REVIEW ARTICLE

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Exploratory evaluation of point-of-care C-reactive protein for febrile urinary tract infection in infants: a prospective multicentre study

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Keywords

Urinary Tract Infections; Infant; C-Reactive Protein; Point-of-Care Testing; Emergency Service; Hospital

Abstract

Introduction
Urinalysis is frequently performed in febrile pre-continent children in the emergency department (ED), but urine sampling can be time-consuming and may require urethral catheterization. Point-of-care (POC) C-reactive protein (CRP) provides rapid information on inflammatory status. We assessed the discriminatory value of POC CRP for febrile urinary tract infection (UTI) and explored whether the available data supported a clinically useful rule-out threshold.

Methods
This prospective multicentre observational study included well-appearing febrile children aged 3-24 months in two Brussels hospitals. Inclusion criteria were based on American Academy of Pediatrics UTI risk factors. Each participant underwent urine sampling and capillary QuikRead go® POC CRP testing.

Results
A total of 217 children were included; 23 (10.6%) met the primary culture-based UTI outcome. Median POC CRP was higher in children with UTI than in those without UTI (76 mg/L [IQR 33-143] vs 20 mg/L [IQR 7-54], p = 0.0005). In the pooled cohort, POC CRP showed moderate discrimination for UTI (AUC 0.72; 95% CI 0.66-0.78). In exploratory analyses, sex, absence of upper respiratory tract symptoms, and higher POC CRP were associated with UTI. However, only 23 UTI events, including five among boys, were available for modelling.

Conclusions
POC CRP was associated with culture-confirmed febrile UTI but the available dataset was insufficient to define a clinically reliable rule-out threshold or stable prediction rule. Larger, prospectively assembled multicentre cohorts with prespecified analyses are needed to determine whether POC CRP can improve selection of febrile young children for urine testing.

What is known
Urinary tract infection (UTI) is a common cause of fever in young children, yet urine collection can be invasive and time-consuming in pre-continent infants. Point-of-care (POC) C-reactive protein (CRP) testing rapidly reflects systemic inflammation and may help in the assessment of febrile children, but its role in selecting children for urine testing has not been clearly defined.

What is new
In this prospective multicentre cohort, POC CRP was significantly higher in children with culture-confirmed febrile UTI and showed moderate discrimination for UTI. Only 23 UTI events were observed. The available data were therefore insufficient to define a clinically reliable CRP rule-out threshold or prediction rule, supporting further study in larger, prospectively assembled multicentre cohorts.

Introduction

Since routine immunisation against *Haemophilus influenzae* type B and *Streptococcus pneumoniae*, urinary tract infection (UTI) has become one of the most common causes of serious bacterial infection in infants, with a prevalence of approximately 7% among febrile infants younger than 2 years (1,2).

Febrile UTI in young children may involve the upper urinary tract and can result in renal scarring (3). Clinical features may include fever, anorexia, vomiting, lethargy and malaise, but signs and symptoms are non-specific in this age group; therefore, a urine sample is required for diagnosis (1).

In the pre-continent child, urine can be obtained through a perineal bag, clean catch (CC), in-and-out urethral catheterization (UC), or suprapubic aspiration (SPA) (4). One possible strategy is a stepwise approach, in which a non-invasive sample is obtained first and UC or SPA is performed only when the screening urinalysis suggests UTI (5). In our study hospitals, empirical antibiotic therapy is commonly started when urinalysis obtained through UC or SPA suggests UTI; final microbiological confirmation is provided by urine culture, which is generally available after 24-48 hours (1).

Given the substantial prevalence of UTI in young febrile children, urinalysis is frequently performed in the emergency department (ED). Urine collection, particularly by perineal bag, can be time-consuming for patients, parents and ED staff, may require several attempts because of bag detachment or faecal contamination, and requires waiting for spontaneous bladder voiding. This practice also has an associated cost (6).

