ORIGINAL ARTICLE

A Randomised Controlled Trial: Evaluating the Effectiveness of Alkalinising Agent as Adjunct Therapy in Paediatric Urinary Tract Infection Management

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ABSTRACT

Introduction: Urinary tract infections (UTIs) are common in children, presenting with clinical symptoms and bacteriuria. While antibiotics are the standard treatment, alkalinising agents like potassium citrate may help alleviate symptoms more rapidly. This study evaluated the effectiveness of potassium citrate as an adjunct therapy for paediatric UTIs. **Methods:** This double-blinded, randomised controlled trial was conducted at a tertiary hospital to assess the benefits of potassium citrate in paediatric UTI treatment. Thirty-three children aged 1 month to 18 years diagnosed with UTIs were randomly assigned to receive either potassium citrate or a placebo alongside standard antibiotics. **Results:** Seventeen children received potassium citrate, and sixteen received a placebo. Baseline characteristics, including age, gender, and septic parameters (C-reactive protein [CRP], full blood counts [FBC], and urine pH), were similar between groups. The potassium citrate group showed a trend towards faster symptom resolution, with 65% improving within 24 hours compared to 50% in the control group (p = 0.311). Both groups had a similar median hospital stay of 3 days (p = 0.715). Bacterial eradication rates were 71% in the intervention group versus 64% in the control group, though not statistically significant (p = 0.709). Adherence to the study medication was high, with no reported adverse events. **Conclusion:** Potassium citrate may serve as a beneficial adjunct therapy for paediatric UTIs, potentially aiding in faster symptom resolution and improving bacterial eradication by increasing urine pH.
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Keywords: Urinary Tract Infection, Bacteriuria, Alkalinising Agent, Potassium Citrate, Urine pH

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INTRODUCTION

Urinary tract infection (UTI) is characterised by a combination of clinical features and the presence of bacteria in the urine (1), resulting from the invasion and multiplication of pathogens in the urinary tract. It is one of the common paediatric infections, with an overall prevalence of 7% in febrile children aged 2 to 24 months and 8% in children aged 2 to 19 years (2). The prevalence, however, varies by age, gender, and circumcision status. The highest prevalence is observed among uncircumcised male infants under three months of age and females under 12 months of age (2). This increased risk is attributed to factors such as a higher concentration of bacterial skin flora under the nappy in infancy, shorter female urethral length, and a larger foreskin surface area in uncircumcised males (3).

The clinical presentation of urinary tract infections (UTIs) varies depending on the site of involvement and is often non-specific, particularly in younger children. Infections affecting the lower urinary tract, or cystitis, may present with urinary symptoms such as urgency, frequency, and dysuria. In contrast, upper urinary tract infections are often associated with more severe or systemic symptoms, where children may present with fever, back or flank pain, and vomiting. However, in infants and younger children, these typical presenting features are often absent. Consequently, diagnosing a UTI can be challenging, yet it is crucial to consider in febrile infants without a definite source of infection. In fact, fever may be the only manifestation of a UTI in infants and younger children under two years of age (4).

The diagnosis of a urinary tract infection (UTI) is based on clinical presentation combined with positive laboratory testing. Both urinalysis and urine culture are critical for detecting UTIs in children and adults. The presence of pyuria is indicated by more than 10 white blood cells per microliter in an uncentrifuged urine specimen, which

closely correlates with the gold standard leukocyte excretion rate. However, most centres in Canada consider a count of more than 5 white blood cells per high power field to be abnormal (5). A positive urine culture is characterised by the growth of at least 50,000 colony-forming units (CFU)/ml of uropathogen in an appropriately collected urine specimen (4). It is essential that urine collection occurs prior to the administration of antibiotics to ensure the accuracy of UTI diagnosis.

In the management of paediatric urinary tract infections (UTIs), targeted antibiotics and supportive care are essential. Most children with UTIs can be effectively managed at home with oral fluids and antibiotics; however, a small percentage may require hospitalisation for intravenous antibiotic therapy. This includes younger children, those who are unwell, children with significant renal tract anomalies, and those who do not respond to oral antibiotic treatment (3). Additionally, supportive medications such as antipyretics, analgesics, antispasmodics, and urinary alkalinisers are integral to management (6, 7). While supportive drugs cannot substitute for antibiotics, the appropriate selection of these medications can play a critical role, particularly in cases that necessitate hospitalisation.

