A survey of patient preferences regarding medical expulsive therapy following the SUSPEND trial

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Introduction: *Several recent trials have reported limited benefit for medical expulsive therapy (MET) in terms of stone passage rates, analgesic requirements, or need for intervention. We evaluated patient attitudes regarding MET after explaining these new findings.*

Materials and methods: *Over a 12 week period, an investigator-designed survey was offered to sequential patients during routine appointments in our urologic clinic. A brief summary of the conflicting data for MET was provided. Patients then answered questions about their attitudes toward using MET.*

Results: *Patients (n = 200; 103 M, 97 F) were 56 ± 14 years old (range 20-103 years) and were mostly being seen for management of kidney stones (88%). Forty-nine percent reported they would try tamsulosin despite the new data; 26% said they would not, and 25% were unsure. Of patients indicating they would take tamsulosin, 35% stated they would also be willing to take steroids. Thirty-five percent of patients said they were willing to pay the full price of tamsulosin if needed. Seventy-one percent said they would prefer to try medical therapy prior to pursuing surgical therapy, again, despite new evidence regarding the efficacy of MET.*

Conclusion: *In this initial report of patient attitudes about MET after SUSPEND trial results, we found that nearly half of patients would still try MET and that the vast majority of patients prioritize medical over surgical therapy when possible. As new research emerges, ways to translate this information to patients and to assess their attitudes and perceptions should be developed.*

Key Words: medical expulsive therapy, tamsulosin, urolithiasis, patient survey, shared decision-making, questionnaire

Introduction

Of course, spontaneous passage of kidney stones is preferable to surgical intervention. However, stone passage is unpredictable and may take days to weeks. Medical expulsive therapy (MET) for renal colic has become a common strategy for patients with symptomatic ureteral calculi. Ever since 1975 when Peters and Eckstein showed a decrease in ureteral resistance and improved urine flow with phentolamine in a canine model;[1] a variety of pharmacologic agents have been studied for their ability to aid stone passage with the most common in use today being alpha-blockers.[2-4]

After the introduction and widespread use of MET, studies further supported its efficacy in terms of reducing the time to stone passage, need for intervention, and patient pain.[5-14] Because of these

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supportive data, the clinical applications of MET have expanded even to pregnant and pediatric patients.[15,16] The 2007 American Urological Association guidelines panel on the management of ureteral calculi performed a meta-analysis of the available literature and concluded that alpha-blockers improved stone passage rates by 29%.[3]

However, several recent studies have shown limited benefit with MET in terms of analgesic use, time to stone passage, or need for intervention.[17-22] Data from these studies have reignited the discussion of MET among urologists. But patients do not commonly read the medical literature and may not be aware of this new information about MET. Furthermore, patient adherence to MET has certainly not been as high as many providers would like. Furyk and colleagues reported that 25% of patients were no longer taking MET as prescribed after 2 weeks.[19]

To our knowledge, no study has assessed patient attitudes regarding MET in light of the concerns over its efficacy. We developed a questionnaire designed to assess patients' preferences about MET and distributed it to patients at our urology clinic.

Materials and methods

As part of a quality improvement initiative, we designed a 10-item questionnaire and offered it to sequential clinic patients of endourology providers over a 12 week period, Figure 1. Patients seen in routine appointments for any indication were offered the survey and participation was voluntary. The questionnaire included a brief statement describing the previous data that showed an improvement in the passage of stones with MET, then described that recent data suggests that MET may not work any better than placebo. The major side effects of tamsulosin and steroids were reviewed, after which questionnaire items asked patients to consider if they would prefer to try MET in the form of tamsulosin alone or in combination with corticosteroids. Patients were then asked if they would be willing to pay full or partial cost of tamsulosin given a cost of $100 for a 30 day supply. Finally, patients were asked if they would try MET prior pursuing surgery for a future stone event. Among patients who completed the questionnaire, additional data about them were collected, including age, gender, history of kidney stones, and health insurance status. Results from the questionnaires were entered into an Excel spreadsheet and tabulated. Chi-square tests and univariable logistic regression were used to evaluate associations of other variables with being willing to take tamsulosin. A p value < 0.05 was considered to indicate statistical significance and SAS 9.4 software (SAS Institute, Cary, NC, USA) was used for all analyses. The local institutional review board determined that this study did not require IRB approval.

Results

During the study period, 200 patients completed the survey (103 male versus 97 female, Table 1). Eighty-eight percent of participants were patients with a prior history of urolithiasis. Patients were a median of 56 years old, interquartile ratio (IQR = 53.5-71.5 yrs). Ninety-one percent reported having health insurance that covered, at least in part, prescribed medications.