Urine bag samples have a high false-positive rate and are unreliable for confirming UTI (4,5). Although significant complications of UC are rare, urologic adverse events can occur (7). Microscopic pyuria may also occur in the absence of UTI, for example in other infections or after vigorous exercise, potentially contributing to unnecessary antibiotic prescription, a concern in the context of increasing antimicrobial resistance (8,9). SPA has the lowest theoretical risk of contamination but is perceived by clinicians and parents as the most invasive and painful sampling method (4).

Febrile UTI is commonly associated with a systemic inflammatory response, but standard laboratory CRP testing entails a delay between sampling and result availability and requires venous blood sampling (10,11). In a busy ED, these steps may contribute to prolonged patient flow and resource use (12).

Point-of-care (POC) C-reactive protein (CRP) testing can be performed on capillary blood obtained by finger prick, is quick to perform, and provides a result within a few minutes (11,13). It may therefore offer a rapid adjunct to clinical assessment in febrile young children.

The primary aim of this study was to assess the discriminatory value of POC CRP for culture-confirmed febrile UTI in well-appearing febrile children aged 3-24 months and to explore whether the available data supported identification of a clinically useful rule-out threshold. Secondary exploratory analyses examined associations between UTI and readily available clinical features.

Methods

Study population

Pre-continent, well-appearing febrile children aged 3-24 months presenting to the EDs of Queen Fabiola Children's University Hospital (QFCUH) and Etterbeek-Ixelles Hospital (EIH), Brussels, Belgium, were eligible. Inclusion criteria were based on the 2011 American Academy of Pediatrics (AAP) UTI guideline (5). Ethnicity was excluded from the AAP-based criteria because of the high proportion of children with mixed and diverse origins in our population.

All well-appearing children aged 3-24 months with a rectal temperature ≥ 38°C lasting ≥ 24 hours were eligible for inclusion if they met the following sex-specific inclusion criteria:

- Uncircumcised boys: systematically eligible.
- Circumcised boys: at least one of the following: rectal temperature ≥ 39°C or absence of another clear source of infection.
- Girls: at least two of the following: age < 12 months, rectal temperature ≥ 39°C, fever lasting ≥ 48 hours, or absence of another clear source of infection.

Subjects meeting any of the following criteria were excluded from the study:

- Hemodynamic, respiratory or neurological instability
- Congenital or acquired immunodeficiency
- Malignant or haematological disease
- Previous episode(s) of febrile UTI
- Known underlying urinary tract pathology or risk factors for a neurogenic bladder
- Antibiotic intake during the 7 days preceding the ED visit
- Previous inclusion in the study

Study design

This multicentre prospective observational study was conducted from September 2023 to February 2025 at both centres. Written informed consent was obtained from one parent. As per local practice, an initial urine sample was obtained by perineal bag, CC, UC, or SPA. When an initial bag sample was screen-positive, a second, less contamination-prone specimen (CC, UC, or SPA) was obtained for confirmation and culture whenever feasible.

During the ED visit, a screening urinalysis prompted confirmatory sampling when leucocyte esterase and/or nitrite were present on dipstick, or automated microscopic analysis of non-centrifuged urine using Sedimax contrustPro® showed > 40 leucocytes/μL; values of 40-100 leucocytes/μL were considered equivocal and > 100 leucocytes/μL clearly positive.

The primary outcome was culture-confirmed febrile UTI. Culture positivity was interpreted according to the 2015 European Association of Urology/European Society for Paediatric Urology guidelines, which use collection-method-specific colony-count criteria: any significant growth after SPA, 10^3-5×10^4 colony-forming units (CFU)/mL after catheterization, and ≥ 10^4 CFU/mL in symptomatic clean-catch or midstream specimens (14). Mixed growth was considered contamination. Pyuria was not required for the primary culture-based outcome. When cultures obtained by different collection methods were discrepant, the result from the less contamination-prone specimen (UC or CC) was used for outcome classification. A positive bag culture followed by a negative UC or CC culture was therefore classified as no UTI. Bag cultures were not considered equivalent to UC or CC cultures; cases without a less contamination-prone confirmatory specimen were retained in the primary analysis only when repeated cultures yielded high-count monoculture and are described separately in the Results section.