This study aims to evaluate the effectiveness of alkalinising agents in resolving UTI symptoms, achieving bacterial eradication, and improving other clinical outcomes in patients at tertiary care hospitals. Alkalinising agents, which are medications that reduce urine acidity, are widely used for the symptomatic treatment of UTIs in some countries and are included in various national formularies (8). Millions of units of urinary alkalinisers, including sodium bicarbonate, sodium citrate, and potassium citrate, are sold annually in Australia, specifically for the treatment of UTIs and acute culture-negative cystitis (9). Once absorbed, these agents are metabolised into bicarbonates and subsequently excreted in the urine, leading to an increase in urinary pH. This increase effectively reduces urine acidity, thereby alleviating the burning sensation and pain associated with UTIs (10). Incorporating urine alkalinisers into UTI treatment is a widely adopted practice, as it aids in symptom relief and serves as an adjunct therapy.

In a normal individual, urine pH is typically slightly acidic, ranging from 5.5 to 6.5 due to metabolic activity, although it can vary between pH 4.5 and 8 (11). The phagocytic function of neutrophils operates more effectively in relatively alkaline urine within a narrow pH range compared to the typical pH of urine (12). Moreover, urinary alkalinisation does not diminish antibiotic efficacy; in fact, certain antibiotics are believed to achieve better concentrations in alkaline environments, thereby enhancing their antimicrobial activity. These antibiotics include Gentamicin, Streptomycin, Penicillins, Macrolides, Fluoroquinolones, and Trimethoprim (13).

A prospective observational study by Kulkarni et al. conducted in India with 80 adult participants highlights the significant role of supportive drugs in the management of UTIs within hospital settings. While antibiotics remain the primary treatment option, integrating supportive therapies such as analgesics, urinary alkalinisers, and antispasmodics can enhance patient outcomes, alleviate symptoms, and potentially reduce the length of hospital stays. The study also indicated that urine alkalinisation accelerated symptom relief and enhanced antimicrobial action when using fluoroquinolones, penicillin, gentamicin, and trimethoprim (12). Similarly, in a pilot study conducted in Turkey by Sonmez et al., the effects of urine alkalinisation with sodium bicarbonate on lower urinary tract symptoms (LUTS) in female patients were explored. The study found a significant reduction in urinary symptoms, including frequency, nocturia, urgency, and urge incontinence, which correlated with an increase in urine pH. The researchers highlighted that acidic urine could irritate the urothelium, leading to discomfort in patients. (13). Furthermore, a study conducted in Japan by Ueda et al., evaluated 76 patients experiencing urinary frequency and episodes of pain/discomfort to assess the effectiveness of urine alkalinisation therapy. The results indicated that an increase in urine pH was associated with a decrease in both urinary frequency and pain episodes. The authors concluded that urine alkalinisation therapy is likely effective in alleviating these symptoms (14).

Therefore, this study aimed to explore the benefits of using a urinary alkaliniser as an adjunct therapeutic agent in reducing the time taken to achieve resolution of symptoms, the duration of hospital stays, and the improvement of clinical septic parameters in the paediatric age group. The secondary objectives include studying the common organisms and their antibiotic sensitivities in urinary tract infections (UTIs).

MATERIALS AND METHODS

Design, Setting and Participants

This is a double-blinded, randomised controlled trial, registered with ANZCTR (Trial No: ACTRN12623000129684), conducted over 17 months from March 2023 to July 2024 at the paediatric outpatient clinic and paediatric ward of a tertiary hospital located on the east coast of Peninsular Malaysia. The study population involved children aged between 1 month and 18 years with both acute upper and lower urinary tract infections (UTIs), who received either an alkalinising agent (potassium citrate) or a placebo (drinking water), both of which were indistinguishable to the naked eye. They were randomly assigned using a computer-generated simple randomisation into two groups. All investigations, including blood tests and urine samples, were conducted upon admission for patients suspected

