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Clinical Predictors of Urinary Tract Infection in the Neonatal Intensive Care Unit

E.E. Foglia* and S.A. Lorch

Abstract

Objective—To identify clinical predictors associated with urinary tract infections (UTI) in patients in a referral neonatal intensive care unit (NICU).

Study Design—We performed a nested case control study of all NICU patients with urine cultures obtained as part of late-onset sepsis evaluations from January 1, 2007 through December 31, 2007 (N=266). Clinical factors and laboratory results were compared between subjects with positive urine cultures (cases, N= 27) and randomly selected subjects with negative cultures (controls, N= 54).

Results—Cases were significantly older than controls at the time of urine culture (75 days vs. 29 days, $p=0.003$). Maximal peripheral white blood cell (WBC) count and C-reactive protein (CRP) did not differ between cases and controls. Only 24% of cases had a simultaneously positive blood culture. In multivariable analysis, only increased chronological age was statistically associated with a positive culture (OR 3.02, 95% CI 1.09, 8.39).

Conclusion—Limited clinical factors exist to identify NICU patients at increased risk for UTI. Peripheral WBC count and CRP do not help discriminate between patients with and without UTI. Clinicians should evaluate chronologically older NICU patients for infection like other young infants, including a urine culture, to adequately identify potential sources of infection.

Keywords

prematurity; neonate; infant; sepsis; “urinary tract infection”

I. INTRODUCTION

The urinary tract is a common site of infection in infants and young children. Urinary tract infections (UTI) are prevalent in up to 5% of febrile children aged 2 months to 2 years with no obvious source of fever [1]. Prospective studies of consecutive neonates place the incidence of bacteriuria between 1-2.4% [2-4]. However, many of these studies were performed in asymptomatic term neonates. It is unclear whether these findings are generalizable to neonatal intensive care unit (NICU) patients, who may have different underlying pathology and immunologic characteristics from febrile term neonates in the newborn nursery or emergency department setting.

Urine cultures are rarely positive in the first 24- 72 hours of life in neonates, but urine cultures obtained in late-onset (3 days of life) sepsis evaluations are positive in up to 5-25% of symptomatic NICU patients [5-8]. The true incidence of symptomatic UTI in

*Corresponding Author Division of Neonatology, Children’s Hospital of Philadelphia, 34th and Civic Center Blvd, 2NW Neonatology Offices, Philadelphia PA 19104, foglia@email.chop.edu (267) 441-7144.

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NICU patients is difficult to estimate, as urine cultures are often not consistently obtained in the course of late-onset sepsis evaluations. The reasons for this are multifactorial and may include the imperfect success rates and limited feasibility of performing urine catheterization and suprapubic aspiration in small and critically ill neonates, the perceived pain associated with these invasive collection methods, and concern of contamination of urine specimens [9-10]. Many practitioners may solely rely on culturing the blood in conjunction with screening tests such as peripheral white blood cell (WBC) count and serum C-reactive protein (CRP) to assess neonates for late onset sepsis. Based on the results of these screening tests, further workup including a urine or cerebrospinal fluid culture may be ordered. However, published studies of the very low birth weight NICU population suggest that less than 50% of patients with positive urine cultures have concomitant positive blood cultures [8,11-13]. This suggests that many UTI are missed when only blood cultures are obtained in late-onset sepsis evaluations in this population.

The correct identification of UTI in the neonate has important therapeutic implications. The American Academy of Pediatrics (AAP) practice parameter regarding UTI in young children aged 2-24 months recommends 7-14 days of antimicrobial therapy for the treatment of UTI [14]. The diagnosis of UTI in young infants also leads to evaluation with diagnostic imaging, including routine ultrasound imaging of the urinary system. While no clear guidelines exist for the evaluation and treatment of neonates with a UTI, many clinicians apply the AAP practice parameter to the neonatal population.

Although ideally urine cultures would be obtained in all patients receiving a sepsis rule out, the ability to identify patients in the NICU who are at increased risk for UTI would help ensure that those patients have urine cultures included in late-onset sepsis evaluations. Risk factors for UTI have been identified in the very low birth weight population; it is unclear whether these risk factors are the same for full term and older NICU patients. Further, the utility of laboratory tests such as WBC and CRP in the diagnosis of nosocomial UTI is uncertain in this patient population. We sought to identify clinical predictors that are associated with an increased risk of urinary tract infections in a referral NICU population.