We found that 49% of patients would take tamsulosin despite the conflicting data on the efficacy of MET for stone passage, Figure 2. The remainder of patients were either unsure (25%) or stated they would not be willing to take tamsulosin (26%). Compared to the nearly 50% of patients who said they would take tamsulosin alone to aid stone passage, only 34% said they would be willing to take tamsulosin with corticosteroids if prescribed. The majority of patients (71%) stated they would prefer to try MET prior to pursuing surgery, despite the new data questioning its effectiveness. Regarding willingness to pay for tamsulosin if needed, just under half (48%) of patients

TABLE 1. **Patient demographics. Data presented represents the age and gender of the questionnaire respondents. Responses to questions asking if the respondent had a previous history of stones and if they had prescription medication insurance are also presented.**

Patient demographics	
Age (years)	
Mean	56
Range	20-103
IQR*	53.5-71.5
Gender	
Male	103
Female	97
History of previous stone?	
Yes	175
No	23
Unsure	2
Prescription medication insurance coverage?	
Yes	192
No	6
Unsure	2

*IQR = interquartile range

Age _____ Gender M F

Have you ever had a kidney stone before? Yes No Unsure

Do you have health insurance that covers medications?

Yes No Unsure Partial Coverage

Previous research showed that a medication called tamsulosin (Flomax) might help people pass kidney stones. Previous studies showed a 29% increase in the passing of stones. Recent research suggests there may be no benefit.

Here are the possible side effects of the tamsulosin:

Dizziness – 5%

Cold/sinus symptoms - 5%

Difficulty with sleep - 2%

Retrograde ejaculation - 8% (some of the ejaculate goes backwards into the bladder instead of the penis.)

The cost for 30 days is about $100 (this may be fully or partially covered by insurance)

Some research suggests that tamsulosin might work better if taken with steroid pills (not the body-building type).

Here are the possible side effects of oral steroids (Prednisone): Fluid retention, weight gain, high blood sugar (occasionally needs to be treated with insulin), stomach upset, and mood changes

Given the information listed above, please answer the following questions:

Based on the information above, would you still take the tamsulosin by itself?

Yes No Unsure

Would you be willing to pay for tamsulosin, if it is **not** covered by your insurance?

Yes No Unsure

Would you be willing to pay for tamsulosin if it is **partially** covered by your insurance?

Yes No Unsure

Would you take tamsulosin with steroid pills if this might help you pass your stone?

Yes No Unsure

In general, do you prefer to take medicines instead of having surgery?

Yes No Unsure

Please add any additional comments:

Figure 1. MET questionnaire. Figure shows the questionnaire that was developed and distributed to patients during this study.

