

Evaluation of a New Strategy for Clean-Catch Urine in Infants

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abstract

BACKGROUND AND OBJECTIVES: A new noninvasive bladder stimulation technique has been described to obtain clean-catch urine (CCU) in infants aged <30 days. Objectives were (1) to determine proportion and **predictive factors for successful CCU** collections using a stimulation maneuver technique among **infants <6 months** and (2) to determine the **proportion of bacterial contamination** with this method.

METHODS: A **prospective** cohort study was conducted in a **tertiary pediatric emergency** department among infants <6 months needing a urine sample. CCU samples were collected using a **standardized stimulation technique**. Invasive technique was performed after CCU for three specific conditions. Primary outcomes were proportions of successful CCU specimens and bacterial contamination. We determined associations between successful urine samples and **4 predictive factors (age, sex, low oral intake, and recent voiding)**.

RESULTS: A total of **126 infants** were included (64 boys, median age: 55 days). The CCU procedure was effective in 62 infants (**49%**; median time: **45 seconds**). Infants 0 to 29 days; 30 to 59 days, and 60 to 89 days had **more successful procedures, compared with infants >89 days** (odds ratios [95% confidence interval (CI)]: 4.3 [1.4 to 13.4]; 3.2 [1.2 to 8.4]; and 4.44 [1.5 to 13.3], respectively). The **contamination** proportion was **16%** (95% CI: 8% to 27%) in the CCU group. **This proportion was not statistically different compared with the invasive method group** (6%, 95% CI: 3% to 15%).

CONCLUSIONS: The CCU procedure is a quick and effective noninvasive method in children aged <90 days. **Contamination proportions were similar to those reported in the literature for urethral catheterization**. Circumstances for which the CCU procedure could be performed are proposed.



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Dr Labrosse conceptualized and designed the study, coordinated and supervised data collection, and drafted the initial manuscript; Dr Lévy designed the study and reviewed and revised the manuscript; Dr Autmizguine designed the study, elaborated definitions of urine culture results, and reviewed and revised the manuscript; Dr Gravel designed the study, carried out the initial analyses, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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WHAT'S KNOWN ON THIS SUBJECT: Standard methods to obtain a urine specimen in the workup of febrile infants are invasive techniques. A new noninvasive bladder stimulation technique has been described to obtain clean-catch urine in infants aged <30 days.

WHAT THIS STUDY ADDS: The new clean-catch procedure is **more effective in children <3 months of age**. Considering the reported contamination proportions, there are circumstances for which it could be performed as a first attempt instead of other methods.

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Urinary tract infections (UTIs) are among the most common serious bacterial infections in febrile infants. Approximately 7% of children 2 to 24 months of age who present with fever without source are diagnosed with a UTI.¹ This diagnosis prompts further treatment, investigations, and contributes to long-term morbidity.²⁻⁷ Suprapubic aspiration and urethral catheterization are considered the standard methods of obtaining urine samples from children who are not yet toilet trained, but these techniques are invasive.^{2,3} Clean-catch urine (CCU) seems to be an interesting noninvasive method, but obtaining these samples can be challenging and time-consuming in this population. This method consists of taking off the child's diaper and obtaining a CCU specimen as the child voids. Davies et al⁸ reported a mean time of 1 hour to obtain a urine sample using this method. A bladder stimulation technique has recently been reported to be quick, safe, and effective in obtaining CCU in infants <30 days of age.⁹ This procedure involves a **combination of fluid intake and repetitive noninvasive bladder stimulation maneuvers until the start of micturition**. CCU sample is then caught in a sterile collector. Authors reported that CCU stimulation techniques were **successful in 86% of 80 admitted patients aged <30 days (mean time 57 seconds)**. Although there were no complications reported, controlled crying occurred in 100% of infants. A similar "finger-tap" technique, without lumbar stimulation, originally published in the *British Medical Journal* in 1986,¹⁰ reported a contamination proportion of 7% in CCU sample among 52 children aged <12 months.

Although the standardized bladder stimulation technique has been reported to be quick, safe, and effective in obtaining CCU in infants aged <30 days, questions remain regarding contamination proportions as well as its usefulness in older

children. In addition, predictive factors associated with success remain unanswered for infants aged <6 months. The aims of this study were to (1) determine proportion and predictive factors for successful CCU collection using the stimulation maneuver technique among infants aged <6 months in a pediatric emergency department and (2) determine the proportion of bacterial contamination of CCU samples obtained with this method.

