Accuracy of the Urinalysis for Urinary Tract Infections in Febrile Infants 60 Days and Younger

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abstract

OBJECTIVES: Reports of the test accuracy of the urinalysis for diagnosing urinary tract infections (UTIs) in young febrile infants have been variable. We evaluated the test characteristics of the urinalysis for diagnosing UTIs, with and without associated bacteremia, in young febrile infants.

METHODS: We performed a planned secondary analysis of data from a prospective study of febrile infants ≤60 days old at 26 emergency departments in the Pediatric Emergency Care Applied Research Network. We evaluated the test characteristics of the urinalysis for diagnosing UTIs, with and without associated bacteremia, by using 2 definitions of UTI: growth of ≥50 000 or ≥10 000 colony-forming units (CFUs) per mL of a uropathogen. We defined a positive urinalysis by the presence of any leukocyte esterase, nitrite, or pyuria (>5 white blood cells per high-power field).

RESULTS: Of 4147 infants analyzed, 289 (7.0%) had UTIs with colony counts ≥50 000 CFUs/mL, including 27 (9.3%) with bacteremia. For these UTIs, a positive urinalysis exhibited sensitivities of 0.94 (95% confidence interval [CI]: 0.91–0.97), regardless of bacteremia; 1.00 (95% CI: 0.87–1.00) with bacteremia; and 0.94 (95% CI: 0.90–0.96) without bacteremia. Specificity was 0.91 (95% CI: 0.90–0.91) in all groups. For UTIs with colony counts ≥10 000 CFUs/mL, the sensitivity of the urinalysis was 0.87 (95% CI: 0.83–0.90), and specificity was 0.91 (95% CI: 0.90–0.92).

CONCLUSIONS: The urinalysis is highly sensitive and specific for diagnosing UTIs, especially with ≥50 000 CFUs/mL, in febrile infants ≤60 days old, and particularly for UTIs with associated bacteremia.

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WHAT'S KNOWN ON THIS SUBJECT: The accuracy of the urinalysis for diagnosing urinary tract infections (UTIs) in young infants is variable in previous reports. The authors of a recent study describe high sensitivity in infants with UTIs and concurrent bacteremia.

WHAT THIS STUDY ADDS: The aggregate urinalysis (including leukocyte esterase, nitrites, and pyuria) exhibits excellent sensitivity and high specificity for diagnosing UTIs in febrile infants 60 days and younger with and without concurrent bacteremia.

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Urinary tract infections (UTIs) account for ~90% of all serious bacterial infections (defined as UTIs, bacteremia, and bacterial meningitis) in febrile infants 60 days of age and younger.[1–3] The evaluation of febrile infants typically includes the urinalysis, a readily available screening test, to make a preliminary diagnosis of UTI. However, the reported test characteristics of the urinalysis in this age group have varied substantially, with sensitivities ranging from 48% to 99% and specificities ranging from 88% to 98%.[4–9]

Some of the variability in test performance of the urinalysis in this age group can be attributed to differing methods of urine collection (catheterized versus noncatheterized samples)[5] or differing methods of performance of the urinalysis (eg, dipstick with or without microscopy, varying laboratory procedures).[4,5,8,10,11] It is only in a few studies that researchers have evaluated the performance characteristics of the different components of the urinalysis (leukocyte esterase [LE], nitrite, pyuria) individually as well as in aggregate.[4,8,9] In these studies, the definition of a test positive for nitrites is standard, but the definitions of tests positive for LE and pyuria vary, potentially affecting the test characteristics.[4,8,9] Additionally, differing definitions of positive urine cultures (ranging from ≥10 000 to ≥50 000 colony-forming units [CFUs] per mL) likely affect the sensitivities and specificities of the urinalysis reported in these young infants.[4–8] The authors of older studies reported relatively poor sensitivities of the urinalysis for identifying the youngest infants with UTIs.[5–7] The authors of a recent study, however, noted excellent sensitivity of the urinalysis in infants younger than 3 months with UTIs and associated bacteremia,[9] a finding that needs further validation.

