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ORIGINAL PAPER

Longitudinal evaluation of the SF-36 quality of life questionnaire in patients with kidney stones

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Abstract Although the 36-Item Short-Form General Health Survey (SF-36) has been utilized to assess quality of life (QoL) in cross-sectional studies, no longitudinal studies have evaluated this instrument in stone formers. Hence, we evaluated the performance of the SF-36 over time in a group of stone formers. From January to May 2007, the SF-36 was administered by independent interviewers to 155 patients with a history of stones, and 96 individuals subsequently completed a second questionnaire at a median interval of 18 months (10.3–28.5 months). Subjects were asked to report changes in stone status, interval procedures, and significant non-stone related changes. Changes in individual and composite scores of SF-36 were compared. Among the 96 patients who completed two SF-36 surveys, 75 patients denied experiencing a stone episode within the month preceding their initial or follow-up SF-36 form. No statistically significant differences in any of the SF-36 domains or the aggregate physical or mental health composite scores over time were noted in these patients. A total of 18 patients reported a stone event within the month preceding completion of the initial questionnaire but no stone event prior to the follow-up survey. No clinically or statistically significant changes in any of the SF-36 domains between the first and follow-up questionnaire were seen among these 18 patients. The results show the stability of the SF-36 over time in patients with no change in their stone status. However, the absence of significant changes in the SF-36 despite a change in stone status suggests that the SF-36 may not be an adequate tool to monitor quality of life over time in stone patients. Validated, disease-specific questionnaires are needed to facilitate comparison of treatment strategies for stone disease.

Keywords Stone disease · Survey · Medical therapy · Endourology · Urolithiasis · Quality of life

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Introduction

The lifetime prevalence of nephrolithiasis in the US is 6–12% [1], and it is often a chronic condition, with nearly half of all stone formers experiencing a repeat stone episode within 5 years of the initial occurrence [2]. In the acute setting, patients with ureteral stones are either managed conservatively in hopes of spontaneous passage or surgical intervention is pursued. Long-term management of patients with kidney stones entails conservative dietary management or the addition of stone-preventive medications. Each of these options, expectant, dietary, medical, and surgical has associated risks and benefits. While stone disease is rarely fatal, there is a significant impact on quality of life (QoL) both in the short term and long term, particularly in

patients with recurrent stone disease, those who require repeated surgeries or those submitting to medical therapy to reduce their stone risk. As such, the use of a tool that effectively compares QoL associated with the various treatment options is attractive because it can assist patients and physicians in deciding on the optimal treatment regimen. Furthermore, such a tool is useful when comparing procedures with similar outcomes such as ureteroscopy and shock wave lithotripsy [3].

Validated disease-specific questionnaires have been utilized successfully to evaluate improvement in QoL of other urologic diseases. These questionnaires, such as the IPSS (International Prostate Symptom Score), urinary bother score, and IIEF (International Index of Erectile Function), have been incorporated into clinical care and clinical trials as a measure of disease severity and impact on QoL [4, 5]. Unfortunately, no validated disease-specific questionnaire has been established for assessment of patients with kidney stone disease. However, two studies utilized the 36-Item Short-Form General Health Survey (SF-36) to evaluate QoL in a cross section of stone patients [6, 7]. These studies identified lower QoL scores in some physical and mental domains in their respective cohorts of stone patients. Unfortunately, no longitudinal studies have evaluated the impact of stone disease on QoL over time. QoL tools must be evaluated over time to determine the reliability of the instrument in detecting changes in QoL related to new stone events, alterations in stone management, and changes in other non-stone related conditions. While a disease-specific tool might be less impacted by non-stone issues, a non-specific QoL questionnaire might be less useful as a tool to guide long-term treatment. It is important to note that QOL tools would be unlikely to benefit patients during an acute stone episode but could help guide long-term management decisions such as starting chronic medications.

Another important consideration with regard to the SF-36 is that it specifically asks subjects to assess their condition "over the last month", a qualifier that can affect responses of patients who have not had a recent event (stone or non-stone related). Accordingly, our previous study found lower QoL scores in patients who had a stone episode within 1 month of completing the SF-36 survey compared with patients who had a stone event more than 1 month prior to the survey [7].

We previously utilized the 36-Item Short-Form General Health Survey (SF-36) to assess the quality of life of stone formers. In this study, we evaluated the reliability of this survey in evaluating QoL of stone-formers over time.

