern for urosepsis, urinalysis concerning for urinary tract infection, or culture documented urinary tract infection or bacteremia with a urinary source, these patients were classified as infection. For those patients that did not meet the above criteria but met criteria for acute kidney injury with or without electrolyte abnormalities then they were classified as acute kidney injury. For patients that had ureteral stent placement solely for treatment of symptoms and did not meet criteria for above, these patients were classified as symptoms. We assessed the post-operative outcomes of the patient in the form of length of stay, post-operative ICU stay, 30- and 90-day readmission rate and 30- and 90-day mortality.

Statistical analysis

For patients that underwent cystoscopy with ureteral stent placement, we further stratified this cohort by whether they had a positive COVID-19 (SARS-CoV-2) viral test. We compared baseline characteristics of the COVID-19 positive and negative patients, using two-tailed Mann Whitney *U* test for continuous variables and Pearson chi-squared test for categorical variables. Subgroup analysis was performed based on whether the patient had received at least one dose of the COVID-19 vaccine prior to the procedure.

Univariate and multivariate logistic regression was performed to identify predictors of 30-day mortality following cystoscopy and ureteral stent placement. Variables that were noted to have a *P* value of less than 0.10 on univariate analysis were included in the multivariate analysis. COVID-19 positivity and vaccination status were included in the multivariate analysis regardless of their significance on univariate analysis.

All *P* values were reported as two-sided and *P* values less than 0.05 were considered statistically significant. Analysis was performed with Microsoft Excel (Redmond, WA, USA) and StataMP (StataCorp, College Station, TX, USA).

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Yale University Institutional Review Board (IRB) (Registration Number 00011725, Protocol Number 2000034818). Waiver was granted for obtaining informed consent and use of protect health information due to retrospective study design.

Results

Over the study period from June 5, 2020 to December 31, 2022, a total of 3,673 unique emergency department visits were made in the setting of renal colic or symptomatic urolithiasis. Given system constraints at the time of the pandemic, our institution limited COVID-19 testing to patients in the emergency department with high clinical suspicion for the infection or those that were planned on being admitted to the hospital. Of these patients that were tested, a total of 121 (3.29%) patients tested positive for COVID-19.

A total of 1,408 (38.3%) patients underwent cystoscopy with ureteral stent insertion in a non-elective manner after presenting to the emergency department. For patients that were added-on and underwent the procedure, a total of 55 (3.91%) patients tested positive for COVID-19. Baseline characteristics for the patients, stratified by COVID-19 status, are demonstrated in *Table 1*. When compared to patients without COVID-19 at the time of ureteral stent placement, patients diagnosed with COVID-19 had a lesser prevalence of chronic lung diseases (asthma, obstructive sleep apnea, chronic obstructive pulmonary disease, emphysema, etc.). The two cohorts were similar in terms of age, distribution of sex and race, COVID-19 vaccination rates, past medical histories (barring chronic lung diseases), procedure duration, indication for ureteral stent and type of anesthesia administered during the procedure.

Post-operative outcomes were assessed for the two cohorts with respect to post-operative ICU stay, length of stay, 30- and 90-day readmission rates mortality rates (*Table 2*). For patients diagnosed with COVID-19, sub-group analysis was performed with respect to vaccination status at the time of ureteral stent placement. A total of 137 (9.7%) patients were admitted or transferred to the ICU during their hospitalization for ureteral stent placement. Of these patients, 9 were COVID-19 positive while 128 patients were

Table 1 Baseline characteristics and perioperative outcomes of patients who underwent ureteral stent placement as a non-scheduled case after presenting to the emergency department and being diagnosed with a ureteral stone

