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Symptomatic urinary stone disease mandates treatment to help patients. Stone-free status has been the principle measure of success to determine how well stone formers have been treated. Although stone elimination remains paramount, success outcomes, as in other disease processes, will begin to include the patient's perception of treatment and hopeful prevention of further disease. Health-related quality of life (HRQoL) addresses more than simple assessments of desired endpoints, such as stone-free status, or physical symptoms, such as pain. Measuring HRQOL includes assessing domains related to physical, mental, emotional, and social functioning in order to evaluate the impact health status has on patient perception of quality of life.

Overview

History

Urinary calculi have plagued humans since early civilization. Uncovered mummies have been found with retained bladder stones from over 4,500 years ago. Written accounts from between 3000 and 1500 BC describe symptoms and give treatment recommendations for stones. While surgery, via perineal lithotomy, was the final alternative for eradication, even then, dietary recommendations were made to preclude these bothersome stones [1].

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Epidemiology

Urinary stone disease is a chronic condition which results in extremely painful episodes that are responsible for a multibillion-dollar financial burden in the United States alone [2, 3]. Most recent calculations of NHANES data in 2012 estimates an 8.8% prevalence of stones in the United States, with males being more affected than females (10.6% and 7.1%, respectively) [4]. Incidence rates have been reported between 10% and 15% which is comparable with other developed countries [5, 6]. The prevalence of urolithiasis has increased in the last several decades and is projected to continue its uphill climb as the risk factors for stones also increase in prevalence [7, 8].

Those at increased risk for urinary calculi include the male gender, those living in warmer climates, the obese, those with a family history, and the working, social age groups (20–60 years of age) [7]. Without preventative treatment, the recurrence rate is 50% at 5 years, 50–60% at 10, and up to 75% at 20 years [2, 6, 8]. With the help of pharmacotherapy, dietary changes, or both, the risk of stone recurrence rates can be decreased [9, 10].

General

The formation of urinary calculi is a condition that depends on the tipping of a delicate balance of biologic ions in saturation, leading to a crystallization and ultimately stone formation at the filtration level. Stone formation has been associated with obesity, GI pathology, dietary patterns, and certain pharmacotherapies [7, 11, 12]. There are many solute concentrations which influence stone development, including calcium, phosphate, oxalate, uric acid, citrate, magnesium, sulfate, and other proteins and macromolecules [13]. While calcium is the most common stone component, many different stone types exist that affect the urinary tract [2, 14]. Various etiologies of stone formation require different approaches for treatment and prevention.

Management

As our knowledge of these stones has progressed, management has evolved to become two-part; treatment of acute stones and prevention of the secondary stone event.

Acute management consists of surgical intervention and medical expulsive therapy (MET), the two current methods which strive to resolve the episode of renal colic and bring HRQoL back to baseline.

Surgical management has been evolving since the first documented renal extraction in 1550, when 18 stones were drained through the opening of a lumbar abscess [14]. Modern techniques are well known and include shockwave lithotripsy (SWL), ureteroscopy (URS), or percutaneous nephrolithotomy (PNL)

[15]. Rarely, unique or extreme circumstances may require open or laparoscopic procedures for stone removal. Surgery brings stone-free rates that range from 68% to 100%, with PNL (the more invasive of modern techniques) having the highest rate of success.

Although surgical intervention resolves the patient symptoms, complications may occur. Infectious complications include UTI, sepsis, peritonitis, and perinephric abscess [16]. Other complications of surgery, in addition to the anesthesia risk, include major hemorrhage, steinstrasse, ureteral perforation and injury, stricture, and the need for further procedures [15–17]. Additionally, postoperative ureteral stents may be poorly tolerated, preventing patients from returning to usual activities, including their jobs.

In appropriate patients, MET has the potential to spare patients from the morbidity associated with a surgical procedure. MET started making strides in the early 1990s with calcium channel blockers and alpha-adrenergic blockers taking the spotlight, with supplemental NSAIDs and steroids providing marginal benefit [10, 17, 18]. MET stone passage rates see an absolute increase between 9% and 29% with alpha-adrenergic blockers as the only statistically significant therapy. Side effects that are commonly seen with MET are generally mild, including orthostatic reactions, nasal congestion, and ejaculatory disturbances [10]. Unsuccessful MET, however, subjects patients to both the trial of passage and the surgery and the HRQoL impact from both approaches.

