Current use of medical expulsive therapy among endourologists

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Abstract

Introduction: We aimed to characterize current practice patterns among endourologists on medical expulsive therapy (MET) for treatment of ureteral calculi.

Methods: An online survey was administered to Endourological Society members. Respondents' MET usage, index case management, and awareness of recent guidelines and literature were compared based on international status, practice setting, interval since training, and endourological fellowship training.

Results: Of the 237 complete responses, 65% were international, 61% were academic, 66% had >10 years in practice, and 71% were endourology fellowship-trained. MET was used by 88%, with no differences between international, academic, practice length, and fellowship-trained groups. MET was used more frequently for <8 mm and distal stones and more U.S.-based respondents reported use for proximal/mid-ureteral stones (68% vs. 43%; p<0.001). For the index patient, 70% preferred MET as the initial approach and respondents <10 years from training were more likely to choose MET (82% vs. 64%; p=0.006). While 82% of respondents were aware of the SUSPEND trial, 70% reported that it had not altered their use of MET. Current American Urological Association (AUA) guideline awareness was 90%. Mean MET prescription length was 19.9±10.3 days, and was statistically significantly longer for respondents who were U.S.-based, academic, and <10 years from training.

Conclusions: MET is the preferred approach for patients with ureteral calculi <10 mm among endourologists despite conflicting data in the literature. While current AUA practice guidelines are followed by the majority of respondents, our survey suggests MET is being used more liberally than the guideline criteria, specifically in proximal and mid-ureteral stones.

Introduction

Medical expulsive therapy (MET) is a frequently used approach in the management of ureteral calculi. Although it is a recommended initial option as per the current American Urological Association (AUA) guidelines, recent studies have challenged this paradigm.[1] The Pickard et al (SUSPEND) and Furyk et al trials were two large, multicentre, randomized controlled trials published in 2015 that found the spontaneous passage rate of ureteral stones to be similar for patients prescribed MET compared to placebo.[2,3]

Current AUA guidelines published in May 2016 recommend MET only for patients with distal ureteral stones ≤10 mm, while the European Association of Urology (EAU) guidelines recommend use for all ureteral stones.[1,4] Furyk et al also found that MET increased the likelihood of spontaneous stone passage in a subset of larger stones 5–10 mm in size (p=0.03).[3] A recent systematic meta-analysis of MET studies by Hollingsworth et al included both SUSPEND and Furyk data and concluded that MET increased the likelihood of stone passage for stones ≥5 mm regardless of location.[5] The conflicting data in the above studies and guidelines has generated some doubt about the efficacy of MET.

Given the context of recent challenges, we sought to characterize current practice patterns and perspectives on MET for the treatment of ureteral calculi among members of the Endourological Society. A better understanding of current practice patterns, knowledge of the literature, and attitudes with regards to MET among practicing urologists could help determine the need for further studies and improve evidence-based education on the initial management of ureteral calculi.

Methods

An online survey was designed and administered to members of the Endourological Society in August and September of 2016 via the REDCap platform hosted at the Cleveland Clinic Foundation.[6] Study data was collected and managed using REDCap's electronic data-capture tools. Consisting of 22 questions, the survey included an index case that served as the basis for a series of management options. The index case was described as a patient "presenting with ureteral calculi ≤10 mm, adequately controlled pain, and without fever" (full survey in the supplementary tables). Additionally, we captured other metrics, including demographics, international status, type of practice, interval since training completion, and fellowship training in endourology, as well as individual perspectives and knowledge on MET.

Using email addresses in the Endourological Society's member database, the survey was sent twice to 2815 recipi-

ents two weeks apart. Responses were recorded and anonymized automatically through the REDCap system and surveys were eliminated from statistical analysis if ≤14 questions were unanswered (i.e., the equivalent of stopping after the first page). MET usage and index case management were evaluated based on respondents' international status, practice setting, interval since training completion, and fellowship training. Statistical analysis was performed via Pearson Chi-square, Fisher's exact, cross-tabulation, and student's t-tests using IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, NY, U.S).

Results

Two hundred and thirty-seven completed responses were received, with an additional 48 surveys being opened but not completed beyond the first page of the survey, giving a completion rate of 83%. Of the completed responses 65% were international, 61% were academic urologists, 66% had >10 years in practice, and 71% were fellowship-trained in endourology (full demographic data in the supplementary tables). The majority of respondents (88%) reported using MET for patients with ureteral calculi, with no significant differences between the international, academic, practice length, and fellowship-trained groups (Table 1). For the index patient, MET was the preferred initial approach for 70% of respondents, followed by observation in 14%, and surgical options (ureterscopy [URS], shockwave lithotripsy [SWL], and stent placement) in 16%. Respondents within 10 years of training were significantly more likely to choose MET (82% vs, 64%; p=0.006) (Table 1).