of having a UTI, prior to the commencement of treatment, as well as 48 hours after, following the research protocol for analysis. Bacterial eradication was assessed using follow-up urine cultures collected 48 hours after initiating treatment. Eradication was defined as no significant growth, specifically the absence of a uropathogen or growth of fewer than 10^4 colony-forming units (CFU)/mL, based on standard microbiological procedures used by the hospital laboratory. Urine samples were collected either via urethral catheterisation for children who were not toilet trained, or as midstream urine samples for toilet-trained children, by the medical officer in charge of the patient, and were sent to the laboratory within four hours as per guidelines. Standard treatment was initiated once urine samples were obtained. The potassium citrate used in the study was colourless and did not have a manufacturer label attached. Each 10 ml of potassium citrate contained 3 grams of potassium citrate and 0.5 grams of citric acid monohydrate (each 1 ml provided 2.8 mmol of potassium, 0.9 mmol of citrate, and an equivalent of 2.8 mmol of bicarbonate), comparable with the standard manufactured product (pre-packaged and labelled medication that has been produced by a pharmaceutical company, for example Ural). The dosage of potassium citrate for all ages varied over a range of 0.5–1 mmol citrate/kg/day in three divided doses for five days, organised by weight strata to simplify medication administration and reduce potential dosing errors. It was administered orally. The designated pharmacist, who had no clinical involvement in the trial, determined the group assignments and prepared the solutions accordingly. All patients, researchers, and nursing staff involved in managing the patients were blinded to their group allocation to ensure the concealment of allocations.

The data were organised using a pre-designed proforma that included patients' demographic details (age, race, gender, and weight), presenting symptoms, and investigation results at admission and 48 hours later. Patients remained in their allocated groups until they completed the study or were withdrawn for various reasons, including severe anaphylaxis, loss to follow-up, and non-compliance. Participants who experienced any adverse events, such as allergic reactions and gastrointestinal disturbances from the investigational products, were treated appropriately and monitored until the adverse event resolved. Those withdrawn from the study were replaced with new recruits.

The primary outcomes measured were urine pH, time taken to achieve symptom resolution, duration of hospital stay, improvement of septic parameters (assessed through white blood cell (WBC) count, platelet count, and C-reactive protein (CRP)), and bacterial eradication during the trial period. Secondary outcomes included adherence to treatment, incidence of adverse events, and identification of causative organisms.

Patient progress, including compliance, assessment of outcome measures, safety, and any adverse effects, was monitored within five days of starting the investigational products. This was done through daily reviews for inpatients and by using a diary or phone calls for outpatients.

Inclusion and exclusion criteria

The inclusion criteria for the study comprised all children aged between 1 month and 18 years diagnosed with either upper or lower urinary tract infections. A urinary tract infection was defined by positive microscopic urinalysis, indicated by the presence of more than 10 white blood cells (WBCs) per mm or a single uropathogen culture positive (growth of more than one organism, growth of a typical skin organism, or low colony-forming unit (CFU) counts should be considered contaminated), alongside clinical features such as febrile episodes, irritability, failure to thrive, and urinary symptoms.

Exclusion criteria included patients who had been previously treated with antibiotics prior to presentation, those allergic to potassium citrate, and patients with underlying chronic renal failure, untreated Addison's disease, or those on potassium-sparing agents.

Sample size calculation

The sample size was calculated using a two-means hypothesis formula via an online calculator (16). Based on the study by Ueda et al., the estimated sample size was 27 in each group, resulting in a total of 54 participants for both arms of the study.

Data analysis

The data collected were analysed using the Statistical Package for the Social Science (SPSS) version 28. The baseline characteristics of the groups were analysed using the descriptive statistics, reported as count (percentage, %) for categorical variables, and median (interquartile range, IQR) for continuous variables. The comparisons between interventional group and control group were assessed using an independent t-test for continuous variables and chi-square tests for categorical variables. Duration of hospital stay was analysed using Kaplan-Meier curve. Time to achieve the resolution of the symptoms, improvement of septic parameters, bacterial eradication and incidence of any adverse event were analysed using Chi-Square test.

RESULTS

As demonstrated in Figure 1, initially thirty-three patients were enrolled into the study but two were excluded due to complication of appendicitis and poor compliance issue. This left thirty-one patients were available for analysis with seventeen patients assigned to the intervention group and fourteen in the control group, respectively.

