Abstract

Objective: The objective of the study was to determine whether the use of volumetric ultrasound by trained pediatric emergency department (ED) nurses improves first-attempt urine collection success rates.

Methods: This randomized controlled trial was conducted in children aged ≤36 months requiring diagnostic urine samples. Children were randomized to either the conventional (nonimaged) or the ultrasound arm. Demographics, number of catheterizations required for success, postponements, and collection times were recorded.

Results: Forty-five children were assigned to the conventional and 48 to the ultrasound arm (n = 93). First-attempt success rates were higher in the ultrasound arm: 67% (conventional) vs 92% (ultrasound) (P = .003). Both urinalysis and culture were less likely to be completed on conventional group specimens (91% vs 100%; P = .04). However, mean conventional group urine collection time was less than the ultrasound group’s collection time (12 vs 28 minutes; P < .001).

Conclusions: Although there is a time delay, urine collection in the ultrasound arm generated a significant improvement over conventional catheterization in obtaining an adequate urine sample.

1. Introduction

Urine collection is a routine component of pediatric emergency medical care, particularly in the workup of the febrile infant and child. Prior studies in infants have demonstrated that urinary tract infection is the most
commonly diagnosed serious bacterial infection, with an incidence ranging from 2% to 10% [1-7]. It is crucial that these infections be diagnosed at initial presentation because infants have a higher risk of renal scarring and bacteremia [6,8]. Consequently, laboratory examination of the urine in young, febrile children is considered standard of care; and an adequate and contaminant-free specimen is imperative. In infants and very young children, clean voided midstream urine specimens are generally not feasible. Invasive methods such as transurethral bladder catheterization and suprapubic aspiration (SPA) provide better quality specimens, with SPA considered the criterion standard for obtaining uncontaminated specimens [9-11].

Although there is a slightly higher incidence of contamination, transurethral bladder catheterization has emerged as a rapid and somewhat less invasive method of obtaining urine, with urinalysis results rivaling those of SPA [12,13]. When compared with SPA, bladder catheterization also has a lower complication rate. Yet, bladder catheterization is still not without risk. With each catheterization, the child is placed at a small (<1%) but real risk for urethral perforation or stricture, formation of false tracts, bladder perforation, and device failure [14-19]. More immediate, and certainly the most common concern for caregivers, is the discomfort experienced by children undergoing this procedure, a likely major factor influencing caregiver refusal for repeated attempts [20,21]. Given both the risks and the frequent caregiver refusal after a first failed attempt, health care providers try to increase the odds of success by delaying catheterization attempts after recent urination or by hydrating children before urine collection attempts. Neither of these methods is fail-safe, and both may further delay urine collection without assured benefit [22].

Ultrasonography has improved the success rates of bladder aspiration in the pediatric population, either via confirmation of sufficient bladder volume or via ultrasound guidance of the procedure [23-26]. The implementation of ultrasound to guide the timing of bladder catheterizations in the acute care setting, specifically the pediatric emergency department (ED), however, is a fairly new application of this imaging modality [27,28]. Only 2 studies have been conducted, but both have demonstrated dramatic improvements over conventional catheterization (from 68%-72% to 94%-100%) using physician sonographers [22,29].

In most EDs, however, physicians are typically not the care providers obtaining urine samples from patients; rather, nurses routinely perform this procedure. Use of 2 health care providers to conduct one procedure is an inefficient use of valuable resources, particularly if nurses are able to successfully perform both imaging and catheterization. This study attempted to address this inefficiency by training nurses to perform the sonograms and to use the resultant bladder measurements (volumetric ultrasound) to guide their timing of the catheterizations. We posited that volumetric ultrasound would improve first-attempt success rates over conventional catheterization when performed by pediatric ED nurses.

2. Methods

This randomized, controlled trial conducted in a convenience sample of consecutive pediatric patients assessed the success rate of first-attempt conventional catheterization vs catheterizations performed after volumetric ultrasound in an urban, tertiary care pediatric ED from July 2005 to June 2006. Didactic and experiential training was provided to the 3 nurses performing the catheterizations before initiation of participant enrollment. After attending a 30-minute lecture detailing the sonographic imaging and measurement procedures, each nurse was required to successfully image and record bladder dimensions on a minimum of 5 children. The dimension-based volumes obtained by the nurses had to be within 15% of the voided volume, which is consistent with published ranges of measurement error obtained in previous investigations [29-31]. All 3 nurses met these requirements. The enrollment of children in the trial proceeded in such a way to balance the hours worked by the nurses. The 2 full-time nurses were each required to catheterize 30 to 40 children, and the part-time nurse (two thirds full-time position) was required to catheterize 20 to 30 children.