Methods

Between January and May 2007, 152 patients were recruited from our Urology practice to participate in an institutional review board approved survey. During this initial interview, patients were queried about current previous health issues and stone-specific history. Research personnel, not directly involved in patient care, were responsible for obtaining consent and gathering relevant patient data such as gender, BMI, co-morbidities, age, stone-related information, and prior stone treatment procedures [such as shock wave lithotriopsy (SWL), percutaneous nephrostolithotomy (PCNL), and ureteroscopy (URS)]. We specifically questioned patients about the time interval since their last stone episode, since the SF-36 specifically inquires about one's mental and physical state in the past 30 days. Theoretically, a patient with a recent stone episode might be expected to score lower on a QoL survey than one whose last stone episode preceded the survey by more than 30 days. Stone composition and the use of stone-preventive medications (such as allopurinol, thiazide diuretics and potassium citrate) were also elicited. More than 95% of stone patients seen during this time period agreed to participate in this study. After obtaining baseline information, the SF-36 survey was administered to establish a baseline QoL that would subsequently be prospectively followed [8].

In order to conduct a longitudinal study, these 152 patients were later contacted by phone, mail or in person during a follow-up office visit and asked to complete a follow-up SF-36 questionnaire. In addition, patients were queried about stone events and other factors that might potentially impact their quality of life, including changes in their stone status, recent stone procedures, medication changes, significant non-stone related health problems, changes in a family member's health, and changes in marital status.

SF-36 questionnaire

The SF-36 questionnaire requires approximately 10 min for the patient to complete [8]. The initial form was provided to the patients during their visit to our urology clinic. The follow-up questionnaire was administered either during the course of a clinic visit or was mailed to the patient's home address. This validated questionnaire is comprised of 36 questions that yield 8 scaled scores in different domains that collectively are used as predictors of QoL. The eight dimensions assess an individual's perception of his or her general health, physical functioning ability, limitations caused by personal emotional problems, limitations caused by physical health problems, bodily pain, levels of energy/fatigue, social functioning, and emotional well-being. In each of these domains the answers are represented as a number on a scale reflecting QoL from 0 (the worst) to 100 (the best). Two physical and mental composite summary scores (PCS and MCS) can be derived from the eight domains and

standardized to the general US population with a normative mean of 50 and a standard deviation of 10. Scores for each domain and the two summary scores were compared using student's *t* test. *P* values <0.05 were considered statistically significant. All analyses were done with SAS, version 9.2 (SAS Institute Inc., Cary NC, USA).

Results

Among the initial 152 patients who completed the survey, 46% were males and 54% females. The mean age of the cohort was 51 ± 14.5 S.D. years, and 72% of the participants were recurrent stone formers.

A total of 96 of the initial 152 study patients completed a second questionnaire at a median interval of 18 months (range 10.3–28.5 months), representing a response rate of 63% for the follow-up phase of the study. The mean age of this group was 53 ± 14.0 S.D. years; 46% of patients were males and 54% were females. In addition, 75% of the respondents were recurrent stone formers, and 76% had a history of undergoing SWL, URS, PCNL, or an open stone procedure. In the time interval between surveys, a total of 11 (11.5%) patients were diagnosed with a new stone and 9 of these patients required surgery. Additionally, 30 patients (31%) reported a change in medications. Four of these patients had medication changes that were intended to prevent future stone formation (i.e., the addition or change of a stone prevention medication). A total of 31 patients (32%) noted changes in their personal health and 20 patients (20.8%) reported changes in a family member's health.

The SF-36 evaluates physical and emotional domains relevant to events occurring over the previous month. As shown in Table 1, 75 of the 96 patients who completed the study did not experience a stone episode in the month preceding either the initial survey or the follow-up survey, and accordingly there were no significant differences in any of the eight domains or the two summary scores of the SF-36 from baseline to the follow-up survey.

A total of 18 patients experienced a stone event in the month preceding their first survey but did not have a stone episode within the month prior to their second questionnaire (Table 2). No significant differences in any of the eight domains or the aggregate physical and mental health composite scores of the SF-36 from baseline to follow-up survey were identified in this group of patients.