II. METHODS

1. Study Design and Setting

We performed a retrospective nested case control study of infants in the Children's Hospital of Philadelphia (CHOP) Neonatal Infant/Intensive Care Unit (NICU). The CHOP NICU is a combined medical and surgical unit; all patients admitted during the study period were outborn. Patients admitted to the NICU include term and preterm infants who require services that are unavailable at referring hospitals such as: pediatric surgical care, subspecialty medical services, or advanced levels of supportive care such as inhaled Nitric Oxide or extracorporeal membrane oxygenation (ECMO). The unit at that time had 50 beds with an average of 75 admissions per month. We identified all NICU patients who had a urine culture obtained as part of a late-onset (> 3 days of life) sepsis evaluation from January 1, 2007 through December 31, 2007 from the hospital clinical microbiology database.

2. Definition of Positive Culture

We defined a positive culture as isolation of $\geq 1,000$ colony forming units/mL (CFU) of a single organism or $\geq 10,000$ CFU of 2 organisms from a specimen obtained by either suprapubic aspiration or urethral catheterization. Cultures that did not meet these criteria were designated negative. Eligible cultures with Coagulase-negative *Staphylococcus* (CoNS) isolated in culture were considered cases and included in our analysis. Secondary analysis was performed after excluding cases with CoNS from analysis to determine if including these cultures significantly changed the results of our study. To determine if a

more stringent definition of positive culture would change the study results, a secondary analysis was also performed defining a positive culture as $\geq 1,000$ CFU of a single organism by suprapubic aspiration or $\geq 10,000$ CFU of 1 or 2 organisms from a specimen obtained by urethral catheterization.

3. Case Definition

Cases were defined as subjects with a documented positive urine culture. Controls were defined as subjects with a documented negative urine culture. In order to limit the study population to neonates and young infants, only subjects who were ≤ 120 days old when the urine culture was obtained were included. Additionally, urine cultures that were obtained within 7 days of a previously positive culture were considered “test of cure” and were excluded. For patients with more than 1 positive culture, only the first positive culture was included in the analysis. Infants who were known to have urologic anomalies prior to culture and patients with a diagnosis of myelomeningocele were excluded. Controls were randomly selected in order to provide a 2:1 ratio of controls to cases. Controls were not matched to cases on the basis of gestational age or birth weight in order to retain the ability to investigate a possible association between these factors and UTI in neonates. Controls with multiple negative cultures only had data from one negative culture included in the analysis; the culture that was included was determined randomly when controls were selected.

4. Clinical Predictors

Information on coexisting medical conditions, clinical factors, and screening test results were included as predictive factors based on prior association with UTI [8,11,13]; their association with a more severe neonatal course, which may change the underlying risk of an infant having a UTI or whether the infant receives a sepsis workup; or because their occurrence would result in a sepsis workup in an infant. Daily clinical and laboratory data were abstracted for the day prior to culture and the day of culture. Clinical factors reported to be associated with UTI in other neonatal and pediatric populations were included: gestational age, birth weight, chronological age, male sex, exposure to indwelling devices, and exposure to enteral feeds [11,13]. Bronchopulmonary dysplasia (BPD) and patent ductus arteriosus (PDA) are commonly measured short-term outcomes in premature neonates that are associated with more severe clinical course and may change the threshold for performing a sepsis evaluation. Clinical signs that often prompt sepsis evaluations include temperature instability (documented temperature $<36^{\circ}\text{C}$ or $>38^{\circ}\text{C}$ on day preceding or day of urine culture) and requirement of higher level of respiratory support (ie, from nasal cannula to continuous positive airway pressure (CPAP), or from CPAP to mechanical ventilation).

Peripheral WBC count and CRP values are laboratory tests that are often obtained in the course of sepsis evaluations to gauge risk of serious bacterial infection in NICU patients; these data were collected and included in analysis to determine if either laboratory test is associated with increased risk of nosocomial UTI. WBC count and CRP obtained within 24 hours of urine culture were included. If multiple laboratory data were obtained in this time period, the maximum value for each laboratory test was utilized. Sensitivity and specificity were calculated for CRP and WBC, as these test characteristics do not depend on the underlying disease prevalence. The following cutoff values were used to define a positive result: CRP > 1.5 mg/dL and WBC $> 15 \times 10^3/\mu\text{L}$. A receiver operating characteristic (ROC) curve was generated to quantify the discriminatory value of the WBC count and CRP in the diagnosis of UTI. The ROC curve plots the probability of a true-positive rate against false-negative rate at various cutoff levels obtained for each laboratory test. The area under the curve (AUC) measures a test's discriminating power, with a value of 0.5 indicating that the test performs no better than chance alone and a value of 1.0 representing perfect diagnostic performance.

