

Manuscript Title: *Chlorhexidine skin cleaning to reduce clean catch urine contamination in infants: a pilot study*

Running title: *Chlorhexidine skin cleaning prior to CCU*

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ABSTRACT

Objective

Clean catch urine (CCU) samples are frequently contaminated. Our aim was to determine if cleaning with 0.1% chlorhexidine before CCU is a safe and feasible method to reduce contamination.

Methods

Prospective interventional pilot study. Children 1-24 months underwent perigenital skin cleaning with 0.1% chlorhexidine. Primary outcome was contamination rate, and secondary outcomes were parent and clinician satisfaction with the procedure.

Results

Twelve of 54 urine samples were contaminated (22%, 95% CI 13-35%). Over 90% of parents and clinicians were either 'satisfied' or 'very satisfied'. No adverse events were recorded.

Conclusions

Cleaning with chlorhexidine solution before CCU is safe and feasible.

INTRODUCTION

Urinary tract infections (UTIs) are common in young children, and urine sample collection is required to confirm or exclude the diagnosis.

Clean catch urine (CCU) is the recommended collection method for pre-continent children in many guidelines, [1] but has a contamination rate of 15-46%. [2-4]

Contamination corrupts test results, delays appropriate treatment, and often necessitates recollection with invasive methods.

Studies of adults and older continent children have demonstrated that skin cleaning before collection with topical antiseptic solution reduces midstream urine (MSU) contamination. [5] However, the CCU collection process differs from MSU, and is more prone to contamination due to collection of the first pass urine, touching of the perigenital area by mobile children, and inadvertent contact between specimen containers and the infant's skin.

Despite this, evidence supporting or refuting skin cleaning to reduce CCU contamination is sparse. Guideline recommendations are based on expert opinion, and clinical practice varies widely. Evidence is required to inform best practice.

We hypothesized that cleaning with a gentle antiseptic solution (0.1% chlorhexidine) before CCU collection would reduce the bacterial load on the perigenital skin, with less bacteria then carried into the sample, reducing contamination rates.

METHODS

Aim: Assess the safety and feasibility of perigenital cleaning with 0.1% chlorhexidine solution prior to CCU.

Design: Prospective pilot study. Ethical approval granted by the Western Health Low Risk Ethics Panel (HREC:57355). Parents/carers provided written consent.

Setting: Paediatric Emergency Department and Paediatric Ward in a large metropolitan hospital, between December 2019 and July 2020.

Participants: Convenience sample of pre-continent children aged 1-24 months who required CCU (determined by their treating clinician). Children were excluded if they had anatomical or neurological conditions affecting voiding, local skin trauma, or a known adverse reaction to any topical antiseptic solution.

Procedure: After removing the nappy, the treating nurse or doctor cleaned the infant's perigenital skin with gauze soaked in 0.1% chlorhexidine solution, for 10 seconds.

Definitions: Following local hospital and laboratory microbiological standards, contamination was defined as growth of two or more organisms at $\geq 10^6$ CFU/L. Positive cultures were defined as growth of a single organism at $> 10^8$ CFU/L.

Outcomes: Primary outcome was urine sample contamination. Secondary outcomes were parent and clinician satisfaction with the method (5-point Likert scale).

RESULTS

Eighty-eight children were recruited and 54 voided urine and were included in the analysis. Twelve of the 54 samples were contaminated (22%, 95% CI 13-35%).

Study population and collection parameters are outlined in Table 1.

Table 1: Study population recruitment, demographics and collection parameters.

Patient Recruitment	
Recruited patients	88
Included patients	54
Excluded patients	34 (total) <ul style="list-style-type: none"> - 1 outside age range - 5 no signed consent - 10 samples not sent for culture - 12 patients did not void - 4 'missed catches' - 2 interrupted attempts
Demographics	
Age in months (median, IQR)	7 months (IQR 3-11)
Female gender (% of total)	27/54 (50%)
Previous UTI	4 (7.4%)
Major medical comorbidity (%)	8 (14.8%)
Antibiotics in past 48 hours (%)	3 (5.6%)
Circumcised (if male)	5/27 (18.5%)
Cleaning and Collection Process	
Time to collection (mean, 95% CI)	25.1 min (16.4-33.8)
Adverse events	0

IQR = Interquartile range, CI = confidence interval

Contamination was the same in males and females. Contamination was more likely in younger infants and when urination took ≥ 5 minutes, although confidence intervals overlapped. Urine culture results are presented in Table 2.

Table 2: Result of urine cultures

Urine Culture Results		
Total samples cultured	54	
Contaminated sample	12 (22%, 95% CI 13-35%)	
Positive culture	13 (24%) - 12 <i>Escherichia coli</i> - 1 <i>Klebsiella oxytoca</i>	
Negative culture	29 (54%)	
Contaminated samples		
	Contaminated (%, 95% CI)	Total Samples (n)
All patients	12 (22%, 13-35%)	54
Age ≤ 12 months	11 (26%, 15-41%)	42
Age > 12 months	1 (8%, 1-35%)	12
Female	6 (22%, 11-41%)	27
Male	6 (22%, 11-41%)	27
Time to urination < 5 min	1 (11%, 1-43%)	9
Time to urination ≥ 5 min	11 (28%, 17-44%)	39
Time not recorded	0 (0%, -)	6

Satisfaction with the cleaning intervention was high among both parents and clinicians. Twenty-six clinicians were very satisfied (48%), twenty-three were satisfied (43%), and five were neutral (9%). Twenty-six parents were very satisfied (48%), twenty-four satisfied (44%), three neutral, and one response was not documented. No parents or clinicians were either unsatisfied or very unsatisfied with the intervention.

DISCUSSION

This pilot study demonstrates that using 0.1% chlorhexidine for perigenital cleaning prior to CCU collection is a safe and feasible intervention. There were no adverse effects, and the procedure was highly acceptable to parents and clinicians.

The rate of contamination of CCU after cleaning with chlorhexidine was 22%. Previous studies have found a baseline contamination rate for CCU of 15-46%[2-4]. Direct comparison of rates is limited by heterogeneity of cleaning practices, ages of participants, and variable definitions of contamination, but this result does provide a signal of potential effectiveness.

To our knowledge, this is the first study to investigate a cleaning intervention prior to CCU in pre-continent children. Parent information handouts, [2] and voiding stimulation methods, [3] have previously shown small absolute reductions in CCU contamination rates, but have not reached statistical significance.

Limitations of this study include the modest sample size and lack of control group. We planned inclusion of 100 participants, however recruitment was interrupted by COVID-19, restricting our sample size to 54 participants. However, this study demonstrates the safety and feasibility of the intervention, and establishes proof of concept for a larger definitive trial.

CONCLUSION

Gentle skin cleaning with 0.1% chlorhexidine prior to CCU collection is a promising intervention. It is safe and feasible, and is well accepted by parents and clinicians.

This was the first study to assess a cleaning intervention prior to CCU, and a larger randomized controlled study can now be undertaken to directly compare contamination rates with chlorhexidine and non-antiseptic cleaning methods.

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Contributors JK and JG were responsible for identifying and refining the research question. All authors contributed to the study design and development of the protocol. JG and SK led study recruitment and data collection. JG was responsible for drafting this paper and finalising the manuscript. All authors provided comments on the drafts and approved the final version.

Data sharing statement De-identified study data and study protocol is available upon reasonable request. Data is available for meta-analysis, or for other purposes approved by the study authors. Proposals may be submitted to the corresponding author up to 5 years following publication.

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