To our knowledge, the performance of the urinalysis specifically in febrile infants 60 days of age and younger has not been examined in any prospective, large-sample studies. Indeed, in the most recent evaluation and management guideline by the American Academy of Pediatrics for UTIs in febrile young children, those younger than 60 days of age are specifically excluded.[12]

Our aim with this study was to determine the test characteristics of the urinalysis in detecting UTIs in a large, multicenter, observational cohort of febrile infants 60 days of age and younger. As a secondary aim, we sought to compare the performance of the urinalysis for detecting UTIs in infants with and without associated bacteremia.

METHODS

Setting

We performed a planned secondary analysis of a large, prospective, geographically diverse, cross-sectional study of febrile infants 60 days of age and younger presenting to any of the 26 emergency departments (EDs) in the Pediatric Emergency Care Applied Research Network between December 2008 and May 2013.[13] The institutional review board at each participating hospital approved this study. Informed consent was obtained from the parent or legal guardian of each enrolled patient.

Patient Eligibility

In the parent study, we enrolled a convenience sample of 4778 infants 60 days of age and younger with documented fevers ≥38°C from whom blood cultures were obtained as part of their ED evaluation for serious bacterial infection. Infants were excluded from the parent study if they had clinical sepsis, a history of prematurity, significant comorbid conditions, or recent systemic antibiotic use.[13] Infants were eligible for the current analysis if they had urinalyses (evaluating both LE and nitrite at a minimum) performed and urine cultures obtained via urethral catheterization or suprapubic aspiration. We excluded infants from this analysis if they had bacteremia without associated UTI, if they had bacteremia and concurrent UTI caused by different pathogens, if the bacteremia status was unclear (such as having a Gram-stain with positive results but no bacterial growth or growth of multiple organisms), or if the urine culture was obtained via a bag specimen or an unknown method. The sample size was based on enrollment in the parent study. Data from all eligible patients were analyzed.

Study Definitions

The urinalyses were completed as per standard procedures at the participating hospitals' clinical laboratories. We evaluated both the individual components of the urinalysis and the urinalysis in aggregate. The 3 individual components of the urinalysis assessed included LE, nitrite, and pyuria. We defined the LE result as positive if any amount, including a trace amount, was detected. Nitrite results were defined as being negative or positive. We defined pyuria as the presence of >5 white blood cells (WBCs) per high-power field (HPF). Previous researchers have noted that clinical laboratories may not perform microscopy if the urinalysis dipstick reveals negative results.[10] Therefore, we also defined pyuria status as negative if urine microscopy was not completed but the urinalysis was otherwise negative for LE and nitrite.

For our analysis of the aggregate urinalysis, we defined a urinalysis as positive if LE, nitrite, or pyuria were present. We considered the aggregate urinalysis to be negative if the LE, nitrite, and pyuria components all revealed negative results. We

also considered the aggregate urinalysis to be negative if the LE and nitrite components revealed negative results and pyuria was not assessed (because of the above considerations). We evaluated test characteristics for the aggregate urinalysis for the entire cohort as well as stratifying by age group (≤28 or 29–60 days old).

We applied 2 different definitions of UTI, given varied definitions of UTI in the literature for this age group based on colony counts.[4–8] For our main analysis, we defined UTI as the growth of ≥50 000 CFUs/mL of a known urinary pathogen from a culture obtained via catheterization or ≥1000 CFUs/mL from a culture obtained via suprapubic aspiration. For our secondary analysis, we defined UTI as the growth of ≥10 000 CFUs/mL of a known urinary pathogen from a culture obtained via catheterization or ≥1000 CFUs/mL from a culture obtained via suprapubic aspiration. In instances in which the reporting of the CFUs per mL was provided as a range that crossed a definition threshold, we excluded the infant from that analysis. For example, if the urine culture was reported as 25 000 to 75 000 CFUs/mL, we excluded that particular infant from the primary analysis because our primary definition of UTI (growth of ≥50 000 CFUs/mL) fell within the range reported, but we included the infant in the secondary analysis using the ≥10 000 CFUs/mL definition. We defined a negative urine culture as one with no growth, growth of a contaminant in the absence of a pathogen, or growth of a urinary pathogen that did not reach the CFUs per mL threshold. Contaminants were defined as bacteria known to be skin or genitourinary flora, such as coagulase-negative *Staphylococcus*, *Lactobacillus*, and *Corynebacterium* species. Additionally, we considered a urine culture to be contaminated and negative if it revealed growth of more than 2 organisms of any type. On the basis of the presence or absence of the same pathogen growing in the blood culture, UTIs were categorized as with or without bacteremia for further analysis.