Table 1 Changes in the SF-36 scores on the follow-up survey for patients who did not have a stone episode in the month preceding baseline and follow-up survey ($n = 75$)

SF-36 domain	Mean (±SD) difference between the first and the second survey	*p* value*
Physical functioning (PF)	1.07 (8.99)	0.31
Physical health problems (RP)	−0.94 (11.53)	0.48
Bodily pain (BP)	−1.81 (11.52)	0.18
Emotional well-being (MH)	−0.50 (9.8)	0.66
Emotional health problems (RE)	−1.44 (10.86)	0.25
Social functioning (SF)	−1.55 (9.8)	0.18
Energy/fatigue (VT)	0.73 (11.3)	0.58
General health perceptions (GH)	−0.61 (8.37)	0.53
Aggregate physical health composite score	−0.18 (8.98)	0.86
Aggregate mental health composite score	−1.06 (10.16)	0.37

* *T* test for whether the mean difference is significantly different from zero

Table 2 Changes in the SF-36 scores on the follow-up survey for patients who experienced a stone event in the month preceding the baseline survey, but not before the follow-up survey ($n = 18$)

SF-36 domain	Mean (±SD) difference between the first and the second survey	*p* value*
Physical functioning (PF)	3.08 (13.52)	0.35
Physical health problems (RP)	−0.79 (12.3)	0.79
Bodily pain (BP)	−1.12 (9.7)	0.63
Emotional well-being (MH)	0 (8.3)	1
Emotional health problems (RE)	−0.58 (13.75)	0.86
Social functioning (SF)	−1.81 (13.3)	0.57
Energy/fatigue (VT)	1.12 (9.73)	0.63
General health perceptions (GH)	−0.52 (10.24)	0.83
Aggregate physical health composite score	0.7 (12.45)	0.81
Aggregate mental health composite score	−0.97 (8.75)	0.64

* *T* test for whether the mean difference is significantly different from zero

Table 3 Comparison of SF-36 scores in patients without a non-stone related episode within a month of the follow-up survey ($n = 83$) and those who did have a non-stone related episode in the month prior to the follow-up survey ($n = 13$)

SF-36 domain	Mean (±SD) difference between the first and the second survey	p value*
Physical functioning (PF)	−5.16 (9.8)	0.08
Physical health problems (RP)	−11.29 (11.2)	0.001
Bodily pain (BP)	−3.86 (11.3)	0.42
Emotional well-being (MH)	−1.5 (9.5)	0.60
Emotional health problems (RE)	−1.7 (11.9)	0.63
Social functioning (SF)	−0.19 (10.5)	0.95
Energy/fatigue (VT)	−0.3 (11.0)	0.93
General health perceptions (GH)	−0.57 (8.6)	0.17
Aggregate physical health composite score	−6.9 (9.3)	0.016
Aggregate mental health composite score	1.37 (9.87)	0.64

* T test for whether the mean difference is significantly different from zero

One patient experienced a stone episode in the month prior to each of the questionnaires, and two patients who did not experience a stone episode within the month prior to the first questionnaire did report a stone event in the month preceding the follow-up survey. The small sample size of these groups precluded meaningful statistical analysis.

We assessed the impact of non-stone events on the SF-36. Patients with non-stone related events within 1 month of the follow-up survey had worse physical health problems and aggregate physical health than patients without non-stone related events within 1 month of the follow-up survey (Table 3).

Discussion

Nephrolithiasis appears to be increasing in prevalence and in many patients is a chronic and debilitating disease [9]. While rarely lethal, stone disease and its treatment can impact quality of life in a variety of ways: it can cause intermittent and unpredictable pain, require surgical intervention, cause loss of work and wage, and necessitate the use of costly medications with associated side effects. Consequently, the impact of stone disease and its treatment on quality of life should play a role in the decision-making process of the physician caring for the stone patient.

Unfortunately, there are currently no stone-specific instruments that have been validated for assessing QoL in stone formers. However, the 36-Item Short-Form General Health Survey (SF-36) has been used in patients with nephrolithiasis. Two published studies found that patients with stones have lower QoL scores than the average United States population [7, 10]. These cross-sectional studies did not assess the SF-36 longitudinally. In order to determine whether the SF-36 is valid for comparing treatment options in stone patients, it is critical to show that changes in stone status (i.e., actively or recently experiencing a stone episode or surgical treatment or initiation of chronic stone-preventing medications) are reflected by changes in survey scores.

