Shockwave Lithotripsy Use in the State of Michigan: American Urological Association Guideline Adherence and Clinical Implications

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OBJECTIVE To understand how treatment of patients with urinary stones by shockwave lithotripsy (SWL) aligns with current published practice guidelines.

METHODS We used the Michigan Urologic Surgery Improvement Collaborative Reducing Operative Complications for Kidney Stones registry to understand SWL use in the state of Michigan. This prospectively maintained clinical registry includes data from community and academic urology practices and contains clinical and operative data for patients undergoing SWL and ureteroscopy (URS). We identified patients undergoing SWL from 2016 to 2019. In accordance with AUA guidelines, we evaluated practice patterns in relation to recommendations for treatment selection for SWL as well as clinical implications of guideline nonadherence.

RESULTS Four thousand, two hundred and nine SWL procedures performed across 34 practices were analyzed. Perioperative antibiotics were administered to 61.3% of patients undergoing SWL. A ureteral stent was placed at the time of SWL in 2.7% of patients. For lower pole renal stones >1 cm or large (>2 cm) renal stones in the registry, 32.2% and 58.9% of patients, respectively, underwent SWL, while the remainder were treated with URS. In these instances, SWL was associated with inferior stone-free rate (SFR) relative to URS. In patients with residual stones after SWL, 34.6% were treated with repeat SWL with lower SFR than those treated with subsequent URS. Postoperatively, 42.1% of patients were prescribed alpha-blockers with no benefit seen in terms of SFR.

CONCLUSION Substantial variation exists among urology practices with regard to SWL use. These data serve to inform quality improvement efforts regarding appropriateness criteria for SWL in Michigan. UROLOGY 137: 38–44, 2020. © 2019 Elsevier Inc.

Shockwave lithotripsy (SWL) is among the most commonly performed surgical procedures for urinary stone disease (USD) in the United States.[1] The procedure is well tolerated, has few complications, and is associated with low rates of postoperative unplanned healthcare encounters.[2,3] However, these beneficial aspects of SWL must be weighed against its clinical effectiveness for stone clearance, which in most instances is inferior to ureteroscopy (URS).[4-6] Indeed, SWL outcomes are highly impacted by a variety of clinical factors. Thus, case selection is critically important to achieve optimal treatment response. To this end, the American Urological Association (AUA) guidelines on surgical management of kidney stones clearly define optimal perioperative management and case selection for SWL.[7]

Despite the recent publication of the AUA guidelines, the extent to which they are followed is not clearly understood. A recent survey-based study evaluating SWL practice patterns among Canadian and American urologists[8] observed that variation existed regarding routine antibiotic use, shockwave rate and intensity, and stent placement at the time of SWL. This study did not assess aspects of case selection such as stone size or location, factors that are intimately tied to SWL success. Moreover, the real-world implications of nonadherence to the AUA Guidelines are also poorly understood.

We utilized data from the Michigan Urological Surgery Improvement Collaborative Reducing Operative Complications from Kidney Stones (MUSIC ROCKS) registry to better understand SWL practice patterns in the state of Michigan. This clinical registry includes patients undergoing SWL and URS from more than 30 diverse urology

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practices across the state. We evaluated whether perioperative management and case selection for SWL aligned with current AUA guidelines and assessed the implications of guideline nonadherence. Our goal is that these findings may prompt more informed case selection thus improving the appropriateness of SWL treatment selection, and patient outcomes.

MATERIALS AND METHODS

Data Source

The MUSIC is composed of a diverse group of academic and private practice urologists across the state of Michigan. Currently, more than 90% of practicing urologists participate in this initiative which is supported by Blue Cross Blue Shield of Michigan.[9] The collaborative maintains a prospective, validated registry containing detailed clinical and operative information for patients with prostate cancer, USD, and renal cancer. Patients with USD treated with either SWL or URS are included in the ROCKS initiative. The MUSIC ROCKS registry was established in 2016 and now includes more than 10,000 surgical procedures performed across 34 urology practices. Practices employ trained data abstractors to prospectively enter data that includes variables on patient demographics, comorbidities, kidney stone history, imaging, treatment, and outcomes including unplanned healthcare encounters. Patient data are entered into the registry 60 days after a procedure. Stone clearance is based on absence of fragments in imaging (abdominal x-ray, renal ultrasound, or computed tomography) reports within this period.