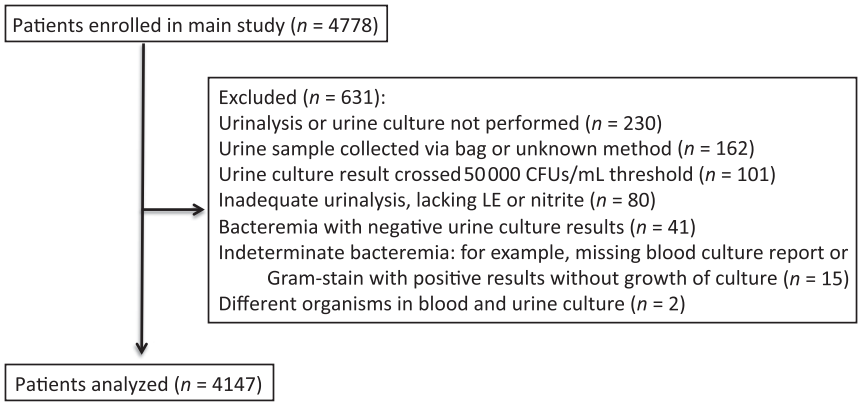

FIGURE 1
Patient flow diagram.

Statistical Analysis

We conducted bivariable analyses to compare the demographic and clinical characteristics between infants with and without UTIs and between infants with UTIs with and without associated bacteremia. We analyzed categorical variables by using the χ^2 test and continuous variables by using Wilcoxon rank tests. We calculated the sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios of the urinalysis results (with 95% confidence intervals [CIs]) for all infants and then calculated these values separately for infants with and without bacteremia. All analyses were performed in SAS version 9.4 (SAS Institute, Inc, Cary, NC).

RESULTS

Overall, 4147 of 4778 (87%) infants enrolled in the parent study were eligible for the current analysis (Fig 1). Of the 4147 infants in this analysis, 289 (7.0%, 95% CI 6.3%–7.8%) had UTIs defined by the growth of ≥50 000 CFUs/mL of a urinary pathogen. Bacteremia was present in 27 of the 289 (9.3%, 95% CI: 6.2%–13.3%) infants with UTIs. In Table 1, we compare the demographic and baseline characteristics of the eligible infants.

In Table 2, we detail the frequency of positivity of the individual components of the urinalysis. Most infants with UTIs had urinalyses positive for LE or pyuria. Nitrites were absent in most infants without UTIs, as well as in most patients with UTIs. All patients with UTIs with bacteremia had either moderate or large LE on urinalysis. In Table 3, we show the test characteristics of the urinalysis components individually and in combination. Of the individual components, LE was shown to have the most accurate test characteristics.

In Table 4, we describe the test characteristics of the aggregate urinalysis. The aggregate urinalysis was shown to have a very high sensitivity (0.94, 95% CI: 0.91–0.97) for diagnosing UTIs, regardless of bacteremia status. The urinalysis was perfectly sensitive (1.00, 95% CI: 0.87–1.00) for diagnosing UTIs with bacteremia. However, the sensitivity was slightly lower (0.94, 95% CI: 0.90–0.96) for diagnosing UTIs without bacteremia. The specificity was similarly high (0.91, 95% CI: 0.90–0.91) for all patients, irrespective of bacteremia status. There were no differences