While a stone-free state is the goal of therapy in acute stone events, surgery and expulsion do not address the underlying cause of the stone formation. Therefore, identification of risk factors and preventative management are the next steps in therapy. Prevention by pharmacotherapy has been studied since the early 1980s and was neglected for a time when advances in SWL and URS lasers were burgeoning [9].

The variety of stones and variability of their etiologies necessitate a variety of therapies to be utilized in prevention. The most commonly utilized drug classes include thiazide diuretics, alkali citrates, xanthine oxidase inhibitors, and chelating agents [10]. Though not all have proven statistically significant, they have all been shown to provide some sort of reduction in stone recurrence. The side effects of these drugs range from minor rashes or GI upset to more major effects, such as thrombophlebitis or leukopenia [10, 19].

Dietary and nutritional changes also play a key role to reduce stone recurrence. While other chapters in this book go into further detail on nutritional approaches, basic principles include increased intake of fluid, reasonable intake of ion-containing products, and, if necessary, restriction of purine-rich foods [10]. Adhering to a healthy diet and maintaining an appropriate weight are also beneficial since obesity is a risk factor for stone formation [20]. These recommendations have shown to have an overall benefit of stone prevention, especially in the population with mild-moderate metabolic abnormalities [21]. While there have been less than a handful of adverse events reported in trials, dietary intervention comes without any well-documented or observed side effects [22].

Health-Related Quality of Life

Am I able to carry on with my essential responsibilities? Am I being hindered from doing the things I love due to pain? Do I have a normal amount of energy? Am I happy with my life?

Quality of life (QoL) is a very personal and individual interpretation of, what most can appreciate to be known as, “effective” life. While calculating and exacting something so subjective seems, at times, inconceivable, QoL has taken a front seat and effective role in our healthcare system [23, 24]. It promotes patient-centered care through consideration of medical outcomes along with the psychosocial implications from disease and its therapies. When evaluating successful outcomes, these patient-reported subjective perceptions provide a different point of view than the physician’s traditional objective endpoints for success.

History

The concept to formally measure “life satisfaction” began in the mid-twentieth century [25]. Most of the initial tools/surveys were single dimension scales, which were disputably only applicable to certain population groups. They addressed general themes such as zest and apathy. In the 1980s, Deiner et al. developed a five-question scale that exhibited potential for both favorable psychometric properties and the ability to be applied to the clinical setting.

As sophistication of disease study and healthcare advanced, health status amended to also include the measure of QoL in patients. The term *health-related quality of life* (HRQoL) emerged to help identify the impact of disease, or its treatment, on patients [26]. The HRQoL concept encompasses life duration, impairments, individual perceptions, and social circumstances. The early 1990s brought SF-36, a relatively brief survey that would prove valid, reliable, and a springboard for many modern HRQoL surveys [24, 27]. The SF-36 survey displayed utility for all different populations, spanning all disease types. This survey like many others correlates a lower score with a lower HRQoL.

The desire for disease-specific surveys was encouraged when unique QoL profiles were noted among different chronic diseases [23, 26]. The subtle nuances of disease-specific tools could provide a better understanding of treatment responses. And it was postulated that if they were properly formed and used, predictions of populations and their prognoses might be possible [5, 26].

Urology in HRQoL

HRQoL has been incorporated into the urologic community; however much of its earlier attention was focused on prostatic disease and malignancies [28, 29]. While those topics expanded concurrently with the blossom of all HRQoL topics, nephrolithiasis remained mostly unexplored [5, 23, 30]. At the turn of the millennia, there

were still only a handful of studies addressing the HRQoL in nephrolithiasis patients, and they only focused on HRQoL comparisons between different surgical preferences [31–33].

Only in the last decade have there been strides to understand HRQoL in recurrent urolithiasis patients. Most of those studies have utilized SF-36 survey. In 2010, in a study designed to assess the reading level of questionnaires in urology, Bergman concluded that, while stones remained one of the most financially burdensome urologic diseases, there were no disease-specific instruments in existence [34].