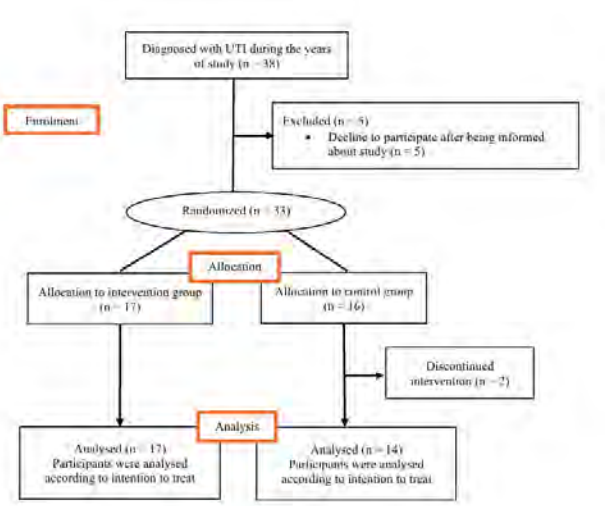

Figure 1: Study Flow Chart

Table I showed the baseline characteristics of the patients from both groups. There were no significant differences between the groups at baseline in terms of age, gender, baseline septic parameters, and urine pH at presentation. The median age at presentation was 6 years for the intervention group and 2 years for the control group, respectively. The baseline WBC, platelet levels and urine pH were similar between the two groups. Although the baseline CRP levels was lower in the intervention group (32 mg/L) compared to the control group (61 mg/L), this difference was not statistically significant. Overall, both groups demonstrated comparable haematological profiles at baseline, particularly in terms of the body's response to infection. Klebsiella pneumoniae was the most frequently isolated organism in both the intervention and control groups, accounting for 24% and 21% of cases, respectively.

The primary and secondary outcomes of this study were summarised in Table II. There were no statistically significant differences in post-treatment WBC, platelet and CRP levels between the two groups. Similarly, there was no statistically significant difference in post-treatment urine pH between the groups, though the intervention group had a slightly higher mean urine pH (6.5) as expected compared to the control group (6.0). Despite no statistical difference between the two groups on the resolution of the symptoms, most of the patients achieved resolution of the symptoms within 24 hours with 65% from intervention group and 50% from control group. The duration of hospital stays was similar in both groups with average of 3 days. There was significant improvement of septic parameters in both group although not statistically significant. In addition to that, the eradication of the bacterial was better in intervention group in which 71% of patients grew no organism post treatment.

As illustrated in Figure 2, the most used antibiotic to

Table I: Baseline Characteristics of the Participants between Intervention and Control Group

Characteristic	Group		p-value
	Intervention (n = 17)	Control (n = 14)	
Age (years), median (IQR)*	5.8 (4.6)	2.4 (4.4)	0.065
Gender, No (%)**			0.815
Male	9 (53%)	8 (57%)	
Female	8 (47%)	6 (43%)	
Baseline WBC level (cells/ µL), median (IQR)*	11.8 (6.1)	12.7 (12.7)	0.258
Baseline platelet level (platelets/ µL), median (IQR)*	453 (210)	510 (217)	0.242
Baseline CRP level (mg/L), median (IQR)*	32 (112)	61 (135)	0.662
Urinalysis*			
Urine pH (pre), median (IQR)	5.5 (1.0)	6 (1.5)	0.563
Bacteriuria on admission, No (%)			
Escherichia coli	2 (12%)	1 (7%)	
Klebsiella pneumoniae	4 (24%)	3 (21%)	
Proteus mirabilis	1 (6%)	0 (0%)	
Mixed growth	5 (29%)	4 (29%)	
No growth	5 (29%)	6 (43%)	

Normal value of CRP: < 5 mg/L
**Mann-Whitney Test for continuous variable*
***Chi-square Test for categorical variable*

Table II: Primary and Secondary Outcomes

Outcome	Group		p-value
	Intervention (n = 17)	Control (n = 14)	
TWC level (cells/µL) (48H post), median (IQR)*	8.5 (4)	9.6 (4.7)	0.351
Platelet level (platelets/ µL) (48H post), median (IQR)*	376 (203)	439 (147)	0.525
CRP level (mg/L) (48H post), median (IQR)*	18.2 (46.2)	16 (37.2)	0.889
Urine pH (48H post), median (IQR)*	6.5 (1.0)	6.0 (1.1)	0.149
Time to achieve resolution of the symptoms, No (%)**			0.311
Within 24 hours	11 (65%)	7 (50%)	
24 – 48 hours	4 (24%)	3 (21%)	
48 – 72 hours	1 (6%)	4 (29%)	
> 72 hours	1 (6%)	0 (0%)	
Duration of hospital stay (days), median (IQR)*	3 (3)	3 (2)	0.715
Improvement of septic parameters, No (%)*	14 (82%)	13 (93%)	0.393
Bacterial eradication, No (%)*	12 (71%)	9 (64%)	0.713
Adherence to study medications, No (%)	17 (100%)	14 (100%)	