TABLE 1 Demographic and Clinical Characteristics by UTI and Bacteremia Status

	UTI With Bacteremia	UTI Without Bacteremia	*P*	UTI (Regardless of Bacteremia)	No UTI	*P*
N	27	262		289	3858	
Sex			.06			.008
Female	14 (51.9)	88 (33.6)		102 (35.3)	1669 (43.3)	
Male	13 (48.1)	174 (66.4)		187 (64.7)	2189 (56.7)	
Age in d, median (IQR)	24 (12–46)	34 (20–47)	.2	33 (20–47)	38 (26–48)	.002
Age category			.3			<.001
≤28 d	14 (51.9)	110 (42.0)		124 (42.9)	1172 (30.4)	
29–60 d	13 (48.1)	152 (58.0)		165 (57.1)	2686 (69.6)	
Race			.9			<.001
White	18 (66.7)	153 (58.4)		171 (59.2)	2206 (57.2)	
African American	4 (14.8)	39 (14.9)		43 (14.9)	959 (24.9)	
Other	4 (14.8)	45 (17.2)		49 (17.0)	430 (11.1)	
Unknown[a]	1 (3.7)	25 (9.5)		26 (9.0)	263 (6.8)	
Ethnicity			.09			<.001
Hispanic or Latino	7 (25.9)	110 (42.0)		117 (40.5)	1134 (29.4)	
Not Hispanic or Latino	20 (74.1)	147 (56.1)		167 (57.8)	2652 (68.7)	
Unknown[a]	0 (0.0)	5 (1.9)		5 (1.7)	72 (1.9)	
Qualifying[b] temperature, °C, median (IQR)	38.6 (38.3–39.1)	38.6 (38.3–39.1)	.5	38.6 (38.3–39.1)	38.3 (38.1–38.7)	<.001
ANC × 10^3 cells/μL, median (IQR)	7.1 (4.9–11.3)	7.2 (4.4–10.0)	.6	7.2 (4.6–10.0)	3.0 (1.9–4.8)	<.001
Serum WBC × 10^3 cells/μL, median (IQR)	14.1 (10.7–17.4)	14.5 (10.5–18.5)	.8	14.4 (10.6–18.1)	9.6 (7.1–12.7)	<.001
Urine organism			.05			NA
E coli	23 (85.2)	214 (81.7)		237 (82.0)	NA	
Klebsiella	1 (3.7)	12 (4.6)		13 (4.5)	NA	
Enterococcus	0 (0.0)	9 (3.4)		9 (3.1)	NA	
Enterobacter	3 (11.1)	5 (1.9)		8 (2.8)	NA	
Other	0 (0.0)	22 (8.4)		22 (7.6)	NA	
Method of urine collection			NA			NA
Catheterization	27 (100.0)	262 (100.0)		289 (100.0)	3851 (99.8)	
Suprapubic aspiration	0 (0.0)	0 (0.0)		0 (0.0)	7 (0.2)	

All data presented as *n* (%) except where indicated. ANC, absolute neutrophil count; IQR, interquartile range; NA, not applicable.

[a] Category not used in the statistical test.

[b] Qualifying fever was the height of fever documented at home or in the ED before enrollment.

TABLE 2 Urinalysis Results Based on UTI and Bacteremia Status

	UTI With Bacteremia, *N* = 27	UTI Without Bacteremia, *N* = 262	*P*	UTI (Regardless of Bacteremia), *N* = 289	No UTI, *N* = 3858	*P*
LE concentration, *n* = 4147			.1			<.001
Small (trace or 1+)	0 (0.0)	26 (9.9)		26 (9.0)	94 (2.4)	
Moderate (2+)	5 (18.5)	51 (19.5)		56 (19.4)	39 (1.0)	
Large (3+)	22 (81.5)	163 (62.2)		185 (64.0)	35 (0.9)	
Negative results	0 (0.0)	22 (8.4)		22 (7.6)	3690 (95.6)	
Nitrites, *n* = 4147			.8			<.001
Positive	11 (40.7)	100 (38.2)		111 (38.4)	21 (0.5)	
Negative	16 (59.3)	162 (61.8)		178 (61.6)	3837 (99.5)	
Pyuria,[a] *n* = 4100			.6			<.001
Positive (>5 WBCs/HPF)	17 (77.3)	199 (82.2)		216 (81.8)	248 (6.5)	
Negative (≤5 WBCs/HPF)	5 (22.7)	43 (17.8)		48 (18.2)	3588 (93.5)	

All data presented as *n* (%).

[a] If LE and nitrite results were negative, pyuria was defined as negative if absent; this definition applied in 889 of 4100 cases.

in the aggregate urinalysis test performance when comparing infants ≤28 days to those 29 to 60 days old.