In our study, we found, not surprisingly, that SF-36 survey scores were unchanged over an average of 18 months in patients who did not experience new stone events. On the other hand, we failed to detect differences in the SF-36 scores in the group of patients who had experienced a recent stone event prior to their baseline survey but reported no recent stone event prior to their follow-up survey. This finding is unexpected, as one might expect these patients to perceive superior QoL during a stone event-free period than after a recent stone episode. This absence of change in QoL scores among these patients suggests that the SF-36 may not be a sensitive enough tool for assessing longitudinal QoL in stone formers.

Of note, the SF-36 questions only ask about the health status of the individual within the past month. Thus while a stone episode within the past month is likely to influence the SF-36 scores, it is not clear whether a stone episode that happened longer ago than a month would still influence the QoL scores. We identified eight patients with stone events between the surveys, but this sample size was too small to analyze for the impact of varying time intervals between the event and completing the survey.

In the past, effective stone management was primarily based on high stone free rates and reduction in recurrence rates. Recent studies, however, have challenged this notion, and now treatment decisions take into account the combination of social, physical, economic, and psychological impact associated with particular management options [11, 12]. Our cohort, with an average age of 51 years, constitutes a socially active and economically productive group of patients who would be expected to be particularly impacted by acute stone episodes and treatment and would be highly burdened by the physical and financial hardships associated with nephrolithiasis. Our previous QoL study found that chronic thiazide or allopurinol use had no impact on SF-36 scores, but that potassium citrate therapy showed

a positive correlation with physical cumulative score, as well as bodily pain and social functioning domains in univariate analysis [7]. In addition, the number of previous ureteral stent placement procedures predicted lower scores in general health perception, emotional well-being, and role limitation caused by emotional problems domains and also predicted a lower mental cumulative score. Unfortunately, surgical treatments such as SWL and URS, which have similar stone-free outcomes in patients with ureteral stones, have not been sufficiently compared regarding their impact on QoL [2]. One study using the SF-36 to evaluate QoL in 22 patients undergoing percutaneous nephrolithotomy for symptomatic caliceal diverticula and deep lower-pole calculi found that in spite of a high stone-free rate, fewer than half of patients benefited subjectively from the procedure in terms of improvement of QoL [18].

For patients and physicians to arrive at the best individualized decisions regarding treatment approach, it is important to understand not only surgical outcomes and recurrence rates, but also QoL associated with each treatment strategy. This is especially true for medical management of stones in which there is significant variability between patient and physician perceptions of the value of medical management [13]. Future trials evaluating medical management strategies would benefit from QoL assessment. As such, failure of the SF-36 to detect differences in QoL of stone patients who experienced a recent stone event before the initial but not the follow-up survey suggests that this instrument it is not sensitive or specific enough to monitor stone-related treatment differences.

The SF-36 was initially designed as a general scale to predict QoL of an individual. Indeed, we found that patients with non-stone related events within 1 month of the follow-up survey had worse QoL than patients without non-stone related events during that time period, thus confirming that it is sensitive to changes or events in the life of an individual. The question of whether the SF-36 is useful as a disease-specific tool is controversial. Many studies have sought to identify whether the SF-36 is sensitive enough to quantify QoL with regard to a specific medical condition. For example, a 2009 study conducted in the Neurosurgery Department at Addenbrooke's Hospital in Cambridge concluded that the SF-36 demonstrated predictive validity in measuring the morbidity in patients with spinal disease. In contrast, a 2007 Korean study determined that the SF-36 had poor content validity for women with urinary incontinence [14, 15].

Ideally, a validated QoL tool that is accurate and reliable over time is required to compare treatment modalities/strategies. Validated instruments such as the International Prostate Symptom Score and International Index of Erectile Function have been used both clinically and in trials to evaluate changes in urinary and sexual parameters, respectively [16, 17].

For nephrolithiasis, a disease-specific tool may be necessary to capture changes in QoL that are related to changes in stone status, surgical treatment, or long-term preventive management. There are other important considerations with regard to QoL that need to be explored. The impact on QoL for different severity of stone disease must be explored. While most patients in this study were recurrent stone formers, there is variability in number and frequency of stones, severity of pain, frequency of surgical intervention, and effectiveness of medical management. A disease-specific QoL questionnaire will need to take these differences into consideration. Further research in this area is warranted.

Conclusions

The SF-36 demonstrates stability over time in patients with no change in their stone status. However, the absence of significant changes in SF-36 scores despite changes in stone status suggests that the SF-36 may not be an adequate tool to monitor QoL in stone patients. Validated, disease-specific QoL tools are needed for comparison of treatment strategies in stone disease.

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