Caregivers of children presenting to the pediatric ED were approached for consent if their child was 36 months or younger, was not toilet trained, and required a catheterization for urine as part of their medical evaluation. Children were not eligible if they had a known genital anatomical abnormality or an indwelling catheter. Children who were critically ill or for whom a caregiver was not present were not enrolled. After informed consent was obtained from the caregiver, children were then randomized using block randomization via sequentially numbered sealed packets to receive conventional (standard of care) or volumetric ultrasound before catheterization. Block randomization was used given the potential for inclusion of several children during an individual nurse’s shift.

Those randomized to the conventional arm underwent immediate catheterization unless there was evidence that the child had recently voided (ie, by caregiver report, newly soiled diaper). In these instances, the catheterization was typically postponed at the discretion of the on-duty attending. If randomized to the ultrasound arm, an immediate measurement of the transverse bladder diameter was obtained using a Sonosite 180 Plus 5-MHz curved transducer (Sonosite Inc, Bothwell, WA). If the transverse diameter was ≥2 cm, demonstrated in previous studies to correspond to a bladder volume ≥2.5 cm³, a sagittal view of the bladder was obtained; and both length and transverse diameter were recorded [22,30,31]. Total urinary bladder volume was calculated using the formula volume (cubic centimeters) = width (centimeters) × depth (centimeters) × 4/3π [32]. If the calculated bladder volume was ≥2.5 cm³, catheterization proceeded. If the transverse measurement was <2 cm, the catheterization was postponed until a repeated measurement reached or exceeded 2 cm³. Repeated measurements were at the
discretion of the nurses. A urine volume of 2.5 cm$^3$ was the minimal acceptable volume for a urinalysis and culture by our institution’s laboratory and, for the purposes of this investigation, constituted a successful catheterization.

Before catheterization, each child was placed on a preweighed absorbent pad, which was weighed again at the conclusion of catheterization attempts. Occasionally, a child’s urine would overfill the collection vial and/or seep out alongside the catheter. Using a conversion of 1 g change in pad weight = 1 cm$^3$ of urine, the uncollected urine volumes were estimated. The total urine volume was calculated as the sum of the volume in vial plus the change in pad weight. For the purpose of this investigation, a minimum of 2.5 cm$^3$ of urine had to be collected in the vial to qualify as a successful catheterization attempt. Total urine volumes were estimated using volumetric ultrasound calculations (sum of leakage and collected) were calculated to compare volumes obtained using volumetric ultrasound to actual (total) volumes.

All postponements, catheterizations attempts, successes, and failures were recorded. Additional data collected included demographic data, indication for urine catheterization, times of collection attempts, final disposition, and urinalysis and culture results. Catheterized cultures were considered positive if there were $>10^4$ colony-forming units per milliliter, and bagged specimens were considered positive if there were $>10^5$ colony-forming units per milliliter. Cultures were considered contaminated if $>3$ organisms were isolated [33]. This study was approved by our institutional review board, and all participants’ caregivers provided written informed consent.

### 2.1. Data analysis

Using success rates from a preliminary study and assuming a 2-sided $z$ of .05 and 80% power, we calculated that a sample size of 42 participants in both arms was required to detect a difference in success rates of 68% (standard catheterization) vs 94% (ultrasound) [22]. An additional 10% recruitment was planned to allow for potential dropouts due to caregiver refusal after randomization. The total required sample size was 92 participants.

All data analyses were performed using Stata 8 (StataCorp, College Station, TX). Data are presented as proportions, means with 95% confidence intervals (CIs), or medians with interquartile ranges (IQRs). First-attempt success rates in the conventional and ultrasound arms were compared using Fisher exact test or $\chi^2$ analysis. A 2-tailed Student $t$ test was used to compare the mean time intervals. Significance was set at $P \leq .05$. The bivariate association between the ultrasound estimated volume and the actual urine volume is presented as a Pearson correlation coefficient ($r$).

