



Validated Methods of Assessing Quality of Life in Stone Disease

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Abstract

Purpose of Review With the emphasis on quality standards when determining reimbursements rates, patient reported outcomes are now of particular interest to clinicians. This review addresses health-related quality of life (HRQOL) detriments that have been studied in patients with stone disease.

Recent Findings Several instruments been validated for use in stone formers. Previously, generic instruments revealed decreased HRQOL in urolithiasis patients. Recently, a disease-specific tool has been developed and has provided more insight into the specific symptoms that negatively affect the patient experience.

Summary Evidence now reveals lower HRQOL in both symptomatic and asymptomatic patients with calculi, as well as varying determinants after certain interventions. Disease-specific tools have been shown to be more sensitive to urologic-related complaints. These findings should be considered in management decisions to allow for patient-centered care. Further application and standardization of these assessment tools into prospective studies may have value in refining current treatment guidelines.

Keywords Patient-centered care · Quality of life · Urolithiasis · Nephrolithiasis · Stone disease

Introduction

Urolithiasis, one of the most common urologic pathologies, places a heavy economic burden on the United States (US) healthcare costs. According to recent literature, the prevalence of stone events in the US population is estimated to be 10.6% for men and 7.1% for women [1]. Over the last several decades, there has been an increase in the lifetime risk of developing a symptomatic episode of kidney stones [2, 3]. Nephrolithiasis recurrence rates approach 50% in select patients groups, compounding the issue further. All of these factors contribute to the over \$2 billion stone-related healthcare spending [4].

Given the economic ramifications of stone disease, it is imperative that medical professionals assess the effectiveness of diagnosis, management, and outcomes of stone disease using measurements such as patient reported outcomes (PRO). PRO is increasingly utilized in clinical research, but is also beginning to be emphasized in routine clinical practice to assess symptoms, inform treatment decisions, facilitate communication, and track outcomes [5]. By assimilating PRO into management decisions, providers are able to encourage patient engagement and strengthen the shared decision-making process by highlighting the patient perspective regarding symptom severity and treatment response. This information also helps to guide discussions regarding prognosis, expectations, and goals of care. Population norms also provide patients with an understanding of the pathologic process and standard by which to compare patient experiences with disease, especially useful in chronic conditions [5]. Furthermore, tracking the natural course of disease in a given subject can be incorporated into personalized medicine algorithms for individualized care.

One important PRO is health-related quality of life (HRQOL), which is a multidimensional construct of how illness and treatment may affect an individual's mental, physical, and social well-being [6]. Measuring HRQOL is particularly relevant in patients with stone disease due to the wide

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spectrum of disease activity observed over time, which may not correlate with traditional objective indices, such stone-free status on imaging [7].

Currently, both AUA and EUA guidelines consider stone size, obstruction, and failed response to medical or expectant management as indications for more invasive therapy [8]. Both extracorporeal shock wave therapy (ESWL) and ureteroscopy (URS) are commonly utilized interventional therapies; ESWL has lower mortality and complication rates, while ureteroscopy has high rates of stone-free status after a single procedure. Both treatment modalities are generally offered to patients, and these treatments are both shown to be equal in outcomes [8]. However, assessing HRQOL parameters associated with each intervention in addition to stone-free status may provide insight into the treatment of choice with respect to a patient's self-perceived health status, as well as social functioning related sequelae of medical versus surgical management.

HRQOL

Health-related quality of life, a general term encompassing five categories, considers a patient's duration of life, impairments, functional states, perceptions, and social opportunities in relation to their health status [9]. Each of these can be affected by disease states, and an assessment of the aforementioned categories provides insight into general well-being, beyond the criteria that is usually evaluated in the acute clinical situation.

