



Failed validation of risk prediction model for intervention in renal colic patients after emergency department evaluation

Tanya Dean,* Jack Crozier,† Sharon Klim‡ and Anne-Maree Kelly‡§

*Department of Emergency Medicine, Western Health, Melbourne, Victoria, Australia

†Western Health, Melbourne, Victoria, Australia

‡Joseph Epstein Centre for Emergency Medicine Research, Western Health, Melbourne, Victoria, Australia

§The University of Melbourne, Parkville, Victoria, Australia

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Correspondence

Professor Anne-Maree Kelly, Joseph Epstein Centre for Emergency Medicine Research, WHCRE, Sunshine Hospital, Western Health, Furlong Road, St. Albans, Vic. 3021, Australia. Email: anne-maree.kelly@wh.org.au

T. Dean MBBS; **J. Crozier** BMBS, BBiomedSc; **S. Klim** BN; **A.-M. Kelly** MD, FACEM.

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Abstract

Background: It has been reported that three criteria (size of calculus ≥ 6 mm, visual analogue scale pain score at discharge ≥ 2 cm and location above mid-ureter; the Papa criteria) were sensitive for predicting patients who require intervention (surgery or lithotripsy) within 28 days of index emergency department (ED) visit for ureteric colic. It was suggested that absence of these criteria identified a group for whom early follow-up may not be needed. No validation has been reported. We aimed to validate these criteria.

Methods: Retrospective cohort study of patients with clinical presentation of ureteric colic and radiologically proven renal tract stones. Data collected included demographics, clinical features, features of the stone, imaging results and 28-day outcome. Outcome of interest was performance of the Papa criteria for prediction of urological intervention by clinical performance analysis. We also undertook a post hoc analysis to identify predictors of urological intervention for the group overall and for the subgroup discharged from ED.

Results: Two hundred and twenty-four patients were studied (median age 49, 79% male) with 75 (33%) requiring urological intervention within 28 days. The presence of any of the Papa criteria had sensitivity for urological intervention of 83.9% (95% confidence interval (CI) 71.2–91.9%) with specificity of 47.7% (95% CI 38.9–56.6%), positive predictive value of 40.9% (95% CI 31.9–50.4%) and negative predictive value of 87.3% (95% CI 76.8–93.7%). Nine patients with no Papa criteria had intervention: 12.7% (95% CI 6.8–22.4%).

Conclusion: The Papa criteria are not sufficiently accurate to determine which patients require intervention or a subgroup who do not need specialist urological follow-up.

Introduction

Ureteric colic (also known as renal colic) is a common reason for presentation to emergency departments (ED). Stone formation in the urinary tract affects about 5–10% of the population in industrialized countries¹ and ureteric colic accounts for approximately 0.6% of total ED visits.² Previous studies have shown that approximately 20% of patients evaluated in ED for ureteric colic require urological intervention within 30 days of the index visit.³ Accurate prediction of patients likely to require intervention could improve efficiency of referral to outpatient urology services by making alternative follow-up arrangements for patients unlikely to require intervention.

Previously, Papa *et al.* attempted to develop a risk prediction model for intervention in ED patients with ureteric colic.³ It found three variables that significantly correlated with having a procedure. They were size of calculus ≥ 6 mm (odds ratio (OR) 10.7, 95% confidence interval (CI) 4.6–24.8%), location of calculus above mid-ureter (OR 6.9, 95% CI 3.0–15.9%) and visual analogue scale score for pain at discharge from the ED ≥ 2 cm (OR 2.6, 95% CI 1.0–6.8%). It reported that if all three variables were present, there was a 90% probability of the patient having an intervention performed within 4 weeks but if none of the variables were present, there was only a 4% probability of an intervention. They reported that this prediction model had sensitivity of 92% (95% CI 89–96%) and a specificity of 63% (95% CI 57–69%). No validation of this model

has been reported. In addition, there have also been significant changes to treatment in the intervening period, in particular the increased use of medical expulsion therapies (MET) that may alter both the rate of intervention and the predictive factors.

This study aimed to validate the previously developed prediction model in an independent population with the availability of contemporary therapies.

Methods

This was a retrospective observational study conducted by explicit medical records review. Inclusion criteria were adult patients (aged >18 years) with ED diagnosis (as identified from the ED data management system) of ureteric colic (or equivalents) between 1 July 2012 and 30 June 2013 treated at ED of a community teaching hospital in Melbourne, Australia. Patients were excluded if renal colic was not confirmed by computed tomography (CT) at the index ED visit or if they had previously been included in the study.