Study Population

We identified all patients 18 years of age and older who underwent surgery for USD (URS or SWL) between June 2016 and February 2019. Nearly all SWL in Michigan are performed using a third party company that operates and maintains a mobile lithotripsy service. This is due to Michigan's status as a certificate of need state. We excluded patients with a nephrostomy tube, those who underwent staged procedures following percutaneous nephrolithotomy, those treated with a synchronous bilateral procedure, and patients in whom concomitant nonstone-related surgery was performed.

Outcome Measures and Statistical Analysis

Our intent was to determine how SWL use in Michigan aligned with AUA guidelines regarding perioperative management and case selection. The AUA guidelines on antimicrobial prophylaxis for urologic surgery[10] and the surgical management of kidney stones[7] were evaluated and statements relevant to SWL were included. We first identified the cohort of patients with USD who were treated with either SWL or URS. Within the SWL cohort, we assessed adherence to each guideline statement as well as potential implications of nonadherence as follows:

1. "*Routine antibiotic prophylaxis is not required prior to SWL unless there are risk factors*."

We determined the proportion of patients who had SWL that received perioperative antibiotics (single dose at time of surgery). We further examined variation in antibiotic prescribing patterns at the practice-level. The AUA guidelines state that antibiotics at time of SWL may be reasonable in those with risk factors (ie, urinary tract infection). We used preoperative urine culture status (positive vs negative) and comorbidity (assessed using Charlson index[11]) as a surrogate for high-risk patients. To understand implications of nonadherence, we determined whether receipt of antibiotics vs no antibiotics was associated with an increase in postoperative urinary tract infection, emergency department visit, or hospitalization.

2. "*Routine stenting should not be performed in patients undergoing SWL*."

We determined the proportion of patients who had a ureteral stent placed at the time of SWL. To understand implications of nonadherence, we determined whether the stone-free rate (SFR) differed between patients stented at the time of surgery and those who were not.

3. "*Clinicians should not offer SWL as first-line therapy to patients with >10 mm lower pole stones*."
4. "*In patients with total renal stone burden >20 mm, clinicians should not offer SWL as first-line therapy*."

We determined the proportion of patients who were treated with SWL for lower pole stones greater than 10 mm or renal stones greater than 2 cm relative to those treated with URS. We also assessed practice variation in SWL performance for lower pole stones greater than 10 mm in those practices who performed at least 10 such cases during the data collection period. This variation was not possible to assess for renal stones >2 cm due to low case volume. To understand implications of nonadherence we evaluated the SFR of SWL compared to URS after accounting for the need for auxiliary procedures (repeat SWL or URS). At present, percutaneous stone removal is not collected in the MUSIC ROCKS registry. Thus the proportion of patients reported herein are those who underwent SWL.

5. "*If initial SWL fails, clinicians should offer endoscopic therapy as the next treatment option*."

We identified patients treated with initial SWL who went on to have a second or staged ipsilateral procedure within 4 weeks. We calculated the proportion who were treated with repeat SWL vs URS. To understand implications of nonadherence we compared the SFR of those treated with repeat SWL to those treated with URS.

6. "*Clinicians may prescribe α-blockers to facilitate passage of stone fragments following SWL*."

We calculated the proportion of patients who underwent SWL that were prescribed adjuvant alpha-blocker therapy. We assessed variation in alpha-blocker prescribing patterns at the practice level. To understand implications of nonadherence we compared the SFR of those prescribed alpha-blockers vs those who were not.

Bivariate comparisons were made using *t* test or chi-square testing where appropriate. For SFRs, multivariable logistic regression analysis was performed to account for measured differences. We performed 2-sided significance testing and set a type I error rate at 0.05. All the statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC). Each MUSIC practice obtained an exemption or approval for collaborative

participation from a local institutional review board. Because it is part of a quality improvement initiative, the University of Michigan institutional review board deemed this project exempt from review.

RESULTS

We identified 11,813 procedures (SWL and URS) between June 2016 and February 2019. Of these procedures, 4209 were SWL and 7604 were URS. The majority of SWL cases were performed under sedation (61.0%) with the remainder being performed under general anesthesia. The overall postoperative imaging rate was 78.2% in the SWL group vs 43.0% in the URS cohort with abdominal x-ray representing the predominant modality used (58.2% overall).