Generic instruments allow for broad evaluation of HRQOL outcomes that are easily comparable across varying degrees of disease and diverse pathologies. These assessment tools have low content validity, as they may contain vague items not relevant to all study participants; however, they usually have high test-retest and internal consistency reliability [10]. Disease-specific instruments are utilized to evaluate specific populations, usually with a common diagnosis. These tools are able to detect subtle, yet clinically significant, changes in HRQOL categories. As opposed to generic instruments, they generally have higher content validity as assessment questions are tailored to a narrowed disease state, yet they can have lower test-retest and internal consistency as a subject moves through the acute and chronic phases of their disease [10]. Practically, when assessing HRQOL in patient populations, clinicians often use a mixture of generic and disease specific tools, creating hybrids such as modified generic, generic with disease specific supplements, and batteries of specific measures [10].

QOL Instruments

As discussed above, HRQOL can be assessed either with a generic or a disease-specific instrument [Table 2]. The most

widely used generic instrument is the Short Form 36-Item Survey, referred to as the SF-36, which is a health profile [5]. As a health profile, the SF-36 measures eight domains, which can be combined into a physical and mental composite summary score [11]. These composite summary scores can be compared to population-based norms. The instrument has excellent reliability and validity with minimal administrative burden [11].

There are several other generic instruments, which may demonstrate superior measurement characteristics. For example, the EQ-5D is a preference-based measure, which allows the respondent to generate a health profile across five domains and then assign a preference value or utility to their overall health status at that point in time using a visual analog scale [11]. This measure has demonstrated success in several other disease states [12].

Recently, a robust set of PRO measures were developed through a partnership of US academic institutions and the National Institutes of Health [13]. The purpose of the Patient-Reported Outcomes Measurement Information System (PROMIS) was to provide researchers with an item bank of precise, efficient, and flexible PRO measures [13]. Several PRO measures covering diverse domains such as physical functioning, fatigue, pain, sleep disturbance, emotional distress, and social health were developed [13]. A major advantage of PROMIS is that scores can be benchmarked to population-based norms and computer adaptive testing can be used to significantly reduce the administrative burden [13]. These measures are growing in popularity, particularly within the surgical disciplines, likely due to their flexibility and ease of use [14].

Previously, only generic instruments were available, but a disease-specific HRQOL instrument, the Wisconsin Stone Quality of Life Questionnaire (WISQOL), was developed in 2012, validated in 2016, and publicly released in 2017 [15•, 16]. The value of a disease-specific instrument is that it includes dimensions relevant to patients with kidney stones, such as urinary symptoms, which are absent from generic instruments. A disadvantage of the WISQOL is that it was only validated in a single cohort, it is unclear if it is responsive, and no population-based norms exist [15•, 16]. Despite these limitations, it remains the only available disease-specific instrument.

Instruments in Validated in Stone Disease

Short Form 36-Item Survey

When assessing HRQOL domains in stone formers, the most commonly utilized instrument in the literature thus far is the generic SF-36 assessment tool. Overall, most of the studies conducted found that stone formers generally have lower

HRQOL than the established population norms or control population, with the majority of deficits being present in the physical health problems, bodily pain, general health perception, and social function domains [17–19, 22, Table 1].

In one of the earliest studies using the SF-36, Penniston and colleagues identified that in 189 patients with nephrolithiasis, there was a clinically significant lower HRQOL in the domains of general health and bodily pain, but not in the other six domains as compared to population-based norms [17]. In addition, women scored significantly lower in all domains, except social functioning [17]. Comorbid conditions also appeared to play a role with patients with multiple conditions expressing a lower HRQOL [17]. Interestingly, the number of stone-related procedures did not impact the scores [17]. A severe limitation of this survey study was that it suffered from a low response rate and was retrospective and cross-sectional in nature precluding evaluation of changes in HRQOL in relation to changes in disease activity over time [17].