After urine sampling, POC CRP testing (QuikRead go®, Aidian Oy®) was performed on capillary blood obtained by finger prick.

Patient management followed local protocols. Additional investigations were performed according to protocol (including venous blood sampling and blood cultures in infants younger than 6 months) or at the treating physician's discretion.

TABLE 1: Demographic and clinical characteristics of the 217 patients included in this study. Categorical variables are reported as percentages and continuous variables as mean ± SD or median (IQR), as appropriate. URT = upper respiratory tract.

	All (n=217)	Circumcised boys (n=32)	Uncircumcised boys (n=80)	Girls (n=105)
Age (months)	9.5 (6-15.5)	12 (9-17)	9 (6-14)	10 (7-16)
Fever duration (hours)	72 (48-100)	72 (48-120)	72 (48-120)	72 (48-96)
Maximal fever (°C)	39.7 ± 0.6	39.9 ± 0.6	39.7 ± 0.5	39.7 ± 0.6
No other symptoms (%)	4.5	3.1	3.8	5.7
URT symptoms (%)	83.0	87.5	87.5	80.0
Diarrhoea (%)	26.8	29.1	20.0	31.4
Vomiting (%)	35.3	46.9	38.8	28.6
Loss of appetite (%)	65.2	78.1	57.5	65.7
Chills (%)	9.4	12.5	11.3	7.6
Demographic and clinical characteristics of the 217 patients included in this study. Categorical variables are reported as percentages and continuous variables as mean ± SD or median (IQR), as appropriate. URT = upper respiratory tract.				

Data collection

Demographic and clinical data were extracted from the electronic health record and an ED report sheet. Data were managed using REDCap® hosted at the Université libre de Bruxelles (ULB). Outcome classification followed the culture criteria and specimen hierarchy described above. All records were pseudonymised using a unique study ID.

Statistical Analyses

Categorical variables were summarised as frequencies and percentages; continuous variables as mean ± standard deviation (SD) or median (interquartile range [IQR]). Normality was assessed with the D'Agostino-Pearson test. Group comparisons used the t-test, Mann-Whitney U test, or Fisher exact test, as appropriate. Receiver operating characteristic (ROC) curves were constructed to describe the discriminatory ability of POC CRP for culture-confirmed febrile UTI and to calculate the area under the curve (AUC) with 95% confidence intervals (CI). Centre-specific AUCs were compared using DeLong's test. Potential clinical associations with UTI were explored using univariable analyses. Variables with $p < 0.20$ were entered into an exploratory logistic regression model, with Nagelkerke R^2 and odds ratios (OR) with 95% CI reported. This data-driven procedure was used to explore associations only; it was not used to derive or validate a clinical prediction rule and is acknowledged as a potential source of overfitting. Statistical significance was set at $p < 0.05$. Analyses were performed in MedCalc® v20.305 (Mariakerke, Belgium).

Ethical Approval and Funding

The study was approved by the Ethics Committees of QFCUH, EIH, and Erasme University Hospital, in accordance with the Declaration of Helsinki. It received Iris-Research Fund support through the 2023 call for "Clinical and Translational Multicentre Research in the Hospitals of the Iris-Network" (King Baudouin Foundation), enabling purchase of QuikRead go® devices and reagents.

Results

Patient characteristics

A total of 217 patients were included, 178 from QFCUH and 39 from EIH. Culture-confirmed febrile UTI prevalence was significantly higher at EIH (9/39; 23.1%) than at QFCUH (14/178; 7.9%; Fisher exact $p = 0.010$). Recruitment at EIH was more selective, which may have contributed to the difference in prevalence.

The overall population included 112 boys (51.6%), of whom 32 were circumcised (28.6% of boys), and 105 girls. Participants' demographic and clinical characteristics are reported in Table 1. Uncircumcised boys were significantly younger than circumcised boys ($p = 0.009$), whereas loss of appetite was more frequently reported in circumcised boys ($p = 0.042$). No other statistically significant differences were found.

The distribution of participants according to the number of AAP criteria met is presented in Table 2.