METHODS

Study Design and Population

A prospective cohort study was conducted at a tertiary care pediatric emergency department in Montreal with a census of 75 000 annual visits. Patient recruitment occurred between May and October 2015. Eligible participants were all infants <6 months of age needing a urine sample for culture and/or analysis requested by the attending physician when a research assistant was present. Infants with a medical condition that made it unfeasible to obtain a CCU sample (eg, urostomy) or for those unable to participate (eg, absence of parental authority, hemodynamic instability) were excluded from the study.

Outcome Measures and Independent Variables

Primary outcomes were the proportion of successful CCU specimens and proportion of bacterial contamination. We assessed the association between successful urine sampling and 4 potential predictive factors: age, sex, low oral intake during the fluid intake period, and parental reporting of voiding in the hour preceding the procedure.

Study Procedure

Once consent and demographic data were obtained, a CCU sample was collected using bladder stimulation technique by trained research nurses or by the principal investigator. Using a **video module** (supplementary data of

Herreros et al⁹), the research personnel received standardized training for the procedure. To enable learning, we decided a priori to exclude the first 3 patients of each research personnel.

As described by Herreros et al,⁹ the technique involves a combination of fluid intake and noninvasive bladder stimulation maneuvers. All infants were given the possibility to **feed during a 20-minute period. After genital cleaning, infants were held under their armpits by a parent, legs dangling in males and hip flexed in females** (Fig 1). Examiners then alternated between bladder stimulation maneuvers, which consisted of **gentle tapping in the suprapubic area at a frequency of 100 taps per minute for 30 seconds, and lumbar paravertebral massage maneuvers for 30 seconds**. These 2 stimulation maneuvers were repeated until micturition began or **for a maximum of 300 seconds**.

Urine specimen was collected in a sterile container before antibiotic administration. The examiner recorded the time interval from the beginning of the stimulation maneuvers to the start of urination. Urine was then immediately sent to the laboratory, and samples were incubated for an 18- to 48-hour period. A pool of blinded technicians, not involved in the study, interpreted culture results independently.

To allow comparison for bacterial contamination and to preserve the standard of care, an invasive method, either urethral catheterization or suprapubic aspiration, was performed after CCU procedures in 1 of the following situations: (1) positive urinalysis, (2) decision to prescribe antibiotics, or (3) unsuccessful CCU sampling.

Definitions

A successful CCU specimen was defined by the collection of a urine

sample of **at least 1 mL** (needed to allow both urinalysis and culture) and obtained **within 300 seconds** of initiating bladder stimulation maneuvers. In the original study,⁹ 300 seconds was considered a reasonable amount of time to perform a urine collection procedure. Laboratory definitions of urine results were based on the collection method³ as it is used clinically (Table 1).^{2,11,12} The designation of “no significant growth” was given to intermediary bacteria counts, which fell between the colony forming units/L cutoffs for infection or no growth¹² regardless of urinalysis results. In a microbiological point of view, those urine culture results are considered “contaminated,” although in clinical practice, they are usually considered as a “nonclinically relevant,” and urine samples are either repeated or managed as negative culture (“no growth”). To reflect clinically relevant contamination, the term “contamination proportion” in this study referred only to urine culture results that meet the definition of “significant growth” (Table 1). We defined low oral intake as <25% of regular fluid intake based on the parental assessment during the feeding period preceding the procedure.

Statistical Analysis

Data were entered into an Excel database (Microsoft Inc, Bellvue, WA) and analyzed using SPSS v21 software (IBM Software Group Inc, Armonk, NY). Primary analyses were the proportion of successful procedures for the CCU stimulation techniques among all participants and contamination proportion. This was measured by dividing the number of contaminated specimens in the group with successful CCU procedures by the total number of successful CCU and dividing the number of contaminated specimens in the group with invasive techniques by the total number of urines obtained by invasive technique.