In another cross-sectional study using the SF-36, Bensalah et al. confirmed that in 155 patients with nephrolithiasis, there was a clinically significant lower HRQOL in the domains of physical functioning, role physical, general health, and social functioning, but not the other domains as compared to population-based norms [18]. There was also a clinically significant lower score in the physical composite, but not the emotional composite summary [18]. Proximity to a stone episode also appeared to influence the score with patients having a more recent episode (< 1 month) scoring lower in the physical composite, bodily pain, general health, and social functioning domains [18]. On multivariate analysis, age, body mass index, number of surgical procedures, and ureteral stent placement were all independently associated with lower domain scores [18]. Again, this investigation suffered from similar limitations, including its cross-sectional nature, but it also demonstrated that the SF-36 may not be responsive to changes in disease activity, as the differences in scores between stone formers and population-based norms were small [18].

In the only prospective study to date examining HRQOL over time, Donnally and colleagues examined 152 patients with the SF-36 at baseline and then a convenience sample of 96 of those patients at a later date when they returned for an office visit [19]. In the patients who had a stone event 1 month prior to the baseline survey, there was no difference in domain scores across the two time points [19]. Similarly, in patients who did not have a stone event prior to either time point, there was no difference in domain scores [19]. This suggests that the SF-36 may not be responsive, although this study was limited by missing data and a lack of standardized follow-up [19].

Wisconsin Stone Quality of Life Questionnaire

In response to the issues faced by the authors of the aforementioned studies when utilizing generic instruments, a disease-

specific HRQOL assessment tool was developed for application in urolithiasis patients. Upon analysis, 89% of WISQOL items had varying responses between patients with and without urolithiasis, whereas only 19% of SF-36 items had varying responses between these same patient populations. Therefore, the creators suggest that WISQOL has the ability to detect stone-specific HRQOL detriments [15••]. Through validation of the WISQOL survey, the creators found that patients with stones and related symptoms scored lower than those with asymptomatic stones or no stones [15••].

Symptomatic stone formers have been found to have HRQOL deficits on both generic and disease-specific instruments. However, even asymptomatic patients with urolithiasis have been shown to have decrements in specific HRQOL domains. In a study by Penniston et al., the authors administered the WISQOL survey to 107 patients with no stone-related complaints at the time of the encounter, 78% of whom were recurrent stone formers who had either passed a stone or required a surgical intervention. Self-perception of stone status was assessed and confirmed by imaging (KUB, CT, or ultrasound). Of the 49% of patients who believed they had stones, 82% were correct [7] (Table 2).

Patients who had perceived positive stone status were significantly more bothered by urinary frequency than those who did not believe they had stones at the time of survey administration. Regardless of perception, patients who were confirmed to have stones on imaging reported significantly higher rates of urinary urgency and anxiety about the future than those without stones [7]. Therefore, even patients in the asymptomatic phase of disease may have HRQOL impairments to be considered by providers.

Given its established validity in patients with urolithiasis, the WISQOL can not only be utilized to retrospectively assess pathologic detriments to HRQOL, but can also be applied prospectively to compare the tolerability of different interventions. In an attempt to assess drainage after percutaneous nephrolithotomy (PNL), a prospective randomized study was conducted where patients received an 18 French (Fr) nephrostomy tube removed on postoperative day 2, 5 Fr ureteral stent removed cystoscopically on postoperative day 14, or a 5 Fr open-ended ureteral catheter attached to a Foley catheter, removed on postoperative day 2. The WISQOL was administered preoperatively and on postoperative day 14 [20].

Patients who underwent nephrostomy tube drainage had significantly longer length of stay and required more analgesia prior to tube removal than those who underwent either ureteral stent or catheter placement. However, in terms of HRQOL parameters assessed with the WISQOL scores, patients who underwent ureteral stent placement report significantly higher rates of stent irritation-related symptoms, such as nocturia, frequency, and urgency. They were also found to have higher rates of anxiety, annoyance, irritability, and lower motivation,