Overall, 82% of respondents reported being aware of the results of the SUSPEND trial, with higher awareness among urologists from the U.S. (89% vs. 78%; p=0.043) (Table 1), those with endourology fellowship training (86% vs. 75%; p=0.038), and those in academic practice (89% vs. 72%; p=0.001). Although awareness was high, 70% of respondents reported that the results had not altered their use of MET. Additionally, 90% reported being aware of the current AUA guidelines on the surgical management of stones, with no significant variation based on duration of practice or academic practice setting (Table 1).

Mean MET prescription length was 19.9±10.3 days for all respondents, and 37% prescribed MET for ≥28 days, the prescription length used in the SUSPEND and Furyk et al trials.[2,3] MET prescriptions were significantly longer for respondents who were U.S.-based (22.9 vs. 18.1 days; p=0.001) (Table 1), in academic settings (22.3 vs. 16.1 days; p<0.001), and within 10 years of training (23.9 vs. 17.7 days; p<0.001).

Respondents used MET more often for distal stones as compared to mid-ureter or proximal stones (98% vs. 59% vs. 44%, respectively) (Table 2). For stones sized 5–8 mm, 8–10 mm, and >10 mm, 76%, 33%, and 8% of respondents reported using MET, respectively (Table 2). U.S.-based respondents were more likely to use MET for proximal and mid-ureteral stones (68% vs. 43%; p<0.001) (Table 3), as well as for stones >10 mm (13% vs. 4%; p=0.009). Twenty-nine percent of respondents reported that they would prescribe MET to pregnant patients with ureteral calculi, and 18% reported that they were unsure or would defer to an obstetrician, with no significant variations based on academic practice setting (Table 4).

U.S.-based respondents within 10 years of training were more likely to agree that additional education of emergency department physicians on MET is necessary (94% vs. 76%; p=0.033). Respondents in academic settings were significantly less likely to report an emergency department to clinic followup time of less than one week (58% vs. 81%; p<0.001) (Table 4).

Discussion

The criteria for the initiation and use of MET have been the subject of debate in the urological community, given the discordance in data from several studies. We evaluated real-world use of MET, as well as the awareness and impact of relevant literature and guidelines among endourologists.

Our results suggest that the majority of endourologists prefer MET as an initial approach to managing ureteral calculi. This trend is consistent across duration, location, and type of practice, as well as endourological fellowship training. Interestingly, our rate of MET usage was slightly lower than a survey by Lloyd et al (88.4% vs. 99.6%), which collected data ending in June of 2015, just prior to the publication of the SUSPEND trial.[7] This could be attributed to a decline in MET usage based on data refuting its efficacy, or perhaps this reflects an overall higher usage in a broader survey target group that included both endourologists and general urologists.

Another finding in our survey is that few endourologists (29%) report use of MET in pregnant patients. Lloyd et al showed a similar trend and further elucidated that concern of legal risk and patient safety contributed significantly to physician non-use of MET during pregnancy.[7] Nonetheless, recent evidence has emerged regarding the safety of using tamsulosin in pregnant females, while the U.S. Food and Drug Administration continues to class tamsulosin as category B, indicating no evidence of fetal harm shown in animal studies.[8]

Respondents with specific endourology fellowship training did not prescribe MET more often than their non-fellowship trained counterparts, but were more likely to report being aware of the current literature. The current AUA guidelines only recommend MET for patients with distal stones <10 mm in size and the EAU recommends MET for all ureteral stones.[1,4] However, it is foreseeable that future