### 3. Results

Over the 12-month period, 341 children were eligible for enrollment, of whom 143 presented during shifts that were staffed by trained nurses. Twenty-one (15%) children were deemed too ill by the on-duty attending physician for enrollment; 15 (10%) were missed because the trained nurse was involved in another, more critically ill, child’s care; and 8 (6%) caregivers were unable to provide informed consent because they did not speak any English and a translator was unavailable. Four (3%) caregivers refused. One caregiver withdrew consent after the child was randomized to the conventional catheterization arm, and another child randomized to the ultrasound arm was withdrawn because of mechanical difficulties with the machine. The remaining 93 (65%) children were enrolled and completed the study, with 45 randomized to the control arm and 48 to the ultrasound arm.

There were no significant differences in participant characteristics by groups. Most participants (69%) were less than 12 months of age, and 80% required catheterization for evaluation of fever or suspected sepsis (Table 1). The attending physician postponed 3 (7%) conventional catheterizations because of caregiver report that their child had recently urinated. Eleven (23%) of the children in the ultrasound group had their catheterization postponed because of transverse bladder diameters <2.0 cm. The mean postponement periods among participants requiring postponement were 20.0 (95% CI: 0-44.8) minutes for the conventional and 41.6 (95% CI: 20.9-62.2) minutes for the ultrasound arm catheterizations ($P = .3$).

First-attempt success rate (collection of $\geq 2.5$ cm$^3$ urine) was significantly lower in the conventional catheterization group than that in the ultrasound group (67% vs 92%, respectively; $P = .003$). Occasionally, urine leaked around the catheter and spilled onto the absorbent pads. When the total urine was calculated, the proportion of children producing $\geq 2.5$ cm$^3$ urine in the conventional group was 78% vs 100% in the ultrasound group ($P = .003$).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Conventional catheterization (n = 45)</th>
<th>Ultrasound guided (n = 48)</th>
<th>$P$</th>
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</thead>
<tbody>
<tr>
<td>Disposition, n (%)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Admitted</td>
<td>15 (33)</td>
<td>16 (33)</td>
<td></td>
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<tr>
<td>Discharged</td>
<td>30 (67)</td>
<td>32 (67)</td>
<td>.99</td>
</tr>
<tr>
<td>Age (mo), mean (95% CI)</td>
<td>10.2 (7.7-12.6)</td>
<td>9.1 (6.4-11.8)</td>
<td>.50</td>
</tr>
<tr>
<td>Indication, n (%)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Fever</td>
<td>36 (80)</td>
<td>38 (79)</td>
<td>.70</td>
</tr>
<tr>
<td>Sepsis work-up</td>
<td>4 (9)</td>
<td>7 (15)</td>
<td></td>
</tr>
<tr>
<td>Crying</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4 (9)</td>
<td>2 (4)</td>
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<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>21 (47)</td>
<td>31 (65)</td>
<td>.10</td>
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<tr>
<td>African American</td>
<td>24 (53)</td>
<td>16 (33)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Hispanic, n (%)</td>
<td>16 (36)</td>
<td>20 (42)</td>
<td>.70</td>
</tr>
<tr>
<td>Hispanic, n (%)</td>
<td>21 (47)</td>
<td>31 (65)</td>
<td>.70</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>27 (47)</td>
<td>30 (53)</td>
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<tr>
<td>Hispanic, n (%)</td>
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<td>20 (42)</td>
<td>.70</td>
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<tr>
<td>White</td>
<td>21 (47)</td>
<td>31 (65)</td>
<td>.70</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>24 (53)</td>
<td>16 (33)</td>
<td>.10</td>
</tr>
</tbody>
</table>
The nurses’ ability to accurately measure bladder volumes was also assessed using the sonographic images. Median sonographic bladder volume was 6.4 cm$^3$ (IQR: 4.1-12.3). Median total urine volume was 7 cm$^3$ (IQR: 4-14.5). Correlation between these 2 measures was excellent ($r = 0.76; P < .001$). To evaluate the possibility of cluster effects, we evaluated success rates by nurse sonographer (Table 2). Significance testing did not show differences across nurses; however, this study was not adequately powered for this assessment.