Table 1 Summary of studies discussed in this review

Author	Publication year	Instrument used	Population	Outcome
Penniston [17]	2007	SF-36	189 patients with nephrolithiasis	Lower HRQOL found in general health and bodily pain domains
Bensalah [18]	2008	SF-36	155 patients with nephrolithiasis	Lower HRQOL in domains of physical functioning, role physical, general health, social functioning
Donnally [19]	2011	SF-36	152 patients an outpatient urology center	No significant differences in HRQOL domains between baseline and return visits, or baseline and those who had a stone event in the prior month
Bryant [22]	2012	SF-36	115 patients with nephrolithiasis	Lower HRQOL in physical functioning, role physical, role emotional, vitality, mental health, social functioning, bodily pain, general health, with women scoring significantly lower than men
Penniston [16]	2013	WISQOL	248 patients from an outpatient urology center	Established disease-specific tool for detecting HRQOL detriments in stone formers
Penniston [7]	2016	WISQOL	107 asymptomatic patients with a history of nephrolithiasis	Decreased HRQOL in patients who believed they had active stone disease (regardless of confirmation via imaging) and those who were confirmed to have active disease (regardless of perception)
Penniston [15••]	2017	WISQOL	1609 patients from outpatient urology centers	89% of patients with and without urolithiasis had varying responses on WISQOL versus 19% on SF-36
Jiang [20]	2017	WISQOL	90 patients undergoing PNL randomized to postoperative drainage by nephrostomy tube, ureteral stent, or ureteral catheter	Decreased HRQOL in patients who underwent ureteral stent drainage after PNL versus nephrostomy tube or ureteral catheter
Borofsky [21•]	2017	PROMIS	1162 patients with nephrolithiasis	Decreased pain interference scores in patients after emergency room encounter, ureteral stent removal, and trial of passage
Joshi [23]	2003	USSQ	309 patients with and without indwelling ureteral stents	Development and demonstration of validity of a questionnaire more sensitive in detecting urinary symptoms, body pain, general health, work performance in patients with indwelling ureteral stents

Table 2 Validated HRQOL tools in nephrolithiasis

Short Form 36-Item Survey (SF-36)	Generic instrument	https://www.rand.org/health/surveys_tools/mos/36-item-short-form.html
Patient-Reported Outcomes Measurement Information System (PROMIS)	Generic instrument	http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures
Wisconsin Stone Quality of Life Questionnaire (WISQOL)	Disease-specific instrument	https://www.urology.wisc.edu/wisqol

interest in sex, and socializing. Furthermore, patients who underwent stent placement were less willing to undergo the same procedure (70%) in the future as compared to the other two cohorts (86.7% in the nephrostomy tube cohort vs 96.7% in the ureteral catheter cohort, $p < 0.05$) [20].

The use of the WISQOL survey in the aforementioned study highlights the utility of assessing HRQOL parameters when comparing interventions that have clinically insignificant difference in outcomes. Additionally, despite having a longer hospitalization time and requiring more analgesia with nephrostomy tubes, patients who underwent nephrostomy tube drainage had higher self-perceived health status and were more willing to undergo the same intervention a second time than patients who underwent the more minimally invasive procedure [20]. This study is also limited by the fact that it was conducted only at a single institution, but incorporating the WISQOL across multi-institutional randomized controlled trials would allow us to better incorporate patient-centered care into our urologic treatment algorithms.

Patient-Reported Outcomes Measurement Information System

As referenced in the introductory section of this review, the natural progression of nephrolithiasis involves acute stages of symptomatology. Since PROMIS collects information regarding HRQOL domains retrospectively over the past 7 days, providers are able stratify patients by their phase of disease and obtain data specific to their phase of care. In a study of 2018 surveys collected from patients with urolithiasis, Borofsky et al. stratified their population into four cohorts based on type of outpatient encounter: emergency department follow-up, trial of passage, stent removal, and 1-month post-operative office visits [21•]. Since pain is the most common chief complaint in patients experiencing an acute stone episode, the authors administered pain-specific PROMIS measures to each cohort. They assessed pain intensity to quantify the amount of pain experienced, as well as pain interference, to quantify the extent to which pain has affected the ability to perform daily activities. Within this study, a T-score greater than 60, one standard deviation greater than the population mean, was defined as severe pain for both pain intensity and pain interference [21•].