We replicated the main analyses by using our second definition of UTI (≥10 000 CFUs/mL from a catheterized specimen); 106 additional patients were classified as having UTIs by using this second definition. The differences between groups (no UTI, UTI with and without bacteremia) in the demographic and baseline characteristics were similar to those noted when UTIs were defined by using the 50 000 CFUs/mL threshold. In Supplemental Table 5, we describe the frequency

of positivity of the individual urinalysis components against UTIs defined by the 10 000 CFUs/mL threshold. All patients with UTIs with bacteremia had moderate or high LE concentrations on urinalysis. In Supplemental Table 6, the aggregate urinalysis sensitivity for UTIs, regardless of bacteremia status, using the 10 000 CFUs/mL threshold, was demonstrated to be less (0.87, 95% CI: 0.83–0.90) compared with the 50 000 CFUs/mL threshold. The sensitivity of the urinalysis for UTIs with bacteremia, however, remained very high (1.00, 95% CI: 0.88–1.00), although the sensitivity for UTIs without bacteremia was lower (0.86, 95% CI: 0.82–0.89) compared with that for our primary analysis definition of UTI. The specificity of the aggregate urinalysis did not change when we used this second definition of UTI, compared with our primary analysis.

In Supplemental Table 7, we display the frequency of positivity of individual urinalysis components for UTI in the infants whose urine cultures ranged from 10 000 to 99 999 CFUs/mL compared with those with urine cultures growing ≥100 000 CFUs/mL. As expected, infants without bacteremia whose urine colony counts were in the lower range (<100 000 CFUs/mL) were less likely to have LE, nitrites, or pyuria present on their urinalyses compared with infants with colony counts ≥100 000 CFUs/mL.

Finally, in Supplemental Table 8, we demonstrated that the sensitivities for individual components of the urinalysis and the aggregate urinalysis varied depending on the specific UTI pathogen, based on the UTI definition of ≥50 000 CFUs/mL. In general, the urinalysis sensitivities appeared higher for diagnosing Gram-negative UTIs compared with UTIs caused by *Enterococcus*. However, there were too few infections caused by specific pathogens (except *Escherichia coli*) to make definitive comparisons.

TABLE 3 Test Characteristics of Single Components and Aggregate Urinalysis for Diagnosing UTI, Stratified by Bacteremia Status

	Sensitivity (95% CI)	Specificity (95% CI)
Identification of any UTI (*N* = 289)		
Any LE, *n* = 4147	0.92 (0.89–0.95)	0.96 (0.95–0.96)
Nitrites, *n* = 4147	0.38 (0.33–0.44)	0.99 (0.99–1.00)
Pyuria, >5 WBCs/HPF, *n* = 4100	0.82 (0.77–0.86)	0.94 (0.93–0.94)
LE or nitrites, *n* = 4147	0.93 (0.90–0.96)	0.95 (0.95–0.96)
Aggregate urinalysis (LE or nitrites or pyuria), *n* = 4147	0.94 (0.91–0.97)	0.91 (0.90–0.91)
Identification of UTI with bacteremia (*N* = 27)		
Any LE, *n* = 3885	1.00 (0.87–1.00)	0.96 (0.95–0.96)
Nitrites, *n* = 3885	0.41(0.22–0.61)	0.99 (0.99–1.00)
Pyuria, >5 WBCs/HPF, *n* = 3858	0.77 (0.55–0.92)	0.94 (0.93–0.94)
LE or nitrites, *n* = 3885	1.00 (0.87–1.00)	0.95 (0.95–0.96)
Aggregate urinalysis (LE or nitrites or pyuria), *n* = 3885	1.00 (0.87–1.00)	0.91 (0.90–0.91)
Identification of UTI without bacteremia (*N* = 262)		
Any LE, *n* = 4120	0.92 (0.88–0.95)	0.96 (0.95–0.96)
Nitrites, *n* = 4120	0.38 (0.32–0.44)	0.99 (0.99–1.00)
Pyuria, >5 WBCs/HPF, *n* = 4078	0.82 (0.77–0.87)	0.94 (0.93–0.94)
LE or nitrites, *n* = 4120	0.92 (0.88–0.95)	0.95 (0.95–0.96)
Aggregate urinalysis (LE or nitrites or pyuria), *n* = 4120	0.94 (0.90–0.96)	0.91 (0.90–0.91)

DISCUSSION

In this large, geographically diverse population of febrile infants 60 days of age and younger, the urinalysis (including LE, nitrite, and pyuria) was demonstrated to have excellent performance as a screening test for UTIs. Indeed, the urinalysis had perfect sensitivity and negative predictive values for UTIs associated with bacteremia