Variables	All patients (n=1,408)	COVID-19 positive (n=55)	COVID-19 negative (n=1,353)	P value
Age (years)	57.3±17.2	59.0±17.7	57.2±17.2	0.62
Male	637 (45.2)	31 (56.4)	606 (44.8)	0.09
Race				0.75
White	955 (67.8)	34 (61.8)	921 (68.1)	
Hispanic	99 (7.0)	6 (10.9)	93 (6.9)	
African American	278 (19.8)	13 (23.7)	265 (19.6)	
Asian	24 (1.7)	0	24 (1.8)	
Other/not listed	52 (3.7)	2 (3.6)	50 (3.7)	
History of COVID-19 vaccination prior to procedure	830 (58.9)	37 (67.3)	793 (58.6)	0.20
Past medical history				
Heart disease	136 (9.7)	5 (9.1)	131 (9.7)	0.88
Hypertension	683 (48.5)	23 (41.8)	660 (48.8)	0.31
Diabetes mellitus	369 (26.2)	17 (30.9)	352 (26.0)	0.41
Chronic lung disease	424 (30.1)	10 (18.2)	414 (30.6)	0.049
Chronic kidney disease	70 (5.0)	4 (7.3)	66 (4.9)	0.42
Liver disease	51 (3.6)	1 (1.8)	50 (3.7)	0.46
Obesity	152 (10.8)	5 (9.1)	147 (10.9)	0.67
Indications				0.89
Symptomatic	645 (45.8)	25 (45.5)	620 (45.8)	
Acute kidney injury	274 (19.5)	12 (21.8)	262 (19.4)	
Infection	489 (34.7)	18 (32.7)	471 (34.8)	
Procedure duration (mins)	31.1±18.5	31.3±18.4	31.1±18.5	0.63
Type of anesthesia				0.17
General	1,298 (92.2)	50 (90.9)	1,248 (92.2)	
Sedation	105 (7.4)	4 (7.3)	101 (7.5)	
Spinal	5 (0.4)	1 (1.8)	4 (0.3)	

Data are expressed as mean ± standard deviation for continuous variables and frequency (percentage of total) for categorical variables. COVID-19, coronavirus disease 2019.

not (16.4% *vs.* 9.5%, $P=0.09$). Patients with COVID-19 had a longer length of stay (8.30 ± 20.98 *vs.* 3.46 ± 4.13 days, $P<0.001$), and 30-day (7.3% *vs.* 1.3%, $P<0.001$) and 90-day mortality (9.1% *vs.* 1.8%, $P<0.001$). There were no significant differences between 30-day (12.7% *vs.* 10.1%, $P=0.51$) and 90-day (18.2% *vs.* 15.4%, $P=0.57$) re-admission rates between patients that tested positive for COVID-19

compared to those that did not. Of the 55 patients that tested positive for COVID-19, 37 had received at least one dose of vaccination while 18 patients had not been vaccinated prior to their presentation with obstructive urolithiasis. There were no significant differences with regards to post-operative ICU stay (10.8% *vs.* 27.8%, $P=0.11$), length of stay (5.91 ± 10.59 *vs.* 13.2 ± 33.51 days,

Table 2 Post-operative outcomes for patients who underwent ureteral stent placement, with sub-group analysis for patients diagnosed with COVID-19 stratified by vaccination status at the time of the procedure

Variables	Patients admitted to the ICU				ICU patients with COVID stratified by vaccination status		
	All patients	COVID-19 positive	COVID-19 negative	P value	COVID-19 but vaccinated	COVID-19 and unvaccinated	P value
Post-operative ICU stay, n (%)	137 (9.7)	9 (16.4)	128 (9.5)	0.09	4 (10.8)	5 (27.8)	0.11
Length of stay (days)				<0.001			0.21
Mean ± SD	3.65±5.85	8.30±20.98	3.46±4.13		5.91±10.59	13.2±33.51	
Median (IQR)	2 (2–4)	3 (2–6)	2 (1–4)		3 (2–6)	3 (3–6)	
30-day readmission, n (%)	143 (10.2)	7 (12.7)	136 (10.1)	0.51	3 (8.1)	4 (22.2)	0.14
90-day readmission, n (%)	218 (15.5)	10 (18.2)	208 (15.4)	0.57	6 (16.2)	4 (22.2)	0.58
30-day mortality, n (%)	21 (1.5)	4 (7.3)	17 (1.3)	<0.001	2 (5.4)	2 (11.1)	0.44
90-day mortality, n (%)	29 (2.1)	5 (9.1)	24 (1.8)	<0.001	3 (8.1)	2 (11.1)	0.71