Table 1. Characteristics of MET usage

							Interval since training					
	U.S.	International	p	Academic	Non-academic	p	≤10 years	>10 years	p	Fellow	Non-fellow	p
Currently prescribe MET	94% (76)	87% (129)	0.115	90% (125)	89% (80)	0.802	91% (72)	89% (133)	0.561	88% (130)	91% (75)	0.473
Preferred initial approach			0.507*			0.077*			0.031*			0.680*
Observation	12% (10)	14% (22)		15% (21)	12% (11)		10% (8)	15% (24)		15% (23)	11% (9)	
MET	76% (64)	67% (102)		74% (107)	63% (59)		82% (66)	64% (100)		71% (109)	69% (57)	
URS	8% (7)	10% (15)		6% (8)	15% (14)		4% (3)	12% (19)		8% (13)	11% (9)	
SWL	2% (2)	7% (11)		4% (6)	8% (7)		3% (2)	7% (11)		5% (7)	7% (6)	
Stenting	1% (1)	2% (3)		1% (2)	2% (2)		3% (2)	1% (2)		1% (2)	2% (2)	
NT placement (excluded)	0% (0)	0% (0)		0% (0)	0% (0)		0% (0)	0% (0)		0% (0)	0% (0)	
Preferred approach – MET only	67% (102)	76% (64)	0.126	74% (107)	63% (59)	0.075	82% (66)	64% (100)	0.006	71% (109)	69% (57)	0.736
Reported being aware of SUSPEND trial controversy	89% (73)	78% (116)	0.043	89% (125)	72% (64)	0.001	84% (67)	81% (122)	0.648	86% (129)	75% (60)	0.038
Aware of the AUA guidelines on the surgical management of stones	--	--		91% (128)	90% (81)	0.844	89% (71)	91% (138)	0.515	--	--	
Mean length of MET prescription in days (SD)	22.9 (10.7)	18.1 (9.7)	0.001	22.3 (10.5)	16.1 (8.7)	<0.001	23.9 (10.7)	17.7 (9.4)	<0.001	20.7 (10.9)	18.4 (9.1)	0.118

Data represents responses to survey questions on MET prescribing practices accompanied by analysis based on respondent demographics. *Fisher's exact test instead of Chi-square due to small sample sizes. AUA: American Urological Association; MET: medical expulsive therapy; NT: nephrostomy tube; SD: standard deviation; SWL: shockwave lithotripsy; URS: ureterscopy.

guidelines will continue to evolve to factor in the results from the SUSPEND trial and other future large-scale randomized controlled studies.[9] Of our U.S. respondents, 13% used MET for stones >10 mm in size and 68% used MET for stones in the proximal or mid-ureter. This reflects a deviation from the AUA guidelines, and is a significantly higher rate than international respondents. Adherence to the AUA guidelines, as measured by MET usage in stones >10 mm or in the proximal/mid-ureter, was not significantly impacted by either endourology fellowship training or interval from training (Table 3). It is important to note that at the time the survey was administered, the new AUA guidelines had been in place for only four months.[1] It is possible that some of the reported use of MET beyond the scope of the AUA guidelines is due to physicians not being aware of the new guidelines or that they are following the EAU guidelines, but these are not conclusions we can draw from our study design.

Table 2. MET usage by stone size and location

Variable	Percentage of respondents (n)
Location	
Proximal	44% (91)
Mid	59% (121)
Distal	98% (200)
Size	
<5 mm	74% (152)
5–8 mm	76% (156)
8–10 mm	33% (67)
>10 mm	8% (17)

Data represents the percentage of respondents reporting MET usage based on stone size and location in ureter. MET: medical expulsive therapy.

A recent patient questionnaire by Bell et al found that 49% of patients would try tamsulosin after being given a summary of the conflicting data for MET and 25% were unsure; 71% preferred trying medical therapy before pursuing surgical options.[10] It appears that both patient and physician preferences do not currently reflect recent prospective evidence, as evidenced by our finding that 70% of endourologists have not changed their usage of MET in response to the recent trials. In addition, with nearly half of patients willing to try MET despite recent evidence based on the Bell et al results and 85% of our respondents recommending

Table 3. MET usage for stone location and size

	U.S.	International	p	Fellow	Non-fellow	p	≤10 years from training	>10 years from training	p
Use MET for proximal or mid stones	68% (57)	43% (65)	<0.001	50% (77)	54% (45)	0.535	58% (47)	48% (75)	0.146
Use MET for distal stones	89% (75)	82% (125)	0.124	83% (127)	88% (73)	0.267	88% (71)	83% (129)	0.318
Use MET for stones <10 mm	88% (74)	84% (128)	0.357	83% (127)	90% (75)	0.102	88% (71)	84% (131)	0.449
Use MET for stones >10 mm	13% (11)	4% (6)	0.009	8% (13)	5% (4)	0.303	11% (9)	5% (8)	0.090

Data represents answer choice percentages and comparative data analysis based on respondent demographics. MET: medical expulsive therapy.

more research on MET, it will be important to disseminate future literature findings to both patients and physicians to aid in clinical recommendations.

