



# Predicting ureteric stone expulsion with patient reported outcomes: a prospective observational study

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# Disclosures

- I have no conflicts of interest to disclose



# Spontaneous Passage

- Guidelines recommend patients with uncomplicated ureteric stones may be offered observation (*trial of spontaneous passage*)
- Patient reported outcomes (PROs) have been utilized as an endpoint in outcome based studies to define successful ureteric stone passage
- Furthermore, clinicians may utilize PROs to make management decisions about when to intervene



# PROs in Clinical Practice

American Urological Association (AUA)  
Endourological Society Guideline

**SURGICAL MANAGEMENT OF STONES:  
AMERICAN UROLOGICAL ASSOCIATION/  
ENDOUROLOGICAL SOCIETY GUIDELINE**

- The quality of the body of evidence regarding the follow-up of an observed ureteral calculus is low (**level C**)

Fulgham et al, 2012.



# PROs in Research

- Lancet, 2015: *Pickard et al.*

## **Medical expulsive therapy in adults with ureteric colic: a multicentre, randomised, placebo-controlled trial**

*Robert Pickard, Kathryn Starr, Graeme MacLennan, Thomas Lam, Ruth Thomas, Jennifer Burr, Gladys McPherson, Alison McDonald, Kenneth Anson, James N'Dow, Neil Burgess, Terry Clark, Mary Kilonzo, Katie Gillies, Kirsty Shearer, Charles Boachie, Sarah Cameron, John Norrie, Samuel McClinton*

- JAMA, 2018: *Melter et al.*

## **Effect of Tamsulosin on Passage of Symptomatic Ureteral Stones:**

**A Randomized Clinical Trial**



# Accuracy of PROs

- Unfortunately, little data exists regarding the accuracy of PROs to assess successful passage of ureteric calculi undergoing observation
- J Urol, 2017:

## **Cessation of Ureteral Colic Does Not Necessarily Mean that a Ureteral Stone Has Been Expelled**

Natalia Hernandez,\* Sarah Mozafarpour,\* Yan Song and Brian H. Eisner†

- Retrospective review of 52 clinic patients
- Cessation of pain had a 75% chance of being stone free



# Objective

- To prospectively determine the accuracy of PROs in predicting ureteric stone expulsion in patients undergoing observation
  - Cessation of pain
  - Patient reported stone passage



# Flow of Participants

**Design:** Pragmatic prospective observation study of patients presenting to the University of Alberta outpatient stone clinic.

## Eligibility Criteria:

- unilateral ureteral stone
- Exclusion criteria:
  - < 18 yo
  - Sepsis
  - Prior intervention

**Included**  
(n=136)

## PROs:

- Cessation of pain (yes/no)
- Stone passed (yes/no)

*Patient Demographics*

*Stone imaging parameters*

*Confirmatory imaging*

*Additional therapies*

Abbreviations: US = ultrasound, PROs = patient reported outcomes





# Methods

- Primary outcome was *confirmed stone passage* as assessed by radiologic imaging at the time of follow-up
- Confirmed stone passage was compared to PROs to calculate its usefulness a diagnostic test
- Multivariate logistic regression and ROC analysis



# Baseline Characteristics

	No. Patients	(%) or SD
Overall	136	
Age	50.6	±12.4
Male	96	(70.6)
Prior stone history	70	(51.4)
Comorbidities:		
Diabetes mellitus	21	(15.4)
Hypertension	42	(30.8)
Inflammatory bowel disease	1	(0.7)
Stone side:		
Left	75	(55.1)
Right	61	(46.9)
Stone Location:		
Distal	68	(50.0)
Mid	12	(8.8)
Proximal	56	(41.1)
Stone Size:		
Average (mm)	6.9	3.2
< 10 mm	110	(80.8)
Prescribed MET	36	(26.4)



# Assessment at Follow-up

	No. Patients	(%) or SD
Time to follow-up (days)	16.9	8.0
Follow-up imaging modality:		
KUB	15	(11.1)
Ultrasound + KUB	120	(88.2)
CT	1	(0.7)
Cessation of pain	55	(40.4)
Patient reported stone passage	45	(33.1)
<i>Reason:</i>		
Visualized it	6	(13.3)
Resolution of pain	32	(71.1)
Reduced pain	3	(0.7)
Physician told them	4	(0.9)
Required operative intervention:	62	(45.5)
Stent	1	(1.6)
ESWL	2	(3.2)
Ureteroscopy	59	(95.2)
PCNL	0	(0)
Subsequent spontaneous passage	16	(11.7)



# Multivariate Analysis

Variable	OR	95% CI	p-Value
Stone size	0.70	0.58 – 0.86	<b>0.001</b>
Stone Location (Proximal)	2.06	0.48 – 8.77	0.328
Stone Location (Distal)	4.33	1.62 – 11.6	<b>0.004</b>
Cessation of Pain	4.45	1.72 – 11.5	<b>0.002</b>
Reported stone passage	5.37	1.93 – 14.9	<b>0.001</b>