Data were collected by researchers (TD, JC) not blinded to the study's hypotheses onto a specifically designed data form. Data collected included demographics, clinical features, imaging results, ED therapeutics and intervention within 30 days.

The primary outcome of interest was urological intervention within 30 days. Analysis was by clinical performance analysis (sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV)) and OR calculation. We also undertook logistic regression analysis to identify independent predictors of urological intervention for the group overall and for the subgroup discharged from ED. Comparison of proportions was by Chi-square or Fisher's test as appropriate. We calculated that for the clinical performance analysis with 95% CI $\pm 5\%$, based on Papa's sensitivity of 92%, approximately 130 eligible patients would need to be studied.

The study was approved by the institution's human research ethics panel as a quality assurance (minimal risk) project. Patient consent for participation was not required.

Results

Two hundred and twenty-four patients were studied with 75 (33%) requiring urological intervention within 28 days. Sample derivation is shown in Figure 1 and clinical characteristics are shown in Table 1. Median age was 49 years, 79% were male and 22% were admitted to hospital from ED.

Screened for inclusion = 506

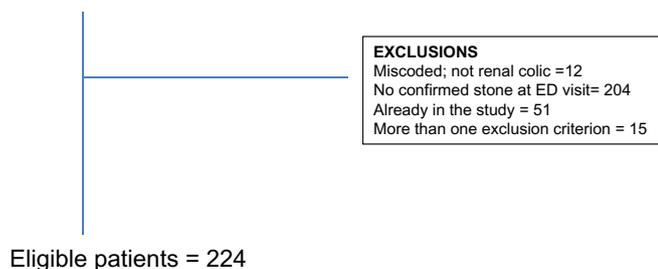


Fig. 1. Sample derivation.

The presence of any of the Papa criteria had sensitivity for urological intervention of 83.9% (95% CI 71.2–91.9%) with specificity of 47.7% (95% CI 38.9–56.6%), PPV of 40.9% (95% CI 31.9–50.4%) and NPV of 87.3% (95% CI 76.8–93.7%). Nine patients with no Papa criteria had intervention: 12.7% (95% CI 6.8–22.4%).

For the post hoc analysis to identify predictors of urological intervention, the predictor variables included were previous ureteric colic, eGFR <90, white cell count >11, presence of fever >38°C, pain score on arrival at ED, treatment with nonsteroidal anti-inflammatory drugs, presence of hydronephrosis on imaging, stone location (above or below mid-ureter) and disposition from ED (admission to ward or discharge home). It should be noted that admission to ward did not include patients admitted to the ED observation unit (or similar) and later discharged; these were regarded as ED patients. On logistic regression analysis, two factors were independently predictive of urological intervention – discharge destination (admission versus ED discharge) and location of stone above the mid-ureter. The OR for discharge destination ‘admission’ was 17.8 (95% CI 7.8–40.4%, $P < 0.001$) and the OR for stone location above mid-ureter was 2.0 (95% CI 1.003–3.9%, $P = 0.049$). Those patients with an ED discharge destination of ward admission had an 82% incidence of urological intervention at 28 days whereas those discharged home had a 20% incidence.

Given the dominance of ED discharge destination ‘admission’ in the analysis, we performed a post hoc logistic regression analysis of the patient group who were not admitted in an attempt to identify predictors of urological intervention in that group. When only those who were not admitted were analysed, hydronephrosis was a significant predictor with OR of 6.2 (95% CI 1.4–28%, $P = 0.016$). Only 9% of those without hydronephrosis had urological intervention (Fisher's exact test = 0.022).

Discussion

This study failed to validate the previously derived prediction model with sensitivity of 84% and NPV of 87%. On this basis, this approach could not be recommended for implementation in ED.

The study found that the strongest independent predictor of the need for urological intervention was ED disposition of admission to a hospital ward. The decision to admit a patient with ureteric colic is the integration of multiple factors which this study was not designed to determine. That said, they are likely to include the ability to achieve lasting pain control, suspicion of infection, presence of single kidney, re-presentation to ED and personal and social circumstances. The clinical accuracy of the decision to admit was high, with >80% of admitted patients undergoing a urological intervention.