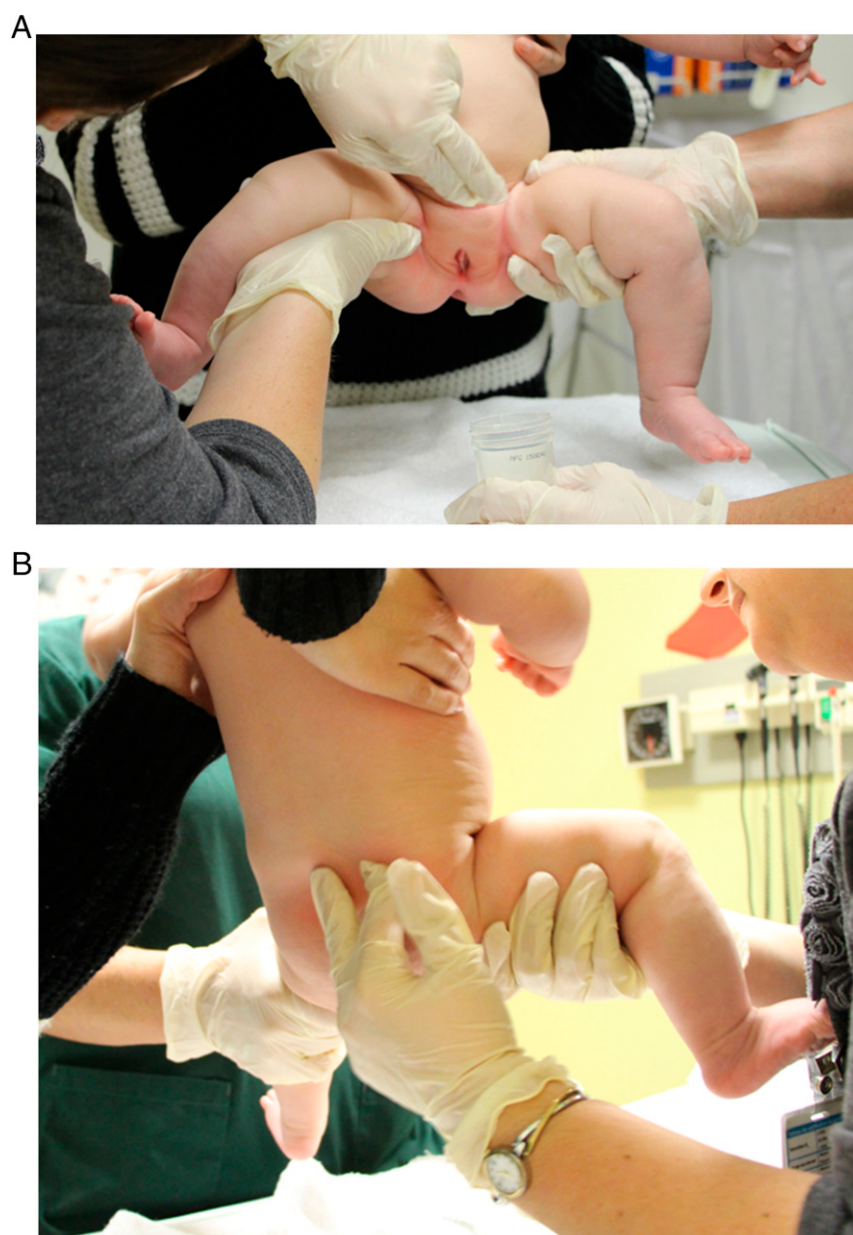


FIGURE 1
Girl positioning for obtaining CCU by using the stimulation technique. A, Tapping in the suprapubic area. B, Massage to the lower back.

Secondary analysis included median delays to obtain urine samples for which a 95% confidence interval (CI) was calculated for each measurement. Finally, secondary analysis was done to identify factors associated with a higher risk of success using logistic regression. As mentioned, potential independent variables were age, sex, poor feeding, and micturition. A sample size of 100 infants was calculated to obtain

a 95% CI margin of $\pm 10\%$ for the proportion of success. On the basis of previous studies and using a pessimistic scenario, we expected to have a success proportion of at least 40% providing at least 40 participants with a clean catch specimen. It was estimated that these 40 participants would provide CIs of $\pm 13\%$ for the proportion of contamination assuming a 25% contamination proportion.