*Mann-Whitney Test for continuous variable
**Chi-square Test for categorical variable

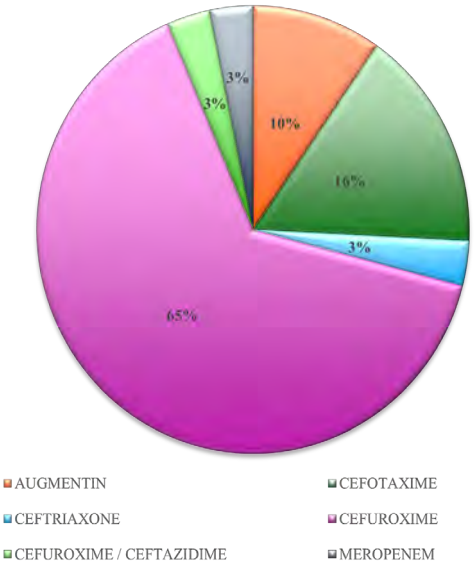

Figure 2: Antibiotics used in treatment of UTIs

treat the UTIs was Cefuroxime followed by Cefotaxime with few reported cases of resistance. The reported cases of resistance were predominantly observed in the extended-spectrum beta-lactamase (ESBL) producing organisms. The presence of ESBLs is a significant marker of multidrug resistance, often necessitating the use of carbapenems. Most of the patients had good adherence to the study medications with only one patient from control group had issue with compliance. There were no reported adverse events throughout the conduction of this study.

Figure 3 showed the Kaplan Meier survival curve for duration of hospital stay between intervention and control groups. The median of duration of stay were similar in both groups and this is not statistically significant.

DISCUSSION

This study aimed to assess the effectiveness of potassium citrate as an adjunctive therapy in the treatment

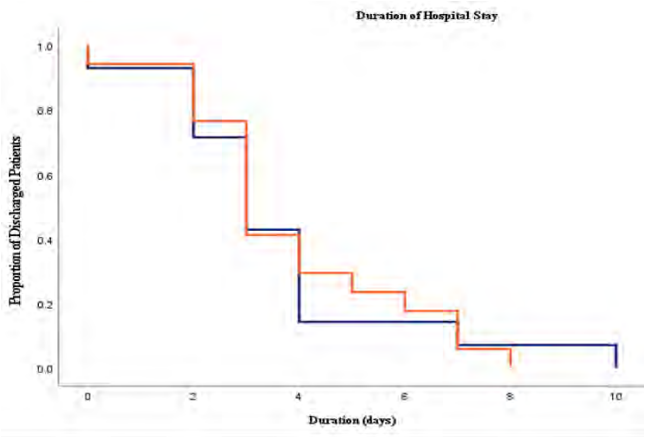

Figure 3: Kaplan Meier survival curve for duration of hospital stay between intervention and control groups

of paediatric urinary tract infections (UTIs). While antibiotics remain the primary treatment for UTIs, supportive therapies such as potassium citrate, an alkalinising agent, have been considered due to their potential role in reducing the discomfort associated with the acidic nature of urine during infection. Potassium citrate works by metabolising into bicarbonate, raising urinary pH and creating a more alkaline environment, which may alleviate symptoms and discomfort in UTI patients (14), especially those with more severe or complicated cases requiring hospitalisation.

UTIs are common in children, particularly in those under five, with fever being the most frequently reported symptom. In this study, most participants presented with unexplained fever, consistent with broader trends seen in paediatric UTIs. Other symptoms included vomiting, abdominal pain, dysuria, and cloudy urine. Although there was a slight male predominance in the study, this differs from the typical trend where UTIs are more common in girls, except in uncircumcised boys. The study was conducted in Kelantan, Malaysia, with the majority of participants being Malay, reflective of the local population and dominant ethnicity in Kelantan.

The primary outcome, time to symptom resolution, showed that 65% of patients in the potassium citrate group experienced symptom relief within 24 hours, compared to 50% in the placebo group. Although this difference was not statistically significant ($p = 0.311$), the trend suggests that urinary alkalinisation may contribute to quicker symptom relief. This observation is in line with previous studies by Kulkarni et al (12) and Ueda et al (14) that have shown faster alleviation of urinary symptoms with alkalinising agents, particularly in adult populations. Notably, this study extends these findings to paediatric populations, highlighting the potential applicability and benefits of such treatments in younger age groups. However, the lack of statistical significance could be attributed to the small sample size, which may have limited the study's power to detect smaller differences between the groups.