# Accuracy of PROs

Patient reported outcome	No. with radiographic passage (%)	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	Positive LR	Negative LR
Cessation of Pain (n=55)	38 (69.1)	79.9 (67.1-89.0)	55.8 (44.1-67.5)	1.81	0.36
Reported stone passage (n=45)	35 (76.4)	59.3 (45.6-77.9)	87.5 (77.4-93.5)	4.56	0.47
Combination = Cessation of Pain + Reported stone passage (n=39)	29 (80.6)	43.9 (31.7-56.7)	90.0 (81.5-96.1)	4.65	0.62

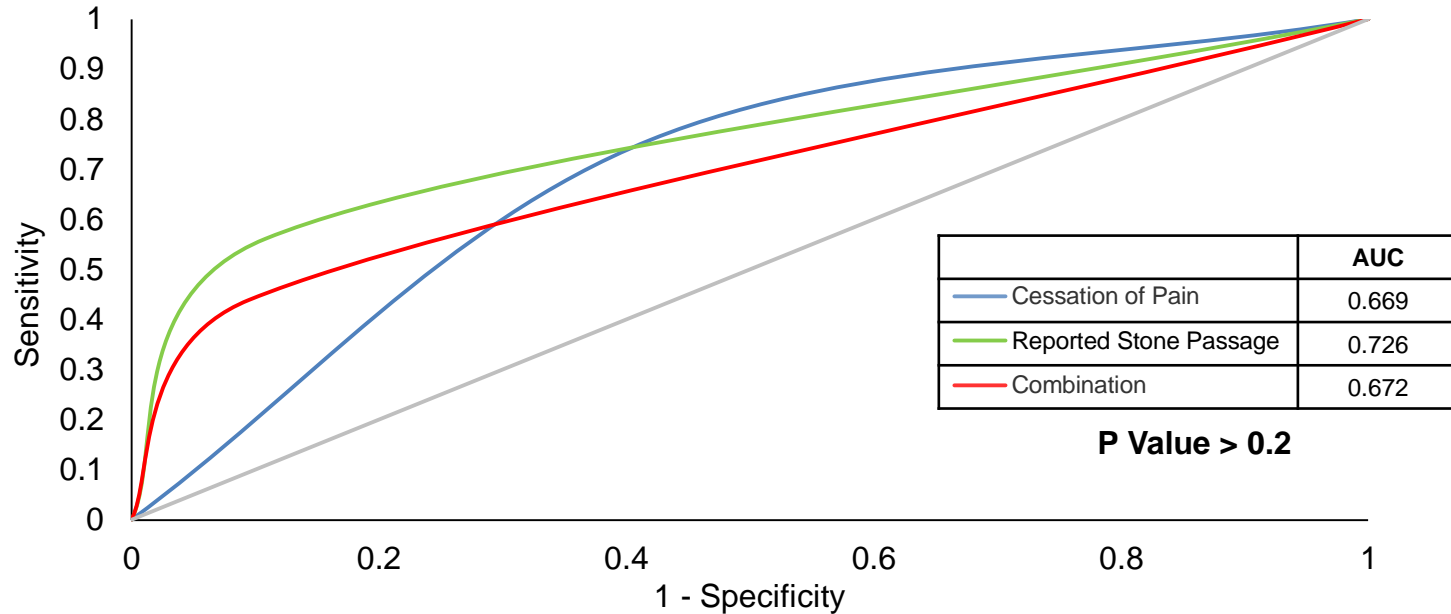


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Reported stone passage (n=45)	35 (76.4) <b>23.6%</b>	59.3 (45.6-77.9)	87.5 (77.4-93.5)	4.56	0.47
Combination = Cessation of Pain + Reported stone passage (n=39)	29 (80.6) <b>19.4%</b>	43.9 (31.7-56.7)	90.0 (81.5-96.1)	4.65	0.62



# Comparing PROs



Comparison of receiver-operating curves for PROs. AUC = area under the curve.



# Clinical Implications

- Limitations:
  - Pragmatic prospective observational study
  - Limited sample, single center
- While PROs are independent predictors in confirming ureteric stone expulsion, they may not have acceptable accuracy
- Argues against sole use of PROs as a clinical endpoint in research protocols and routine clinical care





# Conclusions

- This is the largest prospective cohort study to assess patient reported outcomes on ureteric stone expulsion
- PROs are independent predictors of ureteric stone expulsion
- Cessation of pain displayed a high sensitivity while patient reported stone passage had a high specificity for predicting true stone expulsion
- **PROs may incorrectly assess ureteric stone expulsion, which raises concern for their validity as a uncorroborated clinical endpoint**