For most patients (89.9%), a urine bag was the first sampling method. UC was used as the initial method mainly in girls (n = 18; boys n = 3). Thirty patients underwent a second urine sample, most often by UC (83.3%). No SPA was performed. Collection methods and screening-urinalysis positivity are reported in Table 3. Two boys classified as having UTI had both their first and repeat samples collected by bag; both had repeated cultures yielding > 100,000 CFU/mL of *Escherichia coli* without other bacteria. Because no less contamination-prone confirmatory specimen was available, these classifications were considered diagnostically less certain. The median POC CRP level was 21 mg/L (IQR 7-64). Median POC CRP values were

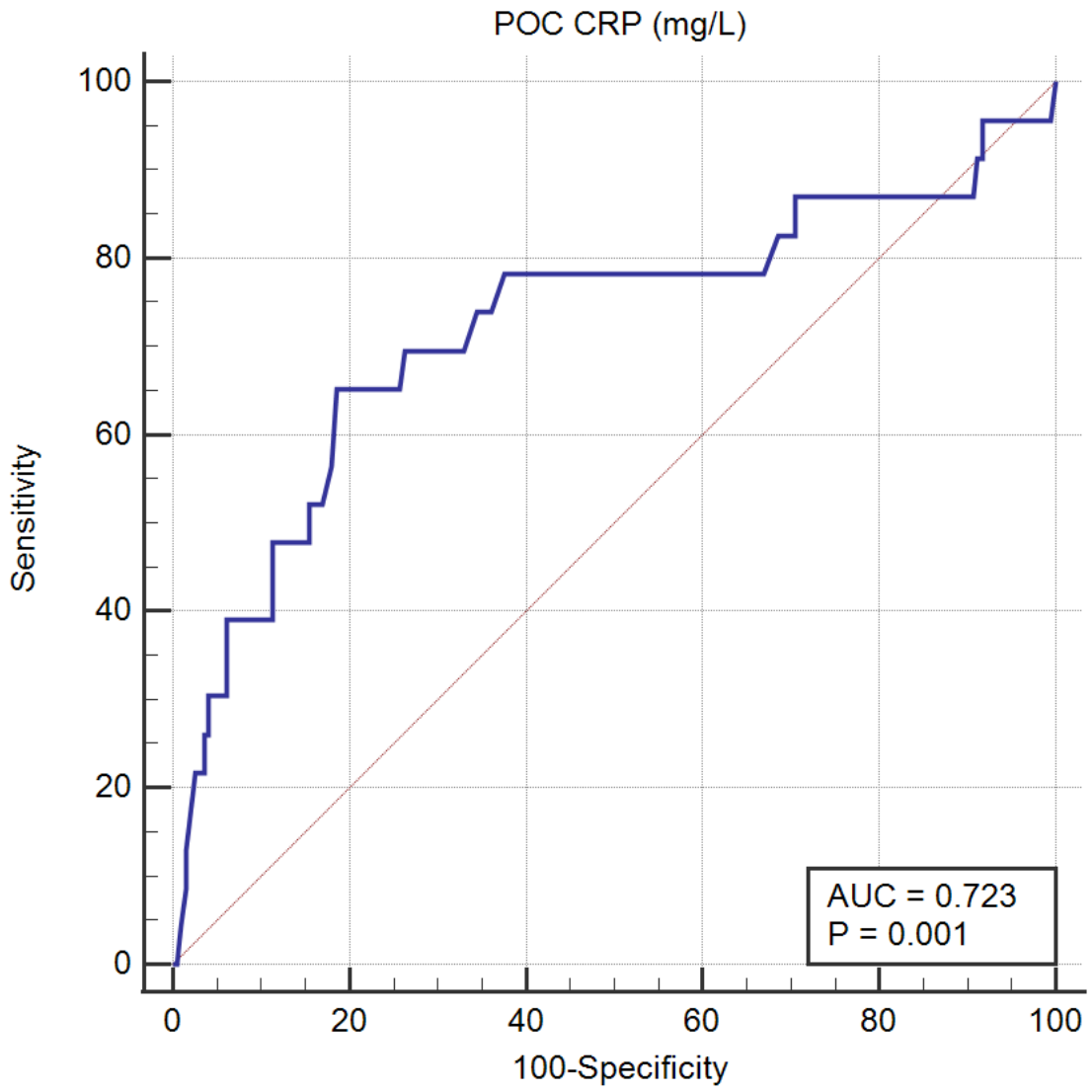

FIGURE 1: Receiver operating characteristic (ROC) curve of point-of-care C-reactive protein (POC CRP) for identifying culture-confirmed febrile urinary tract infection (UTI) in the overall cohort.