Bacterial eradication was also measured, with 71% of the potassium citrate group achieving bacterial clearance, compared to 64% in the placebo group, although this difference was not statistically significant ($p = 0.713$). The modest increase in bacterial eradication in the potassium citrate group could be linked to the rise in urinary pH, as certain antibiotics are known to be more effective in alkaline conditions. Other research suggests that urinary alkalinisation can reduce the minimum inhibitory concentration (MIC) required for antibiotics to be effective (17) and this study suggest a similar potential. If potassium citrate could help antibiotics work more efficiently, it may become a valuable adjunct, especially in cases where antibiotic resistance is a concern. This trend reinforces the idea that potassium citrate may create conditions in the

urinary tract that are less favourable for bacterial growth and survival, potentially enhancing the effectiveness of antibiotics in eradicating infections.

The dosage of potassium citrate in this study ranged from 0.5 to 1 mmol citrate/kg/day, administered in three doses. It is possible that this dosing was insufficient to produce significant urinary alkalinisation in some participants, limiting the clinical effectiveness of the treatment. Individual variations in response to potassium citrate are influenced by factors such as age, body weight, metabolic rate, and the severity of the infection, which may have contributed to the limitations of this study. Some participants may not have received an adequate dose to fully realise the potential benefits of potassium citrate in managing UTI symptoms, possibly leading to an underestimation of its effectiveness. This highlights the need for personalised dosing strategies to optimise clinical outcomes in future research.

In terms of secondary outcomes, the study found no significant difference in the length of hospital stay between the two groups, with both groups having a median stay of three days. Kaplan-Meier survival analysis also indicated no difference in hospital stay duration between groups, suggesting that while potassium citrate may help relieve symptoms more quickly, it may not necessarily reduce the length of hospitalization. The hospital stay length might depend on other factors such as infection severity or institutional policies such as fever resolution, duration of intravenous antibiotic, normalisation of blood markers, and urine culture results which could dictate discharge times more than symptom relief does. Improvements in septic markers such as white blood cell count, platelet count, and C-reactive protein (CRP) levels were observed in both groups, indicating that potassium citrate did not negatively impact overall recovery.

Adherence to the study medication was high, and no adverse events were reported in either group. This aligns with the established safety profile of potassium citrate, which is generally well-tolerated in paediatric patients. However, the long-term effects of repeated use of urinary alkalinisers were not assessed, and future studies should investigate this aspect to fully understand any potential risks associated with prolonged use.

Study limitations

Firstly, the small sample size may have reduced the ability to detect significant differences between the groups, especially regarding secondary outcomes such as bacterial eradication and hospital stay. The limited sample size was due to feasibility challenges and a restricted study timeframe, which affected participant recruitment and resource allocation. Secondly, the study was conducted in a single tertiary hospital, which may limit the generalisability of the findings to other populations. Although the study was double-blinded, some bias may have been introduced during the reporting of symptoms, as relief is subjective and may vary depending on individual perception.

Recommendations for future research

Future studies should involve a larger and more diverse sample to enhance the generalisability of the findings. A longer follow-up period would be beneficial in assessing the sustained effects of potassium citrate as an adjunct therapy in managing paediatric urinary tract infections (UTIs). The ideal duration for follow-up can vary based on the specific condition being studied and the expected timeline for symptom resolution or recurrence. A follow-up period of three to six months could provide insights into both the immediate and long-term effects of the intervention on clinical outcomes.

Additionally, investigating the mechanisms behind the intervention's effects on urine pH and symptom resolution could yield valuable insights into its potential benefits and optimisation. This research could help refine treatment protocols and improve patient outcomes in the management of UTIs.

CONCLUSION

In conclusion, while the primary findings did not reach statistical significance, the study revealed clinically relevant trends suggesting that potassium citrate may contribute to faster symptom relief and improved bacterial eradication rates in paediatric UTIs. The intervention group showed a higher proportion of early symptom resolution and bacterial clearance, with no reported adverse events and excellent treatment adherence. These findings, coupled with the safety profile of potassium citrate and the provision of region-specific data, support its potential role as a safe and beneficial adjunct therapy. Integrating potassium citrate into UTI management could improve patient outcomes, particularly with respect to symptom management. Further research with larger, multicentre trials is warranted to confirm and expand upon these preliminary observations.

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