Antibiotics were prescribed in 61.3% of patients undergoing SWL with substantial variation seen among participating practices (range 0%-100%, P <.01; Fig. 1). Those prescribed perioperative antibiotics did have higher rates of preoperative urinary tract infection than those who did not receive antibiotics (6.5% vs 4%, P <.01). There was no difference in comorbidity between those prescribed antibiotics and those who did not receive them (Charlson comorbidity 0.40 vs 0.39, P = .75). Those prescribed antibiotics had similar rates of postoperative urinary tract infection (4.1% vs 1.2%, P = .68), emergency department visits (4.1% vs 3.3%, P = 1.0), and hospitalizations (2.3% vs 0%, P = .3) as those not prescribed antibiotics.

Only 111 (2.7%) patients had a ureteral stent placed at the time of surgery. Placement of a stent at the time of SWL was associated with a 45% lower odds of stone-free status relative to patients who did not have a stent (odds ratio [OR] 0.55; 95% confidence interval [CI] 0.34-0.89, P = 0.01).

In total, there were 4509 patients in the registry with renal stones treated with either SWL or URS. As shown in Figure 2, patients with renal stones >2 cm and lower pole stones >1 cm underwent SWL 32.2% and 58.9% of the time, respectively. There was substantial practice variation observed with regard to case selection for SWL in patients with lower pole stones >1 cm. As shown in Figure 3, rates of SWL cases performed in this setting ranged from 12% to 100% (P <.01). SFRs decreased as stone size increased such that 41.5%, 30.1%, and 20% of patients with stones <1 cm, 1-2 cm, and greater than 2 cm were rendered stone free with SWL (P <.01). Relative to those treated with URS, patients treated with SWL for >2 cm renal stones or >1 cm lower pole stone had a 57% and 52% lower odds of being rendered stone free (OR 0.43; 95%CI 0.38-0.48, P <.01 and OR 0.48; 95%CI 0.36-0.64, P <.01) after adjusting for measured differences in stone size, body mass index, and practice variation.

Of the 4067 patients who underwent SWL as primary treatment, 526 (12.9%) required a staged procedure. As shown in Figure 4, 182 (34.6%) were treated with repeat SWL, 318 (60.5%) were treated with URS, and 26 were treated with both SWL and URS (4.9%). Stone size did not impact auxiliary treatment modality selection (SWL: 10.8 mm vs URS: 10.3 mm, P = .28) though patients treated with repeat SWL tended to have a higher proportion of stones located in the kidney (vs ureter) relative to those treated with URS (55.0% vs 43.4%, P <.01). The majority of patients who underwent initial SWL had a single auxiliary SWL procedure (n = 172, 82.7%) though 15.4% had 2 subsequent SWL and 1.9% required 3 or more subsequent SWL (range 1-5 procedures). Patients who underwent repeat SWL after initial SWL treatment failure had 69% lower odds of being rendered stone-free relative to those who underwent subsequent URS (OR 0.31; 95%CI 0.17-0.58, P <.01).

Postoperatively, alpha-blockers were prescribed in 42.1% of patients following SWL. The SFR in those prescribed alpha-blockers did not differ significantly from those not prescribed therapy (OR 1.14; 95% CI 0.95-1.36, P = 0.16). Substantial variation existed among practices with regard to alpha-blocker use ranging from 0 to 100% (P <.01).

DISCUSSION

We evaluated how SWL practice patterns in Michigan aligned with AUA guidelines as well as implications of