TABLE 1 Laboratory Definition of Urine Results Based on Collection Methods^a

	Urinalysis Result ^b	Culture Result			
		Number of Organisms Cultured	Significant Threshold for Colony Counts ^c		
			Suprapubic Aspiration	Urethral Catheterization	CCU
UTI					
<2 mo ¹¹	Positive or negative	Single uropathogen	≥50 × 10 ⁶ CFU/L	≥50 × 10 ⁶ CFU/L	≥100 × 10 ⁶ CFU/L
≥2 mo ²	Positive	Single uropathogen	≥50 × 10 ⁶ CFU/L	≥50 × 10 ⁶ CFU/L	≥100 × 10 ⁶ CFU/L
Contaminated					
Significant growth	Negative	≥2 organisms or “mixed growth” ^d	Any growth	≥50 × 10 ⁶ CFU/L	≥100 × 10 ⁶ CFU/L
No significant growth ¹²	Positive or Negative	≥1 organism	n/a	≤50 × 10 ⁶ CFU/L	≤100 × 10 ⁶ CFU/L
Negative	Negative	No growth	No growth	No growth	No growth

CFU/L, colony forming units per liter; n/a, not applicable.

^a Three criteria are needed for each definition.^b Positive urinalysis: bacteriuria, positive leukocyte esterase test and/or ≥10 white blood cells per microliter²; negative urinalysis: do not meet criteria for positive urinalysis^c In circumstances in which the identified organism is regarded as pathogenic based on clinical judgment (eg concomitant bacteremia with the same organism, unusual organisms such as *Pseudomonas aeruginosa* or group B *Streptococcus*, or pure growth of a urinary pathogen with an abnormal urinalysis), a low colony counts could be considered positive.^{2,3}^d “Mixed growth” is defined as ≥3 bacteria >10⁵ CFU/L based on our institution’s laboratory protocol.

In addition, 40 participants with successful CCU samples would allow the evaluation of 4 risk factors using univariate analysis.

The hospital’s research ethics board approved the study. To participate, parental authority had to provide written informed consent.

RESULTS

A total of 137 families were approached between May and October 2015. Eleven patients were not included because of parental refusal to participate (4), hemodynamic instability (3), language barriers (2), suprapubic wound (1), and parents incapable of holding the child (1). All 126 participants were included in the final analysis for success proportion. The study population (Table 2) included 62 girls and 64 boys (16 of 64 circumcision, 25%) with a median age of 55 days. UTI was present in 11 children (9%). The most common indication for urine collection was a fever of unknown origin (77). Figure 2 shows the flow diagram and the distribution of methods used to collect urine specimens.

A total of 66 (52%) infants provided a urine sample within 5 minutes of stimulation procedure. However, 4

TABLE 2 Baseline Characteristics of Study Participants, *N* = 126

Characteristics	Study Cohort
Age, median (IQR)	55 (37–92)
0–29 d	23 (18)
30–59 d	43 (34)
60–89 d	26 (21)
>89 d	34 (27)
Sex, male, <i>n</i> (%)	64 (51)
Circumcision, <i>n</i> (%)	16/64 (25)
Low oral intake before procedure, <i>n</i> (%)	8 (6)
Previous urine <1 h, <i>n</i> (%)	76 (60)

IQR = interquartile range.

samples were considered a failure because of insufficient urine quantity to allow both urinalysis and culture (3) or stool presence in the sample (1), leaving 62 (49%; 95% CI: 40%–58%) successful procedures with a median time of 45 seconds (first quartile 14 seconds and third quartile 158 seconds; Table 3). **CCU procedure was successful in 61% (14 of 23) of infants aged 0 to 29 days, 54% (23 of 43) of children aged 30–59 days, 62% (16 of 26) of children aged 60 to 89 days, and 26% (9 of 34) of children aged 91–180 days.**

In the logistic regression analysis (Table 3), age group was a strong predictor of success (*P* < .001). When compared with the reference group of children aged >89 days, age groups 0 to 29 days, 30 to 59 days, and 60 to 89 days were all statistically associated with a higher proportion

of success. Sex, low oral intake, and having urinated within the hour were not predictors of success.