Unlike others,⁴⁻⁶ we did not find that stone size was an independent predictor of requirement for urological intervention. This may be due to difference in statistical analysis as other papers mostly reported univariate rather than multivariate analyses. It may also be due to different predictor variables being included in the analysis, with ED disposition being included rarely. Many of the older studies used plain radiology or intravenous pyelography to determine stone size. In contrast, CT is digitized and allows more accurate size assessment. We also found a higher rate of urological intervention (33%) than has been reported elsewhere.^{3,6} Reasons for this are

Table 1 Clinical characteristics

| Variable | | |
|--------------------------------------------------------------------|-------------|-----------------|
| Demographics | | |
| Age (years, median, IQR) | 49; 38–62.6 | |
| Gender (male; <i>n</i> , %) | 177; 79% | |
| Previous renal colic (<i>n</i> , %) | 89; 39.7% | |
| Clinical features | | |
| eGFR <90 (<i>n</i> , %) | 133; 59.4% | 5 missing data |
| Pain score at presentation (median, IQR) | 7; 5–9 | 18 missing data |
| WCC >11 (<i>n</i> , %) | 71; 31.7% | 1 missing data |
| Fever >38°C (<i>n</i> , %) | 3, 1.3% | |
| Treatment | | |
| Received NSAID (<i>n</i> , %) | 168; 75% | 2 missing data |
| Morphine dose within 4 h at ED arrival (mg, median, IQR) | 5, 0–10 | |
| Total morphine dose ED stay (mg, median, IQR) | 5, 0–10 | |
| Pain score at discharge (median, IQR) | 0, 0–0.1 | 38 missing data |
| Radiographic features of stone | | |
| Maximal dimension (mm, median, IQR) | 4.75, 3–7 | 8 missing data |
| Evidence of hydronephrosis (<i>n</i> , %) | 164, 73.2% | 13 missing data |
| Stone location (<i>n</i> , %) | | |
| Bladder | 1, 0.4% | |
| VUJ | 76, 33.9% | |
| Lower half ureter | 53, 23.7% | |
| Mid-ureter | 13, 5.8% | |
| Upper half ureter | 50, 22.3% | |
| PUJ | 5, 2.2% | |
| Renal pelvis | 26, 11.6% | |
| Disposition and 28 day events | | |
| Admitted to inpatient ward (<i>n</i> , %) | 50, 22.4% | |
| Discharged from ED or short stay unit (<i>n</i> , %) | 174, 77.6% | |
| Length of stay (h, median, IQR) | 13, 7–32 | |
| Discharged on a course of NSAID (<i>n</i> , %) | 81, 46.6% | |
| Discharged on a course of tamsulosin/similar (<i>n</i> , %) | 61, 35.1% | |
| Discharged on course of NSAID + tamsulosin/similar (<i>n</i> , %) | 30, 17.2% | |
| Representation to ED with renal colic (<i>n</i> , %) | 45, 20.1% | |
| Urologic intervention within 28 days (<i>n</i> , %) | 75, 33.5% | |

ED, emergency department; eGFR, estimated glomerular filtration rate; IQR, interquartile range; NSAID, nonsteroidal anti-inflammatory drug; PUJ, pelviureteric junction; VUJ, vesicoureteric junction; WCC, white cell count.

unclear but as the decision for intervention integrates clinical information and judgment, some variability in rates would not be unexpected.

Other approaches to identify predictors of spontaneous stone passage versus urological intervention have been explored. Park *et al.*⁷ explored the relationship between spontaneous stone passage and serum C-reactive protein (CRP) levels and neutrophil percentages finding that as CRP levels rose the rate of spontaneous stone passage declined and the same was true for rising neutrophil percentage. Similar results regarding CRP were reported by Aldagadosi⁸ who found that for small stones, patients with CRP >21.9 had a low stone expulsion rate and that the success of MET could be predicted by CRP. Unlike Sfoungaristos *et al.*,⁶ we did not find white cell count a significant predictor of intervention.

This study has some limitations that should be considered when interpreting the results. As a retrospective cohort study, it is subject to issues with missing data. It is also possible that some patients with ureteric colic were misdiagnosed or miscoded and thus not included. The researchers were not blinded to the study hypothesis which may have influenced data collection. Some patients may have undergone urological intervention at another hospital which would not necessarily be reflected in the study hospital's medical record. The decision for intervention has subjective ele-

ments, some of which may reflect the culture and practices of the local urologist group thus the findings cannot be assumed to be widely generalizable.

Conclusion

The Papa criteria are not sufficiently accurate to determine which patients require intervention within 28 days or a subgroup who do not need specialist urological follow-up. In the absence of reliable predictors of urological intervention, it would seem prudent for all patients to have early urological follow-up.

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