5. Data Analysis

Data were analyzed using STATA 12.0 (College Station, TX, USA). Dichotomous variables were analyzed using χ^2 testing; Fisher's exact test was used for variables with cell frequencies <5. Continuous variables were analyzed with Student's t test for normally distributed data and Wilcoxon rank sum test for non-normally distributed data. For multivariable analysis, variables that had a p value ≥ 0.1 in univariable analysis were included in the logistic regression model. Birth weight was excluded from the model due to its collinearity with gestational age. Gestational age was included in the model as a categorical variable of prematurity (gestational age <37 weeks), as this variable was thought to hold more clinical significance than looking at differences in gestational age on a week-by-week difference. Likewise, because chronological age of 60 days was a natural breaking point between cases and controls, age at culture was represented in the model with the variable "age greater than 60 days." The Children's Hospital of Philadelphia Institutional Review Board approved this study.

III. RESULTS

There were 266 urine cultures obtained during the study period. Of eligible cultures, 27 were positive. The organisms most commonly isolated were *Escherichia coli* (25%), *Klebsiella* sp. (22%), and *Enterococcus* sp. (19%) (Figure 1). There were no *Candida* species isolated in culture.

Demographic data were compared between cases and controls (Table 1). The gestational age was lower in cases (32 weeks) than controls (36 weeks) ($p=0.01$). Cases also had a lower birth weight as compared to controls (1255g vs. 2280g, $p=0.045$). Cases were significantly older than controls at the time of culture (median 75 days vs. 29 days, $p=0.003$). Urine cultures were more commonly obtained from male than female patients in both case and control groups; no significant difference in sex existed between groups. No significant differences were found between cases and controls with respect to presence of BPD, PDA or death before discharge. There were no other identifiable differences in clinical factors at the time of culture between cases and controls, including temperature instability, exposure to enteral feeds, exposure to breast milk, exposure to TPN, presence of a central line or foley catheter, or change in respiratory support.

Laboratory values were compared between cases and controls. There was no significant difference in maximal WBC value between cases ($16.1 \times 10^3/\mu\text{L}$) and controls ($15.0 \times 10^3/\mu\text{L}$), ($p=0.93$). Likewise, the maximal CRP value did not significantly differ between cases (5.2 mg/dL) and controls (3.8 mg/dL), ($p=0.78$). In this setting, CRP had a sensitivity of 83% and a specificity of 35%, and WBC had a sensitivity of 54% and a specificity of 51%. ROC analysis confirmed the poor diagnostic performance of WBC count and CRP. The AUC associated with WBC count was 0.51 (95% CI 0.37, 0.64), and the AUC associated with CRP was 0.53 (95% CI 0.25, 0.81).

Blood cultures were acquired simultaneously with urine cultures in 90% of subjects, and the proportion of subjects with blood cultures obtained was similar between cases and controls. The concordance of positive blood cultures and urine cultures was low. Among subjects with blood cultures obtained, 24% of cases and 21% of controls had a positive blood culture ($p=0.76$).

Chronological age greater than 60 days remained significantly associated with cases in logistic regression (Odds Ratio 3.02, 95% CI 1.09, 8.39). Neither prematurity (OR 2.29, 95% CI 0.64, 8.14) nor presence of a documented PDA (OR 0.87, 95% CI 0.29, 2.38) was significantly associated with UTI after adjusting for other predictive factors.

The analysis was repeated when cases with CoNS were excluded. In this secondary analysis, CRP, WBC, and blood culture positivity still were not significantly associated with cases. In univariable analysis, birth weight was not associated with cases. Gestational age was significantly lower in cases than controls (33 weeks vs. 36 weeks, $p=0.03$) in univariable analysis, but prematurity was not significantly associated with cases in multivariable analysis ($p=0.52$). Chronological age remained associated with cases in univariable analysis ($p=0.004$) and multivariable analysis ($p=0.02$).