Culture results for CCU samples and invasive method samples are provided in Table 4. The contamination proportion was 9 of 57 (16%, 95% CI: 8%–27%) in the clean catch group compared with 4 of 62 (6%, 95% CI: 3–15) in the invasive method group. We were unable to apply univariate logistic regression for potential predictive factors of contamination because of the small number of contaminated samples. However, proportion of male patients in the contaminated CCU sample group seemed lower than in the uncontaminated group (3 of 9 [33%] and 32 of 48 [67%], respectively). Moreover, none of the 7 circumcised male infants had contaminated urine samples.

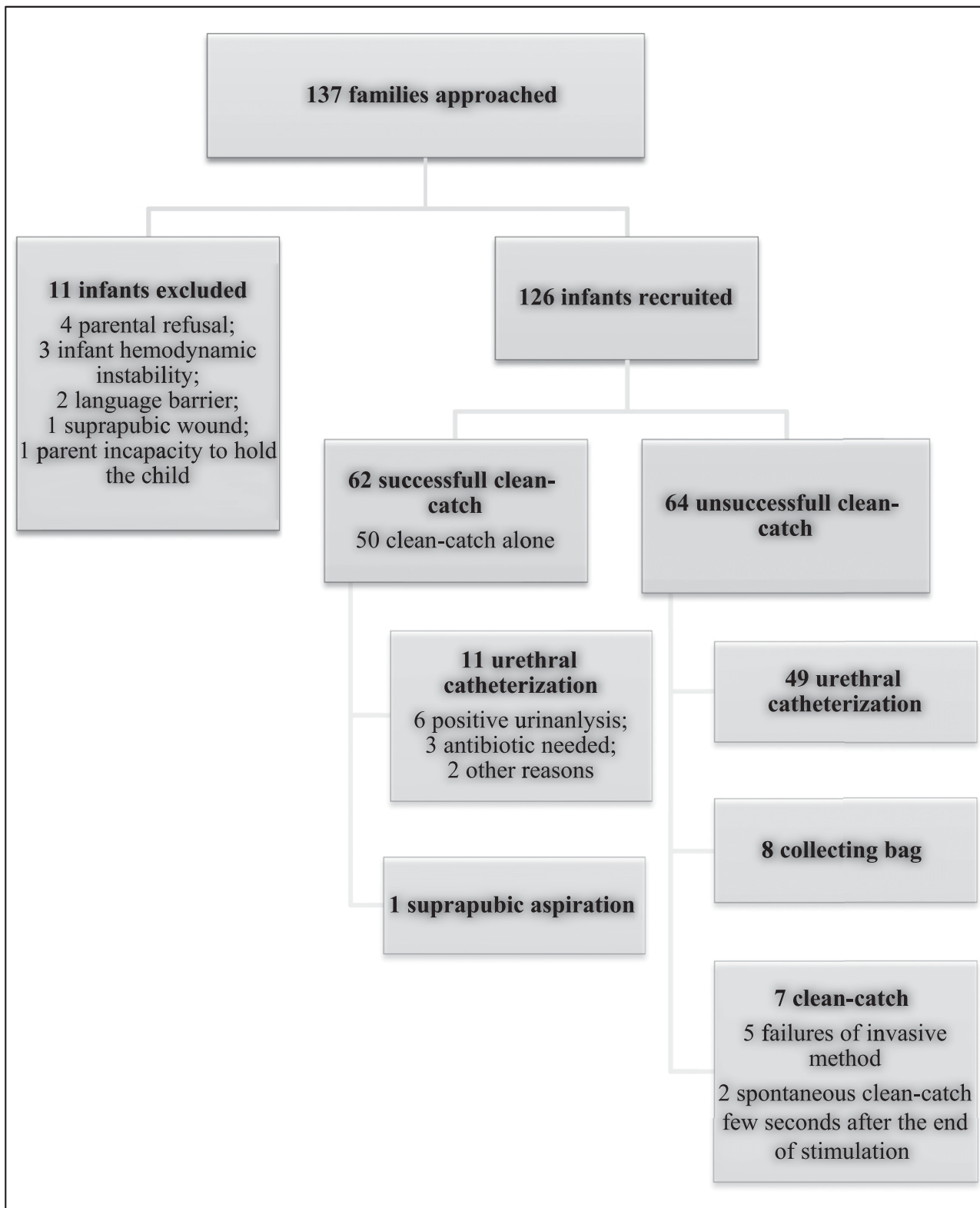


FIGURE 2
 Flow diagram for study cohort and distribution of collection methods for urine specimens