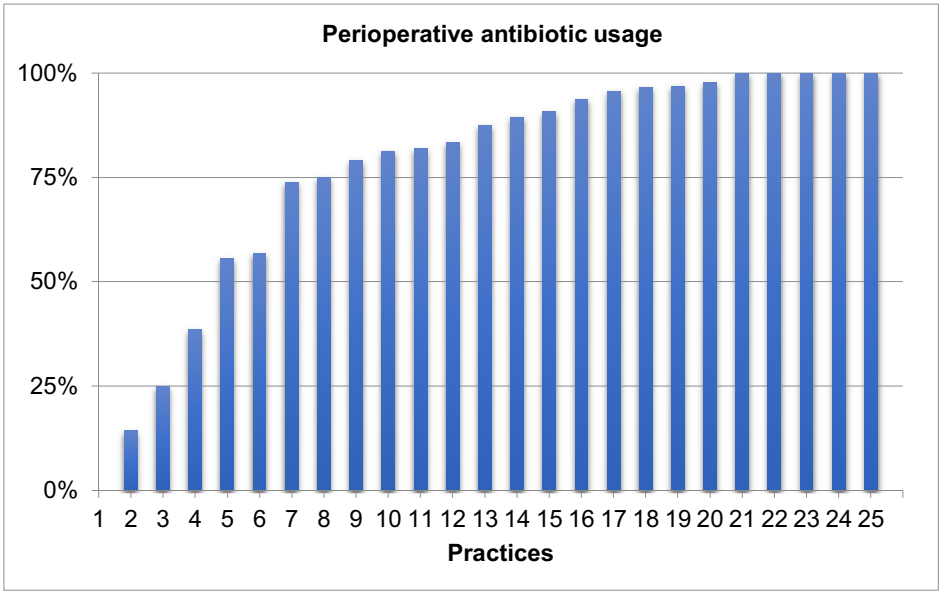

Figure 1. Variation in antibiotic use across practices at time of SWL. SWL, shockwave lithotripsy. (Color version available online.)

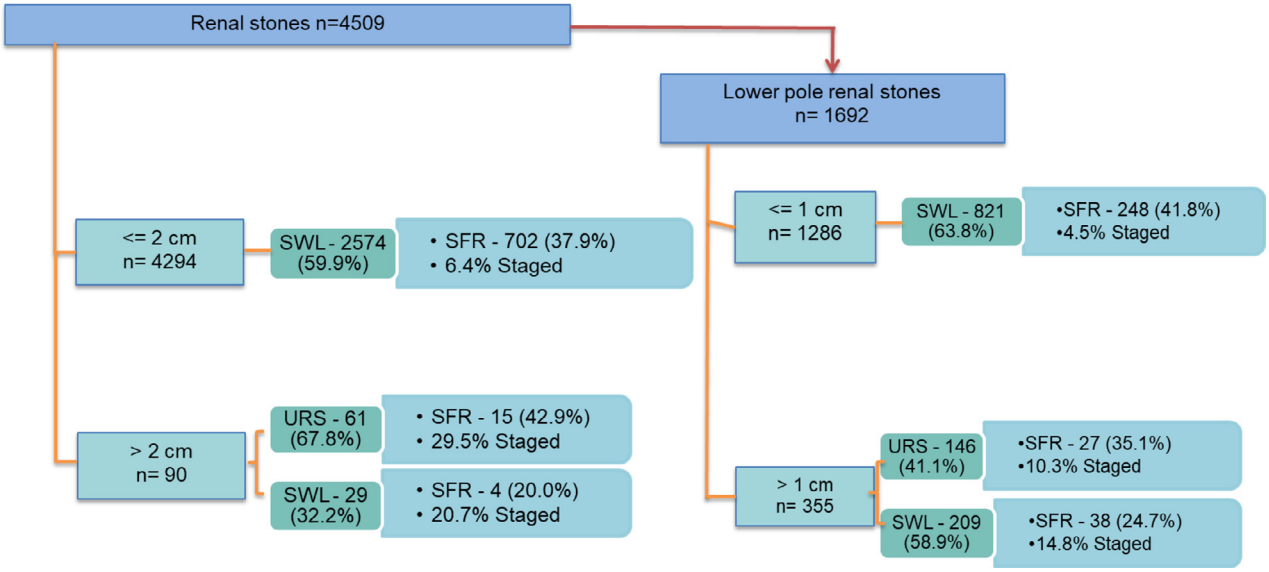

Figure 2. Treatment selection and outcomes for patients with renal stones. (Color version available online.)