Finally, a secondary analysis was performed using a more stringent definition of positive urine culture ($\geq 1,000$ CFU of a single organism by suprapubic aspiration or $\geq 10,000$ CFU of 1 or 2 organisms from a specimen obtained by urethral catheterization). In this analysis, there was no significant difference between cases and controls with respect to CRP, WBC, or percent of positive blood cultures. Gestational age was significantly lower in cases than controls in univariable analysis (32 weeks vs. 35 weeks, $p=0.04$) but not in multivariable analysis ($p=0.2$). Birth weight was lower in cases than controls, although this result did not reach statistical significance (1575g vs. 2380g, $p=0.054$). Older chronological age was significantly associated with cases in univariable analysis ($p=0.01$) but was not independently associated with cases in multivariable analysis ($p=0.18$).

IV. DISCUSSION

We performed a nested case control study to identify clinical predictors associated with UTI in a referral NICU population. In our multivariable analysis, UTI occurred more frequently in subjects who were chronologically older at time of culture; no other clinical or demographic factors were significantly associated with UTI in this population. There was no significant difference in maximal WBC count or CRP value between cases and controls. These tests performed no better than chance at discriminating between cases and controls. The concordance of positive blood culture with positive urine cultures was low in our study, as only 24% of cases had a concomitant positive blood culture. No significant difference in the proportion of subjects with a positive blood culture existed between cases and controls. The practice of exclusively relying on blood cultures, screening laboratory tests, or clinical symptoms to diagnose bacterial infections likely leads to the significant under-diagnosis of UTI in NICU patients, as the majority of patients with UTI in this population had negative blood cultures. Clinicians should workup chronologically older infants in the NICU for infection like other young infants, including a urine culture, to adequately identify potential sources of infection.

UTI in older children are classically thought to originate from ascending colonization and infection of the urinary tract. In contrast, in neonates UTI are considered to originate from hematogenous spread. For this reason, many practitioners rely on blood cultures alone for the identification of potential pathogens. However, only 24% of cases in this study had positive blood cultures. Previous studies have also described low rates of positive blood cultures in neonates with positive urine cultures [8,11-13]. The low concordance of positivity between blood and urine cultures may suggest that more neonatal UTI arise from ascending colonization than previously thought. However, this discordance might result from seeding of the urinary tract from transient bacteremia or could simply reflect the low yield of small volume blood cultures obtained from bacteremic neonates. At this hospital, standard procedure is to obtain at least 1 mL of blood for cultures, which increases the yield of culture [15]. Even given this practice, it is clear that reliance solely on blood cultures is an insufficient method for the identification of all microbial infections in neonates.

The most commonly isolated organisms in this study were enteric bacterial pathogens. There were no fungal organisms isolated in culture. These results are similar to other studies of

nosocomial UTI in NICU patients, which have reported *Klebsiella* sp., *Enterobacter* sp., and *Echerichia coli* as the organisms most commonly isolated in urine culture of NICU patients [8,11]. Other reports in the literature have described a higher proportion of *Candida* sp. isolated in culture, with up to 42% of UTI caused by *Candida* sp. [5,12]. Those studies included subjects with a lower average gestational age and lower average birth weight than our population. Indeed, lower birth weight, younger gestational age, and younger chronologic age at time of culture have been described as risk factors for UTI from *Candida* when compared to bacterial UTI in NICU patients [12]. The fact that our population is generally bigger and older than subjects in those studies may explain why *Candida* was not a significant causative pathogen in this study. Of note, antifungal prophylaxis is not routinely used in our NICU; fluconazole prophylaxis is used only in premature infants <32 weeks gestation with abdominal drains in place following perforated necrotizing enterocolitis.

The utility of elevated CRP and WBC values in predicting serious bacterial infection in young infants is unclear. Obtaining serial CRP values has been shown to have high negative predictive value for both early-onset and late-onset sepsis in neonates, but the positive predictive value of serial CRP values is low [16]. The role of CRP and WBC for predicting UTI in febrile infant has been studied in the outpatient setting; these tests demonstrate high specificity but low sensitivity in that population [17]. In this study, the maximal WBC and CRP values were almost indistinguishable between cases and controls. Additionally the AUC for each test was just over 0.5, indicating that these tests perform no better than chance alone for identifying NICU patients at increased risk for nosocomial UTI.

Previous studies have identified low birth weight as a risk factor for UTI in NICU patients [8,11,13]. We also found lower birth weight and lower gestational age to be associated with UTI in univariable analysis but not in multivariable analysis. Female sex and exposure to breast milk have previously been identified as protective clinical factors [11]; these factors were not associated with a lower risk for UTI in this study. Other studies have demonstrated that the incidence of UTI is much higher in late-onset sepsis evaluations than in sepsis evaluations performed in the first days of life [5, 13]. In our study, we found that the risk of UTI continues to increase with chronological age.