similar between centres (QFCUH 20 mg/L [IQR 7-64] vs EIH 25 mg/L [IQR 8-65]; Mann-Whitney U = 3399, p = 0.84). However, the marked difference in UTI prevalence indicates potential centre-related case-mix heterogeneity despite similar overall CRP distributions. Patients with culture-confirmed febrile UTI had a significantly higher median POC CRP than those without UTI (76 mg/L [IQR 33-143] vs 20 mg/L [IQR 7-54], p = 0.0005). The difference remained significant after stratification by sex, whereas analysis according to circumcision status was limited by the small number of UTI events (Table 4).

Twenty patients received an initial clinical diagnosis of UTI. Four culture-confirmed UTI cases were not initially diagnosed as UTI in the ED (three were diagnosed as viral infection and one as serious bacterial infection [SBI] of unknown origin). Conversely, one patient was initially diagnosed with UTI but the urine culture was negative. Overall, 23 children (10.6%) met the primary culture-based UTI outcome: 18 girls and five boys, four

TABLE 2: Distribution of participants according to the number of AAP UTI risk criteria met. NA = not applicable.

	Circumcised boys (n=32)	Uncircumcised boys (n=80)	Girls (n=105)
2 criteria (n [%])	31 (96.9)	77 (96.2)	57 (54.3)
3 criteria (n [%])	1 (3.1)	3 (3.8)	46 (43.8)
4 criteria (n [%])	NA	NA	2 (1.9)

TABLE 3: Urine collection methods, overall and according to sex and circumcision status, and screening-urinalysis positivity according to the study protocol. CC = clean catch; UC = urethral catheterization; NA = not applicable.

	All (n=217)	Circumcised boys (n=32)	Uncircumcised boys (n=80)	Girls (n=105)
1st sample: bag	195/217 (89.9)	30/32 (93.8)	78/80 (97.5)	87/105 (82.9)
Positive (n [%])	46/195 (23.6)	1/30 (3.3)	7/78 (9.0)	38/87 (43.7)
1st sample: CC	1/217 (0.5)	0/32 (0)	1/80 (1.3)	0/105 (0)
Positive (n [%])	1/1 (100)	NA	1/1 (100)	NA
1st sample: UC	21/217 (9.7)	2/32 (6.3)	1/80 (1.3)	18/105 (17.1)
Positive (n [%])	8/21 (38.1)	1/2 (50)	1/1 (100)	6/18 (33.3)
2nd sample: bag	2/30 (6.7)	0/1 (0)	2/5 (40)	0/24 (0)
Positive (n [%])	1/2 (50)	NA	1/2 (50)	NA
2nd sample: CC	3/30 (10)	1/1 (100)	2/5 (40)	0/24 (0)
Positive (n [%])	3/3 (100)	1/1 (100)	2/2 (100)	NA
2nd sample: UC	25/30 (83.3)	0/1 (0)	1/5 (20)	24/24 (100)
Positive (n [%])	13/25 (52)	NA	1/1 (100)	12/24 (50)

of whom were uncircumcised. *Escherichia coli* was the most common causative pathogen, accounting for 87% of UTIs. One girl classified as UTI had a positive UC culture without associated pyuria and recovered without antibiotic therapy, as confirmed at follow-up one month later; under stricter definitions requiring pyuria, the clinical classification of this case would be uncertain. Most other patients (77.1%) were diagnosed with an infection of presumed viral origin, such as an upper respiratory tract infection or viral exanthema. Other diagnoses included otitis media (8.2%), pneumonia (2.8%), gastroenteritis (1.8%) and SBI (0.9%). Thirty-five patients (16.1%) underwent supplementary blood testing, including ten according to local protocol. Chest radiography was performed in 19 patients (8.8%), and 44 (20.3%) received an antibiotic prescription. No patient underwent lumbar puncture or other invasive testing. POC CRP levels were similar between infants who did (n = 15) and did not (n = 182) undergo supplementary blood testing after excluding infants younger than 6 months, in whom blood testing was mandated by protocol (22 mg/L [IQR 6-75] vs 20 mg/L [IQR 7-54]; Mann-Whitney U = 1241, p = 0.56).