The authors found that 88% of patients reported some degree of pain at outpatient visits within 1 week of emergency room presentation and after removal of a ureteral stent that was usually placed during an endoscopic intervention. Within the emergency room follow-up cohort, 83% of patients had severe pain interference scores (defined as a T-score greater than 60), while only 24% of patients had severe pain intensity scores. In the post-stent removal cohort, 57% of patients reported severe pain interference, with only 8% reporting severe pain intensity. Thirty-eight percent and 4% of patients reported severe pain interference within the trial of passage and postoperative cohorts, respectively. In both of these cohorts, less than 5% of patients had severe pain intensity scores. All of the pain scores varied significantly between all cohorts, with a p value < 0.05 [21•].

Interestingly, in each cohort, the number of patients reporting severe pain interference scores was significantly greater than the number of patients reporting severe pain intensity scores [21•]. This raises the question about a potential confounder that remains unaccounted for within the PROMIS pain scales, but certainly highlights the need for provider to further investigate and integrate impairment to activities of daily living throughout the various clinical phases of urolithiasis.

Ureteral Stent Symptom Questionnaire

In an attempt to create a tool to evaluate HRQOL in patients with ureteral stents for both urolithiasis and ureteropelvic junction obstruction, the Ureteral Stent Symptom Questionnaire (USSQ) was developed in hopes to address specific urinary symptoms. The creators of the study utilized both objective and subjective methods to create an initial database of 116 question items, consisting of a literature review along with patient interviews of men and women with indwelling stents, analyzed by a panel of urologists, a nurse, and a sociologist [23]. Through field testing and elimination of items with both low and high endorsement frequencies, high Pearson's correlation coefficients, and low sensitivity of change, they were left with 38 items found to have significance in the aforementioned statistical tests. They further divided these items into six domains, consisting of urinary symptoms, body pain, general health, work performance,

sexual matters, and additional problems. Upon validation, changes in all domains except sexual matters were statistically significant when comparing scores from week 1 and week 4 post-stent insertion to scores after stent removal [23].

Conclusion

Whether overall quality of life in stone formers is being assessed with a generic or disease-specific instrument, it is clear that there are deficits in at least some specific HRQOL domains. WISQOL, the only currently validated disease-specific instrument, has shown utility in assessing symptoms retrospectively, as well as prospectively when utilized in randomized controlled trials. However, there is still a paucity of data regarding the patient perception in this constantly evolving disease. It has been established that the chronic course of nephrolithiasis leads to waxing and waning symptoms based on various factors, including stone burden, location of stone, medical versus surgical management, etc. However, we have yet to collect HRQOL data and stratify it based on stage of disease.

Although radiographic stone-free status has remained the primary treatment goal in urolithiasis [7], with the advent of bountiful minimally invasive techniques that have similar clinical outcomes, incorporating HRQOL considerations into treatment algorithms is of increasing importance. The Centers of Medicare and Medicaid is placing significant emphasis on quality standards in their determination of reimbursement rates; HRQOL considerations now have an added economic consideration in healthcare. Given the heavy economic burden that urolithiasis places on our nation's medical costs, it is prudent to gather HRQOL data from both generic and disease-specific instruments. Furthermore, it is imperative that we embed the use of disease-specific assessments into our protocols for randomized controlled trials, as HRQOL domains should be given equal emphasis to other clinical outcome endpoints.

As urologists, we help our patients cope with some of the most intimate health complaints, such as urinary incontinence, urgency, and frequency. These irritative symptoms, often observed in patients suffering from urolithiasis, have a significant impact on stone formers, regardless of whether or not they are having an active flare of stone disease [20]. By standardizing the incorporation of HRQOL measures into our clinical decision-making, we have the opportunity to improve the healthcare experience for our patients.

Compliance with Ethical Standards

Conflict of Interest Ruchika Talwar declares no potential conflicts of interest.

Justin Ziembra reports personal fees from Visible Health, outside the submitted work.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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