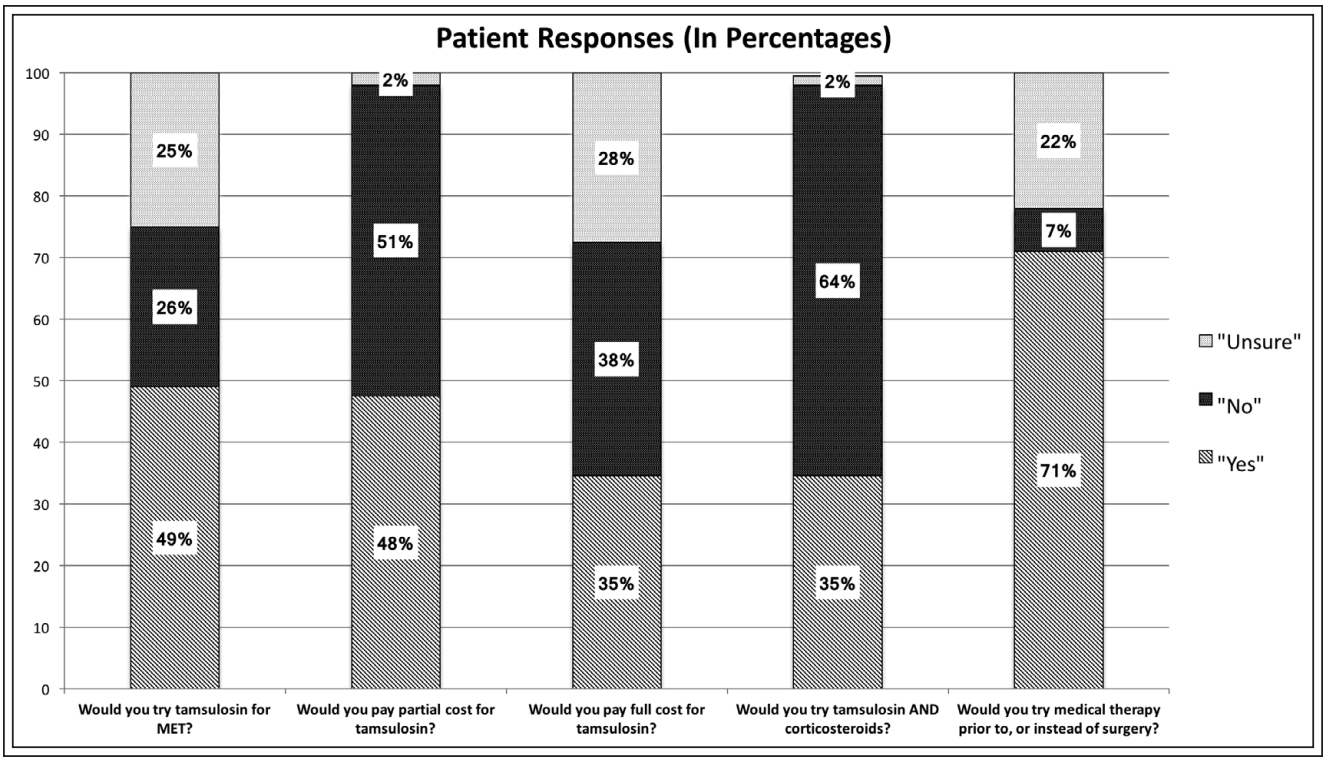

Figure 2. MET questionnaire responses. Data represent responses to questions asked on the MET questionnaire. The percentage are shown for those who answered, "yes," "no," and "unsure" for each of the questions asked.

were willing to pay part of the cost while only 35% were willing to pay the full price of $100 per month.

Gender and a previous history of stones were not predictive of the decision to try MET in the form of tamsulosin (OR 0.92, 95% CI 0.47-1.81, p = 0.81 and OR 2.69, 95% CI 0.94-7.71, p = 0.07 respectively, logistic regression). Patients who were willing to pay in part or pay in full for tamsulosin were more likely to say they would take tamsulosin (OR 56.42, 95% CI 16.03-198.64 and OR 42.7, 95% CI 11.01-165.86, p < 0.0001). Patients who were willing to try tamsulosin with corticosteroids if prescribed were more likely to be willing to try tamsulosin alone (OR 35.6, 95% CI 8.19-154.95, p < 0.0001). Finally, patients who said they would prefer to try a medical therapy prior to or instead of a surgical procedure were more likely to say they would try tamsulosin (OR 9.75, 95% CI 1.96-48.46, p = 0.005). Age was a predictive factor with younger patients being more likely to try tamsulosin compared to older ones. (p < 0.001).

Discussion

We report the results of the first patient survey to assess patient attitudes regarding MET, in a sense, a patient reported outcomes study. Although there are many different medical options for MET, we decided to ask patients specifically about tamsulosin as it is the most widely used and studied medication for MET.[18] The patients in our cohort were mixed with just under half of patients saying they were willing to try MET for a future stone event; a quarter of patients said they would not try it at all. These results are interesting in light of the fact that most patients indicated they would prefer medical therapy prior to a surgical therapy. A possible explanation may be that patients were concerned about potential side effects and cost of MET. However, the design of our study did not allow us to answer this question.

Cost appeared to play a role in patients' willingness to try tamsulosin. About half of patients stated they would be willing to pay part of the cost for tamsulosin. A smaller percentage of patients (35%) stated they were willing to pay the full cost for a 1 month supply. These data suggest that healthcare costs are important to patients and that educating patients on the expected cost and benefit of therapy should be part of the discussion when possible.

There are limitations of our study, including smaller sample size and the fact that not all of the patients

from our stone clinic had a history of stones. While our analysis did not show an association between stone history and the decision to take tamsulosin, we acknowledge that responses from patients without an actual stone may have skewed the data and subsequent analysis. Another limitation is that patients with a positive prior experience with MET may be more likely to try MET despite the new data. Conversely, patients who were told their stone was too large to pass, or who did not have success with MET, may be less likely to try it. Another factor is that several of our patients were told in the past that they could not take tamsulosin due to a sulfa allergy, thus these patients may have been less likely to try MET. As we did not query about prior counseling and experience with MET, we cannot be sure how this influences our findings. We do believe this will be a minor effect. Another feature of our study was that patients were encountered in our stone clinic rather than in a primary care clinic or the emergency room which may have influenced our results.

MET remains a common strategy in most practices in spite of the new studies. As patients continue to assess the recommendations of urologists regarding MET, the new studies, including the SUSPEND trial,[20] offer an opportunity for urologists to re-shape patients' preferences and expectations. This study is important because it brings to light current patient preferences which can better guide future clinical recommendations.

Conclusion

Our initial report of patient preferences and attitudes regarding MET demonstrated that nearly half of patients would try MET in spite of the new studies. As more research emerges, better tools to both translate this information to patients and to assess their preferences will become a clinical priority.

Disclosure

Dr. John Roger Bell is a consultant for Boston Scientific. Dr. Stephen Nakada is a consultant for LaserDock and Boston Scientific. Dr. Kristina Penniston is a consultant for Retrophin. Dr. S.L. Best has nothing to disclose. □

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