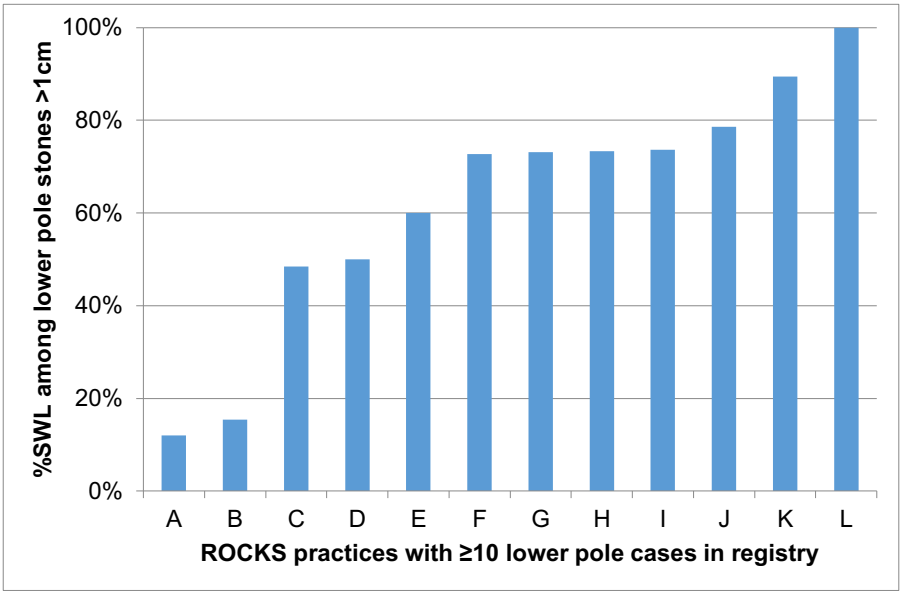

Figure 3. Practice variation in SWL case selection (vs URS) for lower pole stones >1 cm. SWL, shockwave lithotripsy. (Color version available online.)

case selection in a cohort of more than 10,000 patients. There were several principal findings. First, perioperative antibiotics, though not routinely required based on guidelines, were used in 61.3% of patients with no clear benefit relative to antibiotic omission. Second, stent placement at the time of SWL was performed infrequently and did not impact SFR. Third, SWL was performed in 32.2% and 58.9% of patients with renal stones >2 cm and lower pole stones >1 cm, respectively. Fourth, after failure of initial SWL, 34.6% of patient are treated with repeat SWL with substantially lower SFR relative to patients treated with URS. Finally, alpha-blockers were prescribed in less than half of patients undergoing SWL with no apparent impact on SFR.

Our findings regarding routine use of perioperative antibiotics at the time of SWL and their benefit are largely consistent with Alexander et al.[12] In this retrospective study evaluating more than 10,000 SWL cases performed in New Zealand, perioperative antibiotics were prescribed in 62% of cases with no impact on postoperative urinary tract infection or sepsis. Perhaps the most important potential downstream consequence of our findings is that clinicians in Michigan should routinely forego antibiotics unless patients are deemed to have risk factors for