COVID-19, coronavirus disease 2019; ICU, intensive care unit; SD, standard deviation; IQR, standard deviation.

P=0.21), 30-day (8.1% *vs.* 22.2%, P=0.14) and 90-day readmission rates (16.2% *vs.* 22.2%, P=0.58), and 30-day (5.4% *vs.* 11.1%, P=0.44) and 90-day mortality rates (8.1% *vs.* 11.1%, P=0.71). Of the 9 patients with COVID-19 that went to the ICU post-operatively, 7 had a stent placed in the setting of sepsis, 1 had placement of AKI and 1 had placement for symptoms.

Univariate and multivariate logistic regression was performed to identify predictors of 30-day mortality following cystoscopy, ureteral stent placement. On univariate analysis, predictors of 30-day mortality include testing positive for COVID-19 (P=0.002), older age (P<0.001), longer operative duration (P=0.01), sedation for anesthesia (P=0.008), ureteral stent placement occurring in the setting of infection (P=0.004) and a medical history inclusive of heart disease (P<0.001), hypertension (P=0.01) (*Table 3*).

A multivariate logistic regression model was developed consisting of COVID-19 infectious status, vaccination status for COVID-19, and variables that were significant with a P value of less than 0.10 on the univariate analysis (*Table 4*). On multivariate analysis, a positive COVID-19 viral test was a predictor of 30-day mortality [odds ratio (OR) =7.06; 95% confidence interval (CI): 2.03–24.47; P=0.002] when controlling for vaccination against COVID-19, age, type of anesthesia administered, duration of the procedure, indication for ureteral stent placement, and whether the patient had a history of heart disease, hypertension, diabetes mellitus or obesity. Other variables that were statistically

significant on the multivariate model include older age (P=0.01), a past medical history of heart disease (P=0.03) and obesity (P=0.03), longer procedure time (P=0.007), anesthesia in the form of intravenous sedation (P=0.02), and ureteral stent placement in the setting of a urinary tract infection (P=0.041). A positive COVID-19 viral test was the strongest predictor in terms of odds of 30-day mortality. There were no variables that were noted to be protective against 30-day mortality on logistic regression.

Discussion

Key findings

Our study demonstrates that patients who underwent non-elective cystoscopy with ureteral stent placement for an obstructing ureteral stone while also being diagnosed with COVID-19 had a seven-fold increase in risk of 30-day mortality. Thirty- and ninety-day all-cause mortality for patients within this retrospective study was noted to be 1.5% and 2.1% respectively, as compared to 7.3% and 9.1% respectively for patients that tested positive for COVID-19 infection who underwent surgery. While many patients with an obstructing ureteral stone and concurrent COVID-19 infection may not be candidates for delayed elective management, the increased peri-operative risks introduced by the COVID-19 infection should be considered when counselling patients for surgical intervention.

Table 3 Univariate logistic regression analysis for predictors of 30-day mortality following add-on ureteral stent placement