TABLE 4 Test Characteristics of Aggregate Urinalysis for Diagnosing UTI, Stratified by Bacteremia Status and Age

	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR+ (95% CI)	LR− (95% CI)
Identification of any UTI[a] (*N* = 289)						
Entire population, *n* = 4147	0.94 (0.91–0.97)	0.91 (0.90–0.91)	0.43 (0.39–0.47)	1.00 (0.99–1.00)	10.01 (9.04–11.08)	0.06 (0.04–0.10)
Infants ≤28 d, *n* = 1296	0.97 (0.92–0.99)	0.90 (0.88–0.91)	0.50 (0.43–0.56)	1.00 (0.99–1.00)	9.30 (7.84–11.03)	0.04 (0.01–0.09)
Infants 29–60 d, *n* = 2851	0.93 (0.88–0.96)	0.91 (0.90–0.92)	0.39 (0.34–0.44)	1.00 (0.99–1.00)	10.29 (9.06–11.69)	0.08 (0.05–0.14)
Identification of UTIs with bacteremia[a] (*N* = 27)						
Entire population, *n* = 3885	1.00 (0.87–1.00)	0.91 (0.90–0.91)	0.07 (0.05–0.10)	1.00 (1.00–1.00)	10.60 (9.61–11.69)	0.00[b]
Infants ≤28 d, *n* = 1186	1.00 (0.77–1.00)	0.90 (0.88–0.91)	0.10 (0.06–0.17)	1.00 (1.00–1.00)	9.61 (8.12–11.36)	0.00[b]
Infants 29–60 d, *n* = 2699	1.00 (0.75–1.00)	0.91 (0.90–0.92)	0.05 (0.03–0.09)	1.00 (1.00–1.00)	11.10 (9.84–12.52)	0.00[b]
Identification of UTIs without bacteremia[a] (*N* = 262)						
Entire population, *n* = 4120	0.94 (0.90–0.96)	0.91 (0.90–0.91)	0.40 (0.36–0.44)	1.00 (0.99–1.00)	9.95 (8.98–11.03)	0.07 (0.04–0.11)
Infants ≤28 d, *n* = 1282	0.96 (0.91–0.99)	0.90 (0.88–0.91)	0.46 (0.40–0.53)	1.00 (0.99–1.00)	9.26 (7.80–10.99)	0.04 (0.02–0.11)
Infants 29–60 d, *n* = 2838	0.92 (0.87–0.96)	0.91 (0.90–0.92)	0.37 (0.32–0.42)	1.00 (0.99–1.00)	10.22 (8.99–11.63)	0.09 (0.05–0.15)

LR+, positive likelihood ratio; LR−, negative likelihood ratio; NPV, negative predictive value; PPV, positive predictive value.

[a] Positive urinalysis results were defined by the presence of any LE or nitrite or pyuria.

[b] LR− does not have a CI because of a sensitivity of 1.00.

and revealed excellent performance for UTIs without bacteremia. The performance of the urinalysis remained high (although with slightly lower sensitivity) when UTI was defined by a lower colony count (ie, ≥10 000 CFUs/mL).

Historically, the authors of single-center studies have found the urinalysis to have suboptimal sensitivity when used as a screening test for UTIs in very young infants with fever.[5–7] The authors of 3 of these studies defined UTIs by urine culture colony counts ≥10 000 CFUs/mL, and they demonstrated the lowest sensitivities for the urinalysis (48%–81%).[5–7] In more recent studies, in which UTI has been defined by growth of ≥50 000 CFUs/mL, the sensitivities typically have been higher (84%–94%).[4,8] The high sensitivity in our primary analysis may reflect our use of the more stringent definition of UTI, because the sensitivity of the urinalysis was somewhat lower with our secondary definition of UTI (≥10 000 CFUs/mL). Additionally, our analyses of the frequency of positivity of the individual components of the urinalysis with varying CFU ranges in the urine cultures revealed that the urinalysis is more likely to be negative in infants with cultures growing 10 000 to 99 999 CFUs/mL than in infants with cultures growing 100 000 CFUs/mL or greater. This may reflect a higher frequency of asymptomatic bacteriuria in the former group. This finding has implications for clinicians practicing at institutions where laboratories report culture results in ranges that may cross standard diagnostic thresholds (such as 50 000 CFUs/mL).