TABLE 3 Successful CCU Stimulation Procedures, *N* = 126

Outcomes	<i>N</i> (%)		OR (95% CI)	<i>P</i>
	Successful	Unsuccessful		
Primary				
Effectiveness of CCU procedure	62 (49)	64 (51)	NA	NA
Secondary				
Age group				
0–29 d	14 (61)	9 (39)	4.3 (1.4 to 13.4)	.01
30–59 d	23 (53)	20 (47)	3.2 (1.2 to 8.4)	.02
60–89 d	16 (62)	10 (38)	4.44 (1.5 to 13.3)	.008
>89 d	9 (26)	25 (74)	Ref	
Sex male	35 (55)	29 (45)	1.56 (0.78 to 3.16)	.22
Previous urine <1 h	37 (49)	39 (51)	1.05 (0.51 to 2.15)	.88
Low oral intake	5 (63)	3 (38)	1.78 (0.41 to 7.8)	.44

NA, not applicable; OR, odds ratio; Ref, reference group.

TABLE 4 Bacterial Culture Results for CCU Procedure and Invasive Methods

Culture Results	<i>N</i> (%; 95% CI)		Difference in Proportion (95% CI)
	Clean-Catch Sample (<i>N</i> = 57) ^a	Invasive Sample (<i>N</i> = 62) ^b	
UTI	4 (7, 2 to 17)	7 (11; 5 to 22)	4 (–5 to 16)
Contaminated			
Significant growth	9 (16, 8–27)	4 (6; 3–15)	9 (–2 to 22)
No significant growth	25 (44, 32–57)	13 (21, 13–33)	23 (6 to 38)
Negative	19 (33, 22–46)	39 (63, 50–75)	12 (–3 to 28)

Refer to Table 1 for culture results definitions.

^a Five CCU samples were not sent for culture.

^b Two “invasive method” samples were not sent for culture.

Regarding urinalysis, all patients with UTI had an abnormal urinalysis obtain by CCU except for 1 patient with low bacteria counts of group B *Streptococcus* with concomitant bacteremia (Supplemental Table 5). Ten participants provided both CCU and invasive samples for culture (Supplemental Table 6). Among those, 7 had concordant culture results, including 4 with the same bacterial isolates. The remaining 2 showed discrepancies between contaminated and negative culture results, and 1 had a CCU culture result with low bacteria counts of group B *Streptococcus* with concomitant bacteremia but no bacterial growth in the invasive technique culture result.

Interpretation

We found that the bladder stimulation technique to obtain CCU was effective in 49% of infants <6 months of age with a median time of 45 seconds.

This proportion increased to 61% in infants <30 days and to 58% in infants <90 days. Indeed, we found that age <90 days was a strong predictor for success. Bacterial urine contamination proportion was 16% in the CCU group.

Only 2 previous studies evaluated the effectiveness of the standardized CCU procedure described by Herreros et al,⁹ but the study population was limited to infants aged <30 days. Success proportions for CCU in the 2 studies were 86%⁹ and 78%,¹³ respectively. In our population for this age group, success proportion was slightly lower (61%). A possible explanation is that, in contrast to previous studies, we did not exclude children with low oral intake.

There is considerable heterogeneity in reports of contamination for standard CCU specimens in incontinent infants.^{12,14} This is possibly due to great variations in collection techniques. In most studies,

parents themselves collected CCU samples after being instructed by nurses. However, no precautions regarding maintaining sterility were described. Using stimulation maneuvers to quickly obtain CCU specimens in these children therefore seemed interesting to minimize the risks of contamination. In fact, the contamination proportion for CCU specimens was lower in our study¹² or comparable to what is reported in the literature for CCU specimens obtained using standard methods^{15,16} and standardized stimulation technique.¹³ (Supplemental Table 7) Indeed, Altuntas et al¹³ reported that the contamination proportion of 63 CCU samples collected by standardized CCU procedures varied between 14% and 24% depending on the cutoff values for contamination. Herreros et al¹⁷ compared contamination proportions of 2 matched urine samples, obtained using CCU standardized stimulation technique and urethral catheterization on 60 infants <90 days old. They found that 5% of CCU samples were contaminated compared with 8% of urethral catheterization samples. The low contamination proportions may be related to a higher proportion of males in their study, compared with the male population in the current study.