Overall, there were 15 (33%) vs 4 (8%) first-attempt failures in conventional vs ultrasound catheterization, respectively ($P = .003$). In all but one of the first-attempt failures, caregivers refused a second catheterization attempt. The one child catheterized twice was from the conventional group, and the second attempt was also unsuccessful. Further attempts were refused by the caregiver.

Any additional urine collections in those who refused subsequent catheterization were conducted via a collection bag attached to the perineum; or the initial sample was sent for either a urinalysis or a culture, based on attending preference. Perineal bag urine collection occurred in 9 (20%) of the children assigned to the conventional arm and in only 1 (2%) child assigned to the ultrasound arm ($P = .006$). Two of the 10 perineal bag specimens resulted in contaminated cultures, both of which were obtained from children assigned to the conventional arm.

Although our laboratory’s policy required a minimum of 2.5 cm$^3$ of urine to conduct both a urinalysis and culture, these tests were still completed on several insufficient specimens from the conventional group (n = 11) and the ultrasound group (n = 4). Despite this accommodation with insufficient specimens, both a urinalysis and a culture were still less likely to have been completed on children assigned to the conventional than the ultrasound arm (91% vs 100%, respectively; $P = .04$). Of the remaining 4 children in the conventional arm with inadequate laboratory specimens, 3 had only a urinalysis and 1 child had only a urine culture performed by the laboratory.

As seen in Table 3, the only time interval that differed between groups was the time from consent to first catheterization attempt. As reported earlier, both arms had discretionary postponement of catheterization attempts. When the 14 children with postponements were excluded from the analysis, the time from consent to first attempt was reduced to 11.1 minutes (conventional) and 19.5 minutes (ultrasound) ($P = .006$). The time interval from consent to successful urine collection could not be calculated for all participants: Ten children requiring perineal specimen collection had their urine collection continued on the medical floor, which made further data collection for them unfeasible.

### 4. Discussion

This clinical trial in infants and young children demonstrated that administering a brief didactic session followed by 5 practice sonographic imaging sessions to pediatric ED nurses yielded significantly higher first-attempt urine collection success rates when compared with the conventional practice of catheterizing without imaging. The success rate of this investigation (92%) was very similar to those of previous studies in which more extensively trained physicians served as sonographers [22,29]. When total urine was used as the basis for success, the first-attempt success rate for the ultrasound arm increased to 100%, demonstrating that “failures” in the ultrasound group were due to leakage rather than sonographic mismeasurement. This is further supported by the excellent correlation ($r = 0.76$) between actual and measured volumes, which was comparable with that obtained by Witt et al [22].

The results of this study are notable for several reasons. First, children assigned to the ultrasound arm were more likely to have a urine specimen of sufficient volume for laboratory testing obtained on the first catheterization attempt. Second, after the first failed attempt, the likelihood of caregiver refusal of a second catheterization was nearly 100%. In these children, use of a perineal bag was used, of which one fifth resulted in contaminated cultures. These contaminated specimens may have delayed identification

### Table 2  First-attempt success rates by nurse

<table>
<thead>
<tr>
<th>Nurse</th>
<th>Conventional catheterization (%)</th>
<th>Ultrasound guided (%)</th>
<th>$P$</th>
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<tbody>
<tr>
<td>Nurse 1</td>
<td>First-attempt success 9/14 (64)</td>
<td>21/21 (100)</td>
<td>.006</td>
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<tr>
<td></td>
<td>≥2.5 cm$^3$ urine expelled 10/14 (71)</td>
<td>21/21 (100)</td>
<td>.02</td>
</tr>
<tr>
<td>Nurse 2</td>
<td>First-attempt success 7/11 (64)</td>
<td>10/12 (83)</td>
<td>.40</td>
</tr>
<tr>
<td></td>
<td>≥2.5 cm$^3$ urine expelled 8/11 (73)</td>
<td>12/12 (100)</td>
<td>.09</td>
</tr>
<tr>
<td>Nurse 3</td>
<td>First-attempt success 14/20 (70)</td>
<td>13/15 (87)</td>
<td>.40</td>
</tr>
<tr>
<td></td>
<td>≥2.5 cm$^3$ urine expelled 17/20 (85)</td>
<td>15/15 (100)</td>
<td>.20</td>
</tr>
<tr>
<td>All nurses</td>
<td>First-attempt success 30/45 (67)</td>
<td>44/48 (92)</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>≥2.5 cm$^3$ urine expelled 35/45 (78)</td>
<td>48/48 (100)</td>
<td>.003</td>
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</tbody>
</table>
and treatment of urinary tract infections. Third, nurses who performed the catheterizations also conducted the sonographic examinations, allowing the physicians to participate in other health care activities and increasing the overall efficiency of the health care staff. Finally, the difference in collection times (conventional vs ultrasound) may have been slightly inflated because of study procedures. To allow for comparisons between measured and collected urine volumes, nurses in this investigation were required to obtain 3 bladder dimension measurements. Two recent investigations suggest that fewer measurements (transverse bladder alone or transverse bladder and anteroposterior diameter measurements) may be sufficient to guide the timing of bladder catheterization. Neither of these studies, however, have been satisfactorily validated [22,34].