Additional variability in the accuracy of the urinalysis reported across studies may also be due to the different components of the urinalysis evaluated in each study. In a recent, prospective, multicenter study of 3401 febrile infants <90 days old, the urinalysis dipstick had a sensitivity of 84% (95% CI: 80.8%–86.6%) and a specificity of 92% (95% CI: 90.9%–92.9%) for identifying UTIs.[8] In that study, a positive urinalysis dipstick was defined as having >1+ LE or any nitrites.[8] In another study, an automated cell count or Gram-stain of uncentrifuged urine (the "enhanced urinalysis") was noted to have high sensitivity (94%, 95% CI: 83%–99%) but lower specificity (84%, 95% CI: 82%–86%) when compared with the dipstick (positive for LE and/or nitrite) in febrile children <2 years with UTIs.[10] Yet, in another study, the dipstick urinalysis had similar test performance characteristics compared with urine microscopy (defined as >10 WBCs/HPF or any bacteria in centrifuged samples) in identifying UTIs in febrile infants ≤90 days.[4] Finally, in the study of UTIs with bacteremia, the urinalysis components with the highest sensitivity were pyuria (defined as >3 WBCs/HPF) with a sensitivity of 96% (95% CI: 92.5–98.1) or any LE with a sensitivity of 97.6% (95% CI: 94.5–99.2).[9] Our results suggest that the LE is perhaps the most important single component of the urinalysis, and the inclusion of trace or small amounts of LE may be important for achieving high sensitivity. Nitrite positivity did not substantially improve sensitivity, and pyuria identified few additional UTI patients beyond those identified by LE positivity.

We noted that the very high sensitivity of the aggregate urinalysis (the presence of any LE, nitrite, or pyuria >5 WBCs/HPF) in infants with UTIs and associated bacteremia was similar to the 99.4% sensitivity (95% CI: 98.3%–100%) identified in the recent retrospective study of 245 infants with UTIs and bacteremia.[9] With our study, we extend these findings by identifying that infants with UTIs with bacteremia appear to have more obviously positive urinalysis results (all with moderate or large concentrations of LE) than infants with UTIs not associated with bacteremia, suggesting that the urinalysis will be unlikely to miss those patients with UTIs that would be of most concern to clinicians (ie, those associated with bacteremia). The group with UTIs and bacteremia appears to represent a patient population with an extremely high likelihood of having "true" UTIs, whereas a population of febrile infants with bacterial growth in the urine but without bacteremia may at times include patients with asymptomatic bacteriuria.[14] Our results do confirm, however, that the urinalysis is a highly accurate screening test even in the youngest infants with UTIs, regardless of bacteremia status.

Similar to previous research, our data revealed some variation in urinalysis test characteristics based on the specific UTI pathogen. With our data, we corroborate the findings of 2 studies of young infants in which it was noted that the urinalysis had decreased sensitivity in diagnosing enterococcal UTIs.[15,16]

Our study had some limitations. We did not collect information regarding the specific laboratory methods used to complete the urinalyses across the 26 sites. Because the laboratory methods likely differed, however, the overall high sensitivity of the aggregate urinalysis could be viewed as a generalizable finding. Although necessary for our study, we used a definition of UTI based solely on urine culture. In the most recent American Academy of Pediatrics guideline, it is recommended that a definition of UTI includes the presence of pyuria or bacteriuria in addition to urine culture with pathogen growth ≥50 000 CFUs/mL.[12]

Therefore, our definition of UTI may have resulted in incorrectly categorizing some patients with asymptomatic bacteriuria as having UTIs. However, because we were intentionally evaluating the test characteristics of the urinalysis for the diagnosis of UTI, we could not include abnormalities on urinalysis as a criterion in our UTI definition.

CONCLUSIONS

The urinalysis (including any LE, nitrites, or pyuria >5 WBCs/HPF) is a highly sensitive and specific screening test for UTIs in febrile infants ≤60 days old, particularly in those with associated bacteremia. The urinalysis provides valuable and reliable information to clinicians evaluating the youngest febrile infants for serious bacterial infections.

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ABBREVIATIONS

CFU: colony-forming unit
CI: confidence interval
ED: emergency department
HPF: high-power field
LE: leukocyte esterase
UTI: urinary tract infection
WBC: white blood cell

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