The contamination proportion was 16% (95% CI: 8% to 27%) in the CCU group. This proportion was not statistically different when compared with the invasive method group (6%,

95% CI: 3% to 15%). Furthermore, our contamination proportion obtained using CCU maneuvers was similar to that reported in the literature for urethral catheterization (12%–14%) and was much lower than for those reported for collection bag specimens (44%–46%^{12,16}; Supplemental Table 7).

Because the use of urethral catheterization is an invasive method that could be associated with adverse events in up to 20% of children,¹⁸ our findings support the use of the CCU standardized stimulation technique as an alternative to invasive methods to obtain a urine specimen. We suggest performing CCU procedure as a first attempt in well-appearing children in 2 specific situations. The first of these is to rule out UTI in children aged 2 to 6 months because, according to published literature, a child with a negative urinalysis has a <1% chance of having a UTI.² Thus, performing CCU standardized stimulation technique in this circumstance would significantly decrease the number of unnecessary catheterizations, reduce the number of contaminated cultures, and potentially be cost-saving. In infants older than 6 months, the low probability of obtaining successful CCU specimens limits the benefit of considering this technique. In this study, of the 60 infants >2 months of age who required a urine sample, 22 had a successful CCU samples with a negative urinalysis. By performing CCU standardized stimulation technique as a first attempt, we would have avoided more than a third of catheterizations (36%; 22 of 60).

The second situation in which we suggest performing the CCU procedure as a first attempt is in children aged 0 to 6 months who merely need a urinalysis and for whom urine specimens are usually obtained by a noninvasive method (including febrile infants in a low-risk group for having UTI²). Indeed, it would be debatable to put these children at risk for possible adverse

events related to an invasive method, without attempting a noninvasive method first. In addition, trying the CCU procedure instead of using a collection bag seems reasonable, considering the wait time associated with this technique and the logistics involved in changing the bag every 30 minutes. However, until further studies on proportion and predictive factors of contamination become available, it would be more cautious to perform invasive methods in children who appear ill, who have a positive urinalysis, or before beginning antibiotics. Although a recent study¹⁹ reported high sensitivity of urinalysis in infants <3 months with bacteremic UTI, suggesting that urinalysis is reliable even in young infants, it is cautious to pursue using invasive methods to rule out UTI in infants <30 days.

Limitations

Our study has a few limitations. First, the definition of contamination is arbitrary. It is possible that some infants with high colony counts actually have contaminated urine. On the other hand, it is also possible that those with borderline counts may actually have a UTI because the cutoffs for significant colony counts have not been validated in infants and may not apply to dilute urine. Indeed, nuclear scanning with technetium-labeled dimercaptosuccinic acid was not used to confirm or rule out the diagnosis of a UTI. However, no clear definition for contamination is used in the literature, and the inclusion of urinalysis result in the definition of UTI and contamination limits misclassification of culture results. Second, differences in definitions with respect to colony count being dependent on the method of acquisition is a limitation. To ensure that these differences did not affect our results, we also classified culture results according to the same conservative significance threshold of $\geq 50 \times 10^6$ colony forming units/L

across acquisition methods (for contamination and UTI definitions), and it did not change classification for any of our culture results. Third, differences in contamination proportions between CCU and invasive method samples, although not statistically significant, may be clinically significant. Our study was underpowered to address this issue.

In addition, the sample size was too small to establish predictive factors for contamination in CCU specimens. This could eventually be done in a larger study following the implementation of CCU techniques in another setting. Lastly, CCU maneuvers were performed by 1 of 5 trained research personnel at a single site. External validity could potentially be improved by involving more nurses and more sites.

CONCLUSIONS

In an emergency department, a bladder stimulation technique is a quick and effective way of obtaining CCU samples in infants, especially for those aged <90 days. The contamination proportion of CCU specimens was comparable to contamination proportions reported in the literature for urethral catheterization. Considering possible adverse events related to invasive methods, CCU procedure could be a good alternative to invasive methods in some circumstances. Future studies should attempt to understand predictive factors for contamination.

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ABBREVIATIONS

CCU: clean-catch urine
CI: 95% confidence interval
UTI: urinary tract infections

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