This study had several limitations. Our sample size was small, and we may have been underpowered to detect other clinical characteristics that are significantly associated with UTI in NICU patients. A further limitation is the retrospective nature of the study. Other studies have demonstrated that urinalysis is an important adjunct to the diagnosis of UTI [18]. Our analysis was limited to the laboratory data that were routinely obtained in this patient population, and urinalysis was not commonly obtained with urine culture during the study period. We performed our study in a referral NICU with a mixed population of medical and surgical patients. The unique nature of this patient population may limit the generalizability of these findings to NICU settings that consist of only inborn patients.

Lastly, our definition for UTI was based on prior studies and clinical practice. The definition of positive urine culture in children is inconsistent in the literature [13]. In many studies of older, healthier children, thresholds of 50,000 CFU or more of a single pathogen are used to define UTI [19]. Our patient population has different underlying characteristics, such as more immature immune systems and more frequent exposure to invasive devices that increases susceptibility to infection. Therefore, we used CFU cutoffs similar to those found in other published studies of neonates, which range from 100-10,000 CFU [8,11]. It is possible that this more inclusive definition of UTI biased our results toward the null. A secondary analysis of the data using a more stringent definition of positive urine culture did not substantially change the study findings.

Although CoNS is often considered a contaminant in urine cultures of older patients, cultures with CoNS isolated were included as cases in this study. NICU patients are exposed to different underlying pathogens than are healthy outpatients, and CoNS is often considered a causative pathogen of sepsis in NICU patients [20]. Further, CoNS has been demonstrated to be the sole causative pathogen of UTI in NICU patients [13]. To account for the possibility that including these cases distorted the study findings, we performed a secondary analysis performed without these cases. Excluding CoNS did not significantly alter any of the study findings.

In conclusion, we performed a nested case control study to identify characteristics associated with UTI in a referral NICU population. The only identifiable risk factor associated with UTI was older chronological age; no other clinical predictors of UTI were identified in this population. The proportion of positive blood cultures and the maximal WBC and CRP values did not differ significantly between cases and controls. Reliance on WBC, CRP, and blood culture results is an inadequate method of identifying UTI in NICU patients. The only dependable way to identify UTI in NICU patients is to include a urine culture as part of the late-onset sepsis evaluation.

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Figure 1. Organisms isolated in urine culture

*Other: Includes *Serratia*, *Pseudomonas*, *Acinetobacter*, *Staphylococcus* species

Table 1**Clinical Characteristics and Laboratory Results of Cases and Controls**

	Case (n=27)	Control (n=54)	P Value
Gestational age (weeks) *	32 (26, 33)	36 (28, 38)	0.01
Birth weight (g) *	1255 (750, 2500)	2280 (1120, 3000)	0.045
Preterm (GA<37 weeks)	23 (85.2%)	34 (63.0%)	0.04
Male	21 (71.8%)	36 (66.7%)	0.30
Death before discharge	9 (33.3%)	12 (22.2%)	0.28
BPD	19 (70.4%)	29 (53.7%)	0.15
PDA	16 (59.3%)	21 (38.9%)	0.096
Age at culture (days) *	75 (28, 98)	29 (15, 66)	0.003
Age > 60 days at culture	16 (59.3%)	15 (27.8%)	0.006
NPO	17 (63.0%)	39 (72.2%)	0.40
TPN	21 (77.8%)	40 (74.0%)	0.72
Breast milk	10 (47.0%)	15 (27.8%)	0.40
Foley Catheter	4 (14.8%)	12 (22.2%)	0.43
Central Line	20 (74.1%)	34 (63.0%)	0.32
Increased Support	4 (14.8%)	10 (18.5%)	0.68
Temperature Instability	9 (33.3%)	27 (50.0%)	0.16
WBC Count ($10^3/\mu\text{L}$) *	16.1 (12.1, 21.4)	15.0 (12.1, 20.1)	0.93
CRP (mg/dL) *	5.2 (0.7, 17.7)	3.8 (1.1, 8.7)	0.78
Positive Blood culture	6/25 (24.0%)	10/48 (20.8%)	0.76

* Reported as median (IQ range)

Abbreviations used in table: BPD: Bronchopulmonary Dysplasia, PDA: Patent Ductus Arteriosus, NPO: "Nothing by mouth," TPN: Total Parenteral Nutrition, WBC: White Blood Cell, CRP: C-Reactive Protein