There appears to be some disparity between the available evidence on MET and the current guidelines. Additionally, our data suggests expanded use of MET beyond the criteria set by the guidelines. Both of these trends indicate that practice patterns and patient care could benefit from clear guidelines backed by more conclusive literature on the use and efficacy of MET. Better tools for the translation of both current guidelines and recent literature findings to physicians might become a future clinical priority when a consensus on the use of MET is reached.

This report highlights the current trends and preferences among endourologists regarding MET and management of ureteral stones. One limitation of our study is that the survey design limits our abilities to draw conclusions regarding underlying explanations for the observed trends. Additionally, since our sample consisted of practicing Endourological Society members, our respondent population is unique in their expertise with endourology and stone disease, which may limit our ability to generalize the observed trends to the wider community of practicing urologists.

The completion rate for opened surveys was 83% and a total of 237 responses were recorded from the 2815 Endourological Society members contacted. By comparison, Lloyd et al did not record a response rate, but received 537 responses from surveys sent to mailing lists from the regional sections of the AUA, as well as the Endourological Society. Considering this, our response rate and total number of completed surveys seems adequate given only the Endourological Society was used for our survey and the number of opened surveys could have been impacted by inactive or outdated emails.

Table 4. Other MET usage questions

	Academic	Non-academic	p
ED to clinic followup time <1 week	58% (83)	81% (75)	<0.001
Recommends more research on MET is warranted (%)	83% (117)	88% (79)	0.321
Recommends more education of ED personnel on MET is necessary (%)	92% (129)	86% (77)	0.157
Recommends MET for pregnant patients			0.644
Yes	32% (45)	26% (24)	
No	51% (73)	55% (51)	
Defer to obstetrics	18% (25)	19% (18)	

Displays academic and non-academic responses for various MET related questions and analysis based on practice type. ED: emergency department; MET: medical expulsive therapy.

While the AUA or EAU guidelines do not specify length of MET, our data showed an average usage of MET for 19.9±10.3 days, which is shorter than the duration of 28 days examined in large recent scale trials.[2,3] Respondents in the U.S., in academic settings, and with an interval from training of less than 10 years all had significantly longer prescription lengths for MET. With regards to our index patient, the majority of respondents preferred MET as the initial approach, followed by observation and surgical intervention. Interestingly, urologists within 10 years of training were significantly more likely to choose MET.

Respondents in academic practice settings were significantly less likely to report a clinic followup time after initial emergency department encounter of less than one week. Although we did not elucidate the causality of this in our survey, it is possible that less available clinic time and longer duration of prescribed MET in an academic practice pushes back followup appointments to a later time.

Of our respondent population, 82% reported aware of the controversy surrounding the SUSPEND trial results. Significantly, 70% reported that this had not changed their practice regarding MET. This may be a reflection of endourologists awaiting more convincing evidence before changing established practice. It will be interesting to observe the evolution of the use of MET as more data emerges and as the guidelines are updated in the future.

A previous study at our institution estimated that half of emergency department patients who met criteria for MET did not receive it.[11] There was a consensus among our respondents that more education of emergency department personnel is necessary to standardize prescription and usage of MET, suggesting that this might be a commonly encountered issue for our respondents. Additionally, nearly 85% of respondents recommended more research on MET. In light of this, we have developed a standardized stone care protocol in conjunction with emergency department physicians for patients with renal colic.

Conclusion

MET continues to be the preferred initial approach among endourologists for patients with ureteral calculi <10 mm, despite conflicting data in the literature. While the current AUA practice guidelines are followed by the majority of respondents, it is notable that our survey suggests MET is being used more liberally than the criteria established in the guidelines, specifically in proximal and mid-ureteral stones.

Competing interests: The authors report no competing personal or financial interest.

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Supplementary Table 1. Full survey text	
Section 1: Demographic and education information	
Current type of practice	Academic medical centre Private practice urology – solo Private practice urology– group Multispecialty group Federal
Current AUA section	Northeastern New England New York Mid-Atlantic Southeastern North Central Western South Central Not sure Not applicable (international)
Are you an international member of the Endourological Society working outside of the U.S.?	Yes No
Number of years in practice	In training <1 year 1–4 years 5–10 years 11–20 years >20 years
Fellowship completed	Yes* (*one following branching question) No
*Type of fellowship	Endourology/stone disease Minimally invasive surgery (i.e. laparoscopic/robotic) Combined endourology and minimally invasive surgery Other* (*one following branching question)
*Other fellowship	[Text box]

AUA: American Urological Association; ED: emergency department; MET: medical expulsive therapy; NT: nephrostomy tube; SD: standard deviation; SWL: shockwave lithotripsy; URS: ureterscopy.