POC CRP results

Centre-specific ROC analysis of POC CRP for culture-confirmed febrile UTI showed an AUC of 0.67 (95% CI 0.60-0.74) at QFCUH and 0.86 (95% CI 0.71-0.95) at EIH. No statistically significant difference between the AUCs was detected (DeLong p = 0.17), but precision was limited, particularly at EIH, and centre-specific heterogeneity in diagnostic performance cannot be excluded.

In the pooled cohort, POC CRP showed moderate discrimination for culture-confirmed febrile UTI, with an AUC of 0.72 (95% CI 0.66-0.78; Figure 1). Given the limited number of UTI events and the exploratory nature of the analysis, the available data were considered insufficient to define a clinically reliable rule-out threshold. No POC CRP cut-off was therefore retained for clinical use.

Exploratory associations with UTI

In exploratory univariable analyses, sex (p = 0.013), absence of upper respiratory tract symptoms (URTS; p = 0.0002), and POC CRP level (p = 0.0001) were associated with UTI. An exploratory logistic regression containing these three variables had a Nagelkerke R^2

TABLE 4: POC CRP levels according to sex, circumcision status and UTI diagnosis. POC CRP values are reported as median (IQR).

Overall population	All (n=217)	Circumcised boys (n=32)	Uncircumcised boys (n=80)	Girls (n=105)
POC CRP (mg/L)	21 (7-64)	25 (9-63)	20 (7-54)	22 (6-68)
Confirmed UTI	n=23	n=1	n=4	n=18
POC CRP (mg/L)	76 (33-143)	132	92 (47-104)	69 (31-160)
No UTI	n=194	n=31	n=76	n=87
POC CRP (mg/L)	20 (7-54)	24 (8-60)	20 (7-51)	17 (5-53)
POC CRP levels according to sex, circumcision status and UTI diagnosis. POC CRP values are reported as median (IQR).				

TABLE 5: Exploratory multivariable logistic regression of factors associated with culture-confirmed febrile UTI. POC CRP was entered as a continuous variable. Estimates are hypothesis-generating associations from the derivation cohort and should not be interpreted as a validated clinical prediction model.

Exploratory model	Odds ratio	95% CI
Female sex	4.17	1.35-12.90
POC CRP (continuous)	1.02	1.01-1.03
Presence of URTS	0.13	0.05-0.38

of 0.34. Female sex and higher POC CRP were associated with higher odds of UTI, whereas the presence of URTS was associated with lower odds (Table 5). Because only 23 UTI events were observed and predictor selection was data-driven, these coefficients should be interpreted as hypothesis-generating associations rather than as a validated prediction model.

Discussion

This prospective multicentre study explored the potential role of POC CRP in the assessment of febrile, well-appearing pre-continent children considered at risk of UTI. POC CRP was substantially higher in children with culture-confirmed febrile UTI than in those without UTI, and CRP alone showed moderate discrimination. However, only 23 UTI events were observed, including five among boys. We therefore did not retain a CRP threshold or derive a sex-specific clinical rule from these data.

In our cohort, UTI prevalence did not differ significantly between circumcised and uncircumcised boys. This analysis was clearly underpowered because of the small number of circumcised participants and UTI events. The well-established protective effect of circumcision on UTI risk therefore could not be confirmed or refuted in our study.