Donnally et al. conducted a longitudinal study in 2011 to assess the HRQoL over time in stone formers [35]. All patients completed two separate SF-36 surveys with an average 18-month interval. Comparing the scores of the first and second forms, they found no difference in HRQoL over time, even in those patients who had a new stone event within the interval period. This study, and the lack of its ability to find a difference between the groups compared, highlighted how important the creation of a stone-specific instrument would be. So, while SF-36 had utility in assessing HRQoL in a variety of patients, there remained a need for a stone-specific instrument.

In 2013, Penniston and Nakada revealed the development of the Wisconsin Stone-QoL instrument [36, 37]. This 28-question survey, the WiSQoL, demonstrated the ability to distinguish survey responses between stone formers, both with and without active stones, as well as distinguish stone formers from healthy non-stone-forming individuals.

HRQoL in Stone Formers

It is well known that active stone patients commonly present with nausea, vomiting, cramping, hematuria, and/or dysuria in addition to the renal colic pain [11]. This pain can be very debilitating and commonly results in emergency room visits. Heavier prescription analgesics are frequently prescribed for these patients with refractory pain.

In addition to the physical symptoms that these patients endure, they also report sleep disturbances, feelings of isolation, low mood, and problems with intimacy [36, 37]. They bear the obligatory accommodations that come with having kidney stones that includes missing work and social/family time. Most unfortunate is that in between events, stone formers will commonly be, in some part, consumed by anxiety and worry about when their next stone event will be.

The HRQoL in stone formers has been consistently poor when compared to the general public [5, 36, 39, 40]. Because of the novelty of WiSQoL, most formal investigations have measured HRQoL with SF-36 survey.

Penniston et al. conducted a cross-sectional study in 2007 to characterize the HRQoL of stone formers at their institution [5]. They employed the use of SF-36 survey for these patients and compared them to US norms. They found that the overall HRQoL of stone formers was less than US norms, with statistically significant differences in the domains of general health and bodily pain. They also observed

that females reported greater HRQoL detriment when compared to their male counterparts, specifically in physical functioning, general health, and vitality.

Bensalah et al. conducted a similar study with the SF-36 survey comparing stone patients to the general American population [41]. They determined that stone formers had significantly lower physical composite scores along with general health, emotional role, and social functioning. In assessing predictors of QoL, they found that BMI was a strong predictor of lower QoL. Additionally, while the number of stone events did not predict lower QoL, they did observe that the number of surgical procedures negatively impacted both mental and physical components of HRQoL.

Bryant et al. produced a study very similar to the two mentioned above, where they found stone formers had significantly lower scores in six out of eight domains when compared to the average American population [42].

The same year that Penniston et al. defined HRQoL differences between male and female stone formers, Diniz conducted a case-control study investigating the HRQoL of stone formers with recurrent renal colic pain to control patients from an outside outpatient center without associated disease [39]. With the use of the SF-36 form, they determined the HRQoL of stone patients to be worse than the control group and that the number of renal colic pain episodes correlated with worse impact on both functional capacity and vitality [39].

Several studies found the HRQoL in stone formers to be even lower in stone-forming patients with comorbidities that increase stone risk (diabetes type 2, obesity) as well as other comorbidities (hypertension, depression, musculoskeletal complaints) [5, 41].

While there are some variances between studies, it can be safely said that HRQoL is overall worse in stone formers (without active stones) when compared to non-stone-forming patients. While there are a few studies outside the United States that show comparable HRQoL between the two groups [33, 38], a majority of studies found HRQoL of stone formers to be worse in all or most of the eight domains of the SF-36 survey [5, 39, 41, 43]. Table 2.1 lists those domains.

HRQoL has been shown to be decreased even in asymptomatic stone-forming patients. Penniston et al. evaluated a cohort of patients who completed the WiSQoL at a time they were symptom-free [48]. Patients with stones, even when

Table 2.1 The MOS 36-item short-form health survey (Ware, et al. [24])

SF-36 QoL domains
Physical functioning
Role limitations
Bodily pain
Social functioning
General mental health
Role limitations (due to emotional problems)
Vitality
General health perceptions

symptom-free, had a lower WiSQoL score compared to a stone-free cohort. Interestingly, even stone patients who were unaware that they had current stones displayed a decreased WiSQoL score compared to those without stones.