Variables	Odds ratio (95% CI)	P value
COVID-19 positive	6.16 (2.00–18.98)	0.002
Age	1.06 (1.03–1.09)	<0.001
Male	0.74 (0.31–1.80)	0.50
Race		
Caucasian	1.00	–
African American	1.13 (0.26–5.00)	0.86
Hispanic	0.40 (0.09–1.74)	0.22
Asian	n/a	–
Other	n/a	–
History of COVID-19 vaccination prior to procedure	0.62 (0.26–1.49)	0.29
Past medical history		
Heart disease	4.88 (1.93–12.3)	<0.001
Hypertension	3.45 (1.25–9.48)	0.01
Diabetes mellitus	2.13 (0.89–5.12)	0.08
Chronic lung disease	1.43 (0.59–3.49)	0.42
Chronic kidney disease	2.04 (0.46–8.94)	0.34
Liver disease	1.33 (0.18–10.16)	0.77
Obesity	2.63 (0.95–7.30)	0.06
Procedure duration (mins)	1.02 (1.00–1.03)	0.01
Type of anesthesia		
General	1.00	–
Sedation	4.00 (1.43–11.16)	0.008
Spinal	n/a	–
Indication		
Pain	1.00	–
Acute kidney injury	3.17 (0.70–14.26)	0.13
Infection	6.30 (1.80–22.07)	0.004

CI, confidence interval; COVID-19, coronavirus disease 2019; n/a, not applicable.

Strengths and limitations

To our knowledge, this is the only study to evaluate the safety of cystoscopy and ureteral stent placement, one of the most common procedures urologist perform, during the COVID-19 pandemic. The COVID-19 pandemic was novel and dynamic in its course and our medical understanding

Table 4 Multivariate logistic regression analysis for predictors of 30-day mortality following add-on ureteral stent placement with model designed using variables on univariate logistic regression with a P value of less than 0.10

Variables	Odds ratio (95% CI)	P value
COVID-19 positive	7.06 (2.03–24.47)	0.002
Age	1.05 (1.01–1.08)	0.01
Past medical history		
Heart disease	3.14 (1.11–8.87)	0.03
Hypertension	1.40 (0.42–4.61)	0.57
Diabetes mellitus	1.37 (0.52–3.64)	0.52
Obesity	3.37 (1.11–10.19)	0.03
History of COVID-19 vaccination prior to procedure	0.48 (0.19–1.20)	0.11
Procedure duration (mins)	1.02 (1.00–1.04)	0.007
Type of anesthesia		
General	1.00	–
Sedation	3.45 (1.16–10.25)	0.02
Spinal	n/a	–
Indication		
Pain	1.00	–
Acute kidney injury	1.67 (0.35–7.95)	0.52
Infection	3.83 (1.05–13.94)	0.041

CI, confidence interval; COVID-19, coronavirus disease 2019; n/a, not applicable.

of the disease and its treatments increased as the pandemic unfolded. Hence, patients included in the earlier stages of the pandemic may be at increased risk of complication due to undiscovered and unverified treatment options, lack of vaccines, and competition for resources (11). Therefore, the findings of this study should be interpreted within the context of the COVID-19 pandemic.

In this study, selection bias may be present when determining which patients presenting to the emergency department should be triaged for intervention. It is possible that patients diagnosed with COVID-19 had a higher threshold for operation, with surgery limited to indications with a greater risk of requiring post-operative ICU admission, including sepsis from a urinary source or acute kidney injury with electrolyte abnormalities. This was accounted for in the study by including the indication for ureteral stent place within the analysis.

Finally, this study does not capture patients that underwent a trial of medical expulsive therapy and were not admitted to the hospital or percutaneous nephrostomy tube placement. Patients with ureteral stones that were also diagnosed with COVID-19 may have undergone one of these treatment strategies in an attempt to avoid the suspected peri-operative risks of general anesthesia. Future studies may be warranted to compare the post-operative outcomes of patients who underwent ureteral stent placement as compared to one of these other treatment strategies in the setting of an active COVID-19 diagnosis.