Our findings support an association between higher POC CRP and febrile UTI, but CRP is a non-specific marker of inflammation and should not be interpreted as distinguishing bacterial from viral infection on its own. Previous paediatric studies have shown that POC CRP can contribute to the assessment of febrile children when combined with clinical evaluation (13,15). The moderate AUC observed in our cohort similarly suggests that CRP may provide useful information, but is unlikely to be sufficient as a stand-alone rule-out test. The absence of a retained threshold is an important finding rather than a negative result. A clinically useful rule-out strategy would require very high and precisely estimated sensitivity, because a missed UTI carries greater clinical weight than an unnecessary urine sample. With only 23 outcome events, sensitivity estimates at candidate cut-offs would be too imprecise to support clinical implementation, particularly in boys. The present study therefore identifies a signal worth pursuing but does not establish a clinically actionable CRP cut-off.

The observed associations with sex and URTS are consistent with the rationale of risk-based urine-testing strategies such as the AAP approach, and suggest that future models should evaluate CRP together with clinical variables rather than in isolation (5). In the present cohort, the positive predictive value of the AAP-based inclusion criteria was 4.5% in boys and 17.1% in girls, illustrating the burden of urine testing required to identify UTI, particularly among boys. Whether adding POC CRP can improve this trade-off must be tested prospectively in a substantially larger cohort rather than inferred from optimisation within the current dataset.

POC testing has practical advantages because it provides rapid bedside information, but implementation in paediatric settings also raises questions regarding funding, evidence, governance, and downstream clinical behaviour (11,12). Our observational design did not allow us to determine whether knowledge of CRP results affected additional testing, imaging, antibiotic prescription, catheterisation, or ED length of stay. These outcomes should be evaluated separately in future implementation studies.

Strengths and limitations

This study has several important limitations. First, only 23 UTI events were observed, including five among boys. This sparse event count limits the precision of diagnostic-performance estimates and creates a high risk of overfitting and unstable regression coefficients. Predictor screening was data-driven and performed in the same cohort in which associations were estimated; no internal or external validation was performed. For this reason, the exploratory regression results should not be interpreted as a clinical prediction model. Second, selection bias is likely because not all eligible patients were included, particularly during periods of ED crowding, and recruitment differed between centres. UTI prevalence was considerably higher at EIH than at QFCUH, indicating case-mix heterogeneity that cannot be excluded by a non-significant comparison of centre-specific AUCs. Third, partial verification bias and outcome misclassification are possible because not all positive bag samples were confirmed using a less contamination-prone method. Two UTI classifications relied on repeated bag cultures, and one culture-positive case lacked pyuria. These cases highlight the limitations of a culture-based outcome in this setting and should be considered when interpreting the findings. Finally, the candidate clinical strategy was not prospectively implemented. This observational study therefore cannot determine its effect on urine sampling, catheterisation, ED length of stay,

downstream investigations, antibiotic prescribing, or missed UTIs. These outcomes require evaluation after robust derivation and external validation in an adequately powered prospective cohort.

Despite these limitations, the prospective multicentre design provides useful hypothesis-generating data on a rapid, minimally invasive biomarker that is readily available at the bedside. We invite other paediatric emergency and acute-care centres to continue this work in larger, prospectively assembled cohorts using prespecified candidate predictors and transparent threshold-selection criteria. Collaborative multicentre datasets with sufficient UTI events would allow robust model development, precise estimation of sensitivity, and independent external validation. Future studies may also explore additional clinical risk factors such as obesity or breastfeeding history and biomarkers such as POC procalcitonin, which may offer greater specificity for pyelonephritis (16,17).

Conclusion

POC CRP was significantly higher in children with culture-confirmed febrile UTI and showed moderate discriminatory ability in this prospective multicentre cohort. However, the limited number of UTI events, particularly among boys, was insufficient to define a clinically reliable CRP rule-out threshold or to derive a stable clinical prediction rule. These findings should therefore be considered exploratory and hypothesis-generating. Larger, adequately powered multicentre cohorts with prespecified analyses are needed to determine whether POC CRP can meaningfully improve selection of febrile young children for urine testing and, ultimately, reduce unnecessary procedures without increasing missed UTIs.

Statement

The authors have no conflicts of interest to declare with regard to the topic discussed in this manuscript.

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