QoL Between Different Treatment Options

We have discussed the different treatment options for urinary calculi. While there are a few number of studies addressing the HRQoL in different surgical options or in MET, there are even less investigations that address the HRQoL comparing surgical vs. pharmacotherapy vs. dietary intervention of urinary calculi.

Studies comparing HRQoL in surgical options have found conflicting conclusions. While some studies show favorable outcomes for SWL [33, 44], others have found the HRQoL between SWL and PNL to be comparable [31, 32]. Additionally, while there has been SWL popularity in some studies [33, 45], it has been concluded that HRQoL is negatively affected by those patient with residual fragments [43]. And though the HRQoL is largely influenced by the size of those fragments, it is still important to bear in mind their undesirable impact.

Staios et al. prospectively evaluated 22 patients undergoing PNL [46]. They were administered SF-36 before the procedure and again 6 weeks after PNL. While there was an overall improvement of HRQoL, only two of the domains saw statistically significant difference. They concluded that, despite a high stone-free rate (87%), less than half of the patients were found to have benefited subjectively from PNL [46].

Kuo et al. surveyed a group of stone formers to compare surgical vs pharmacotherapy. They were able to observe a preference for a quick and painless solution, which equated to SWL intervention for mild pain [44]. However, patients who had undergone more stone retrievals, or who were further out from their last stone event, were more apt to avoid surgical intervention and choose long-term medical therapy. These findings were similar to the additional results from Bensalah et al. study in 2008 [41] where they found the number of URS procedures as well as stent placement to negatively impact mental well-being. They also found a favorable association with HRQoL with medical therapy, particularly with potassium citrate [41].

A recent Internet-based survey, with a non-validated questionnaire, assessed general satisfaction in 443 patients who had undergone all intervention strategies for an acute stone [47]. Those strategies included surgery, pharmacotherapy, home remedy (dietary intervention), as well as observation for spontaneous passage. While a majority of patients (51%) reported “success of treating stones” for being the reason they liked their treatment method, there were 37% of patients who were favorable to their treatments due to QoL factors such as avoiding surgeries or hospitalizations as well as appreciation for quick recovery times.

While there are no studies that formally investigate HRQoL in medically or nutritionally treated stone formers, much less ones that compare them to non-stone-forming individuals, there are certain aspects that can be taken from complications and withdrawal rates from their trials. Two pharmacotherapy trials not only had a

majority of their studies with higher relative risk (RR) of withdrawal rates when compared to the control group, but they had higher RR of withdrawal due to adverse events [19].

In the investigations of dietary intervention trials, only one of eight studies reported any adverse events. And while one study had a higher RR of withdrawal when compared to the control group, there were none that found higher RR of withdrawal due to adverse events [19].

Future

There are still many HRQoL aspects of nephrolithiasis management that need to be further investigated so that we might be able to improve patient outcomes, and newer evaluation tools, such as the Wisconsin Stone-QoL instrument, will allow even better insight into methods to improve the QoL in our patients. However, what may be gleaned from the currently available information is that:

1. HRQoL in stone-forming patients is negatively impacted by the chronicity of this disease.
2. Surgical options for stone removal can be highly successful, but they come with their own QoL detriments and do not address the primary preventative aspect.
3. Pharmacotherapy provides good evidence in its reduction of stone recurrence but has its assortment of side effects that may negatively affect HRQoL.
4. While the impact of dietary intervention on HRQoL has not been well studied, medical nutrition therapy can certainly decrease the risks of stone formation, with anticipated subsequent positive effects on HRQoL.

With the increasing awareness of patient-reported outcomes, more attention is being given to HRQoL. Perhaps, in order to improve HRQoL, endpoints for acute stone management should not only address physical domains such as stone-free status and pain scores but should also strive to positively impact the mental health, emotional well-being, and social functioning of the patient.

Additionally, maybe the long-term management of this chronic disease could include more than simply screening for recurrence and counseling for future prevention; perhaps a team outside urology could be collaborating in order to monitor and manage the domains of mental health, emotional well-being, and social functioning.

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