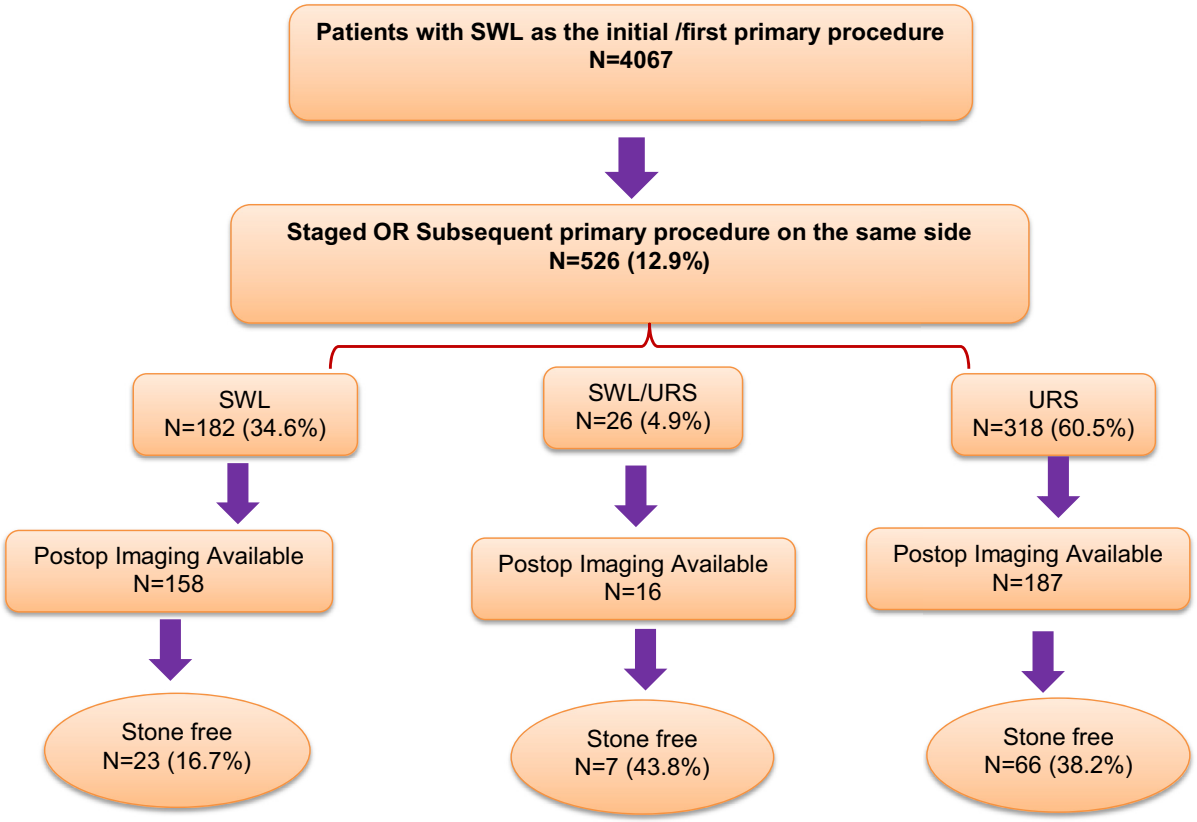

Figure 4. Auxiliary procedures in patients treated with initial SWL. SWL, shockwave lithotripsy. (Color version available online.)

infection. Consistent with a recent systematic review and meta-analysis,[13] we found that stent placement at the time of SWL was not associated with an improvement in SFR. In Michigan, urologists appear to be following this guideline as evidenced by an extremely low rate of intraoperative stent placement at the time of SWL. Alpha-blockers were prescribed in less than 50% of patients following SWL and patients prescribed these drugs did not see any benefit with regard to SFR. While meta-analyses have shown that adjuvant alpha-blocker use is associated with improved SFR after SWL,[14,15] study heterogeneity and issues with blinding/randomization are notable limitations which may explain our discordant results.

Perhaps the most compelling findings from our study relate to case-selection for SWL. In our registry which captures only cases treated with either SWL or URS, 1 in 3 patients with renal stones >2 cm and more than half with lower pole stones >1 cm are treated with SWL. Not surprisingly, SFRs in these settings are very poor. Several studies highlight the poor SFR of SWL for renal stones >2 cm and lower pole stones >1 cm.[16,17] Though no head-to-head comparisons of SWL and URS exist for stones >2 cm, SFRs using URS for large renal stones have been reported to be as high as 57% with single-stage surgery.[18] The data are clearer in the setting of lower pole stones with a recent systematic review and meta-analysis showing a 30% higher odds of stone-free status in those with lower pole stones >1 cm treated with URS relative to SWL.[19]

Interestingly, there was wide variation in practice patterns with regard to SWL case selection for lower pole stones >1 cm. When examining practices with at least 10 such cases in the registry, we were surprised to find that some practices routinely perform SWL on large lower pole renal stone. Though practice identity is blinded in our collaborative, this offers useful insight into potential avenues for quality improvement. For instance, perhaps this is driven by a practice issue such as lack of operative time or low surgeon confidence in URS technique. Findings such as these underscore the importance of continued quality improvement efforts in this area.

It is not clear why patients in our cohort undergo SWL in apparent contradiction to AUA guidelines, though there are several possible explanatory factors. SWL is unparalleled in its noninvasiveness relative to URS or percutaneous stone removal with overall complication rates of less than 6% with most being minor.[20] These factors may contribute to both patient choice as well as urologist preference for the procedure. However, this tolerability and noninvasiveness has to be reconciled with our finding that only 1 in 4 patients with large renal or lower pole stones are rendered stone free by SWL in Michigan. Further work is needed to understand whether patients advised of these real-world outcomes, may choose a different treatment modality.