Despite the benefits of ultrasound, there were a few unfavorable outcomes: Our rates of caregiver refusal of further catheterization attempts after a first failed attempt were higher than our previous experience would have indicated [22]. Seventeen of eighteen (94%) caregivers refused. This may have been due to increased caregiver expectations: Several caregivers whose children were assigned to the conventional arm commented that had their child undergone ultrasound, the urine collection attempt would not have failed and repeated attempts would not have been necessary. In fact, one enrolled child was withdrawn from the study after the caregiver was informed that the child was assigned to the conventional arm. Although this caregiver was told that the standard method of urine collection would be used, she refused to allow her child to participate in the study, stating that ultrasound should be used on all children. These heightened expectations on the part of the caregivers may have predisposed them to refuse additional attempts. Likewise, several of our attendings may have been less likely to strongly advocate repeated catheterization attempts, given that our laboratory was able to conduct at least a urinalysis or culture on specimens of insufficient volume.

Urine collection based on volumetric ultrasound measurements takes longer. When the children who had postponed catheterization attempts were excluded from the analysis, this time difference was reduced (though still present). As noted earlier, nonstudy conditions would necessitate only one transverse bladder dimension assessment. This would likely reduce the catheterization time further, by approximately 3 to 5 minutes, bringing the urine collection time closer to that of conventional catheterization. The relatively small time delay with ultrasound, then, is likely outweighed by the greater first-attempt successes, improved specimen quality, and volume adequacy.

There were several limitations to this study. First, there was no blinding. Blinding of nurses was not feasible because they were primarily responsible for the urine collection. Similarly, blinding of physicians was not feasible; decisions to postpone urine collection attempts required physician knowledge of the child’s assignment. We were unable to test whether this lack of blinding led to significant effects on results. Second, repeated attempts at catheterization were rarely attempted. This was primarily due to caregiver preference. Ascertainning the total number of catheterizations needed per child for the collection of a successful volume of urine (≥2.5 cm³ urine) would have been preferable, but was not ethical given caregiver choice. Yet another limitation was that the time to collection of an adequate sample was not calculated for those children who provided perineal bag specimens. Many of these children were admitted and transferred to the hospital floor with their specimen bags, and practical considerations curtailed inpatient assessment of time to successful collection. Finally, this study was not adequately powered to test for differences between nurses. Testing for such differences was not an objective of this investigation, and this possibility should be tested in future studies. Until such studies are completed, institutions that implement the use of volumetric ultrasound to guide the timing of bladder catheterization should ensure that quality assurance procedures are in place and require additional training of those nurses whose success rates fall below a preestablished criterion.

5. Conclusions

We demonstrated that nurses with a limited amount of sonographic training are able to accurately determine bladder volumes and appropriately use these measurements to guide catheterization attempts. By placing the imaging in the collector’s control and freeing the physician to perform other tasks, bedside sonography as an aid to pediatric urine collection is a viable and likely preferable option in those EDs that have bedside ultrasound capability. Future investigations are needed to determine whether our findings are generalizable to other pediatric EDs and to determine whether success rates remain consistently high across nurses and over time. A cost/benefit analysis, examining how delays in obtaining specimens and the actual monetary cost of the examination compare with the improvements in efficiency and urine specimen quality, would also be worthy of future study.

Acknowledgment

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References

Pediatric bladder ultrasound