Supplementary Table 1 (cont'd). Full survey text	
Section 2: The following questions refer to an index patient presenting with ureteral calculi ≤10 mm, adequately controlled pain, and without fever	
What is your preferred initial approach?	Observation MET URS SWL Stenting NT placement
What is the typical time interval from initial presentation in ED to followup in your clinic?	<48 hours 48 hours–1 week 1–2 weeks >2 weeks
What percentage of patients with ureteral calculi are given MET in your hospital ED?	<25% 25–50% 50–75% >75% Not sure
Do you currently prescribe/encourage medical expulsive therapy (e.g., Flomax/Tamsulosin) to your patients with ureteral calculi?	Yes* (*four following branching questions) No Not applicable
*For the index patient above, how often do you prescribe medical expulsive therapy?	Never Rarely Sometimes Often Always
*Which stone locations would you use medical expulsive therapy (choose all that apply)	Proximal ureter Mid-ureter Distal ureter
*Which stone size(s) would you use MET (choose all that apply)	<5 mm 5–8 mm 8–10 mm >10 mm
*For the index patient above, how long would your MET prescription be for?	[Text box] "Number of days in prescription"
Would you prescribe medical expulsive therapy to pregnant patients with ureteral calculi?	Yes No Unsure/would defer to obstetrician
Would you prescribe medical expulsive therapy postoperatively to patients who received SWL treatment for ureteral calculi?	Yes No
If you were the index patient above, what would be your preferred treatment choice?	MET URS SWL Stenting NT placement

AUA: American Urological Association; ED: emergency department; MET: medical expulsive therapy; NT: nephrostomy tube; SD: standard deviation; SWL: shockwave lithotripsy; URS: ureterscopy.

Supplementary Table 1 (cont'd). Full survey text	
Section 3: Recent trials of medical expulsive therapy	
Are you aware of the controversy surrounding MET based on the recent paper (SUSPEND trial) published the *Lancet* in July of 2015 by McClinton et al?	Yes* (*one following branching question) No
*Did this controversy alter your use of MET?	Yes No
Are you aware of the current AUA guidelines on the surgical management of stones?	Yes No
Is more research on MET warranted?	Yes No
Is more education of ED personnel on MET necessary?	

AUA: American Urological Association; ED: emergency department; MET: medical expulsive therapy; NT: nephrostomy tube; SD: standard deviation; SWL: shockwave lithotripsy; URS: ureterscopy.

Supplementary Table 2. Full demographic data

	U.S. (n=84)	International (n=153)	Academic (n=144)	<10 years in practice (n=81)	Endo fellow (n=154)	Total (n=237)
Type of practice (n)						
Academic	61% (51)	61% (93)	-	64% (52)	69% (106)	61% (144)
Private, solo	7% (6)	11% (16)	-	7% (6)	6% (9)	9% (22)
Private, group	20% (17)	14% (22)	-	11% (9)	14% (21)	16% (39)
Multispecialty group	8% (7)	7% (11)	-	7% (6)	6% (9)	8% (18)
Federal	4% (3)	7% (11)	-	10% (8)	6% (9)	6% (14)
Years in practice (n)						
In training	0% (0)	1% (2)	1% (2)	-	1% (1)	1% (2)
<1 year	2% (2)	0% (0)	1% (1)	-	1% (1)	1% (2)
1–4 years	12% (10)	12% (18)	14% (20)	-	14% (21)	12% (28)
5–10 years	25% (21)	18% (28)	20% (29)	-	23% (35)	21% (49)
11–20 years	37% (31)	30% (46)	35% (51)	-	37% (57)	32% (77)
>20 years	24% (20)	39% (59)	29% (41)	-	25% (39)	33% (79)
Fellowship-trained (n)						
Yes	79% (66)	67% (102)	21% (30)	25% (20)	-	71% (168)
No	21% (18)	33% (51)	79% (114)	75% (61)	-	29% (69)
Fellowship type (n)						
Endourology/stone disease	21% (14)	52% (52)	40% (45)	25% (15)	-	39% (66)
Minimally invasive surgery (MIS)	12% (8)	8% (8)	7% (8)	13% (8)	-	10% (16)
Combined endourology and MIS	59% (39)	33% (33)	47% (53)	58% (35)	-	43% (72)
Other	8% (5)	7% (7)	6% (7)	3% (2)	-	8% (14)