Our study must be viewed within the context of some limitations. First, while we sought to understand alignment of SWL use with AUA guidelines, we could not account

for patient preference. It is possible that patients were accurately counseled as to the inferior outcomes associated with SWL yet still chose the procedure.[21] In attempting to determine the implications of guideline nonadherence we assessed SFR. It is clear that SFR for SWL depends on a multitude of factors, not the least of which are calyceal anatomy, skin to stone distance, stone density, and type of lithotriptor. These factors are not collected in the registry. In addition, while percutaneous stone removal is often the preferred treatment modality for large renal and lower pole stones, these cases are not captured at present in the MUSIC ROCKS registry. Finally, imaging was performed in approximately 70% and 50% of patients undergoing SWL and URS, respectively, with abdominal x-ray predominating. Though these rates of postoperative imaging and use of abdominal x-ray are consistent with national data,[22] this very likely leads to overestimation of SFR.

Despite these limitations, we present the first large-scale data on alignment of SWL with AUA guidelines for the treatment of USD. The use of SWL is declining across the United States and Canada based on recertification data.[23,24] The purpose of the present study was not to highlight the limitations of SWL or perpetuate the trend of lower utilization. Instead we seek to identify opportunities to improve SWL outcomes. To this end, we have established a working group of committed urologists and have identified 5 potential targets for quality improvement. These include:

1. Enhancing patient education by focusing on the tolerability of SWL while being clear about realistic SFRs.
2. Limiting inappropriate antibiotic use at the time of SWL.
3. Establishing accepted guidelines regarding stone size and location to improve case selection and outcomes.
4. Optimizing SWL delivery by working toward a more standardized operative approach. This could include aspects such as guidance on coupling gel application and voltage ramping, which have been shown to improve SFRs.
5. Increased postoperative imaging use so we understand our outcomes and can track the effects of our quality improvement efforts over time.

CONCLUSION

Both SWL and URS are common surgical procedures for the treatment of USD. In Michigan, there is variability in AUA guideline adherence with respect to recommendations for SWL. In particular, SWL is used in the setting of large renal stones and large lower pole stones, with corresponding lower SFRs in comparison to URS. Using these data, we plan to establish collaborative-wide SWL appropriateness criteria in order to prospectively track case selection and outcomes moving forward. Our ultimate goal is to improve SWL outcomes in Michigan.

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EDITORIAL COMMENT

This outstanding investigation reports the real-world practice patterns for shockwave lithotripsy (SWL) across multiple practice settings in Michigan. This is a unique study that could only be accomplished by leveraging the Michigan Urological Surgery Improvement Collaborative Reducing Operative Complications from Kidney Stones registry. The authors developed a list of process and outcome measures utilizing the AUA guidelines as a framework and assessed adherence to these guidelines.

Perhaps the most notable deviation from AUA guidelines was the popularity of SWL to treat lower pole stones >1 cm (58.9% of the time). While Michigan Urological Surgery Improvement Collaborative Reducing Operative Complications from Kidney Stones does not currently track percutaneous nephrolithotripsy, a key alternative to SWL for the treatment of large stones, we feel that proportions of SWL used in conjunction with the low stone-free rates achieved are sufficient to suggest that SWL is overutilized in these settings. However, patient preferences should not be undervalued. The authors found that while the stone-free rate with SWL for lower pole stones >1 cm was a dismal 24.7%, but it was not much better for ureteroscopy (35.1%). Only the patient can determine if the 10% difference in stone-free rates sways the pendulum for them. It is up to us as the urologists to guide the patient through selecting the procedure that balances the individual tolerance of morbidity, success rates, and personalized priorities rather than dictate the procedure.

Also surprising were the high rates of preprocedural antibiotic prophylaxis use, despite guidelines recommendations that prophylaxis is unnecessary. Antibiotics were given in 61.3% of SWL cases and yet failed to show a reduction in rates of postoperative urinary tract infections, emergency room visits or hospitalizations. The extremely low complication rates in both groups in a prospective, community based study may further reassure practitioners of the safety of eliminating prophylaxis.

This is a remarkable example of large-scale quality improvement in action. It is paramount that we as a profession undertake efforts to analyze our compliance with our professional guidelines. Furthermore, we must assess the harm, if any, caused by deviating from guidelines in order to update, revise and remove guidelines when appropriate. This analysis has identified multiple deficiencies and we eagerly await the follow-up study assessing the effect of the proposed targeted interventions.

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