Comparison with similar researches

Perioperative outcomes have been evaluated for patients undergoing elective surgery for urologic conditions during the COVID-19 pandemic. A national study based out of Italy identified no increased peri-operative risks for patients undergoing elective surgery with a negative COVID-19 nasal swab test (12). Predictors for increased risk of respiratory symptoms following surgery for COVID-19 negative patients were number of patients within the facility and predictors against an increased risk were the absence of COVID-19 patients within the facility. A study based out of Ireland assessing the peri-operative outcomes of patients undergoing urologic surgery during the first seven weeks of the pandemic, identified seven patients who developed COVID-19 infectious symptoms post-operatively, of which three developed significant pulmonary complications of which one patient died (13). However, within the field of pediatric urology, in an analysis of 49 pediatric patients undergoing urologic surgery during the COVID-19 pandemic, regardless of COVID-19 status, only four complications were noted, to be Clavien-Dindo grade II at highest (14).

Our findings are consistent with the assessments of other surgical fields and their rates of post-operative complication in the setting of an active COVID-19 infection. A multi-institutional study based out of London revealed that for COVID-19 patients who sustained hip fractures, there was an increase in length of stay, ICU admissions, peri-operative complications and mortality rates (15). These findings reflect the conclusions that were ascertained in this study. An international collaborative group, CovidSurg, analyzed the risk of undergoing general, hepatobiliary and colorectal surgery, and noted a nine-fold increased risk in peri-operative mortality for a patient with COVID-19, as well as increases in major surgical complications and respiratory

complications (16). A study performed out of New York City assessed 39 patients who underwent surgery with a positive COVID-19 test, noting an increased risk of ICU admission and mortality, notably for patients with American Society of Anesthesiologist Class 3 or higher (17).

Explanations of findings

In our multivariate logistic regression analysis, patient comorbidities in the form of heart disease and obesity had a statistically significant impact on predicting 30-day mortality for patients undergoing cystoscopy with ureteral stent placement. During the COVID-19 pandemic, adult heart diseases and obesity were adverse prognostic co-morbidities associated with an increased risk of hospitalization and critical care needs for all patients, regardless of whether they underwent surgery (18-20). For patients with COVID-19, ventilator requirements were greatest for patients with a history of hypertension, diabetes mellitus and obesity, while mortality was noted to be greater for patients with cardiovascular disease, obesity and diabetes mellitus (11,21).

For our study population, a majority of the patients who underwent cystoscopy and ureteral stent placement did so with general anesthesia. Our study demonstrated an increased risk of 30-day mortality for patients who underwent cystoscopy with ureteral stent placement with intravenous sedation as compared to patients that underwent surgery under general anesthesia. It is possible that patient-related factors and clinical status at the time of surgery guided providers to decide upon this choice of anesthetics, hence introducing selection bias, and only 5 patients with COVID-19 received sedation for anesthesia. Many of the early urologic recommendations suggested the role for percutaneous nephrostomy tube position as an alternative to retrograde ureteral stent placement to avoid the peri-operative risks of general anesthesia. However, our data suggests that the risks for perioperative mortality may be more inherent to modifiable and non-modifiable patient related factors rather than receipt of general anesthesia.

Implications and actions needed

While cystoscopy and ureteral stent placement is often performed in a non-elective manner, patients should be counselled on the potential risks of COVID-19 infection on peri-operative outcomes. Potential mechanisms for the increased mortality seen following surgery is a potential cardiopulmonary complication secondary to anesthesia or a

compromised immune response to counter bacterial sepsis, whether that is by the COVID-19 virus or medications used to treat the viral infection. For patients with COVID-19 symptomatic from an obstructing ureteral stone without signs of sepsis or AKI, consideration should take place at trial of medical expulsive therapy to avoid general anesthesia. For those patients with COVID-19 with concern for AKI or infection, patients and providers should be aware of the potential impact on peri-operative outcomes.

Conclusions

Patients who underwent cystoscopy with ureteral stent placement for an obstructing ureteral calculus had an increased 30-day all-cause mortality if they tested positive for COVID-19.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Yale University Institutional Review Board (Registration

Number 00011725, Protocol Number 2000034818) and waiver was granted for obtaining informed consent and use of protect health information due to retrospective study design.

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