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Urinary Tract Infections in 1- to 3-Month-Old Infants: Ambulatory Treatment With Intravenous Antibiotics

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Urinary Tract Infections in 1- to 3-Month-Old Infants: Ambulatory Treatment With Intravenous Antibiotics

WHAT'S KNOWN ON THIS SUBJECT: It is common practice to hospitalize 1- to 3-month-old infants with febrile UTIs and to treat them with intravenously administered antibiotics.

WHAT THIS STUDY ADDS: This is the first study to examine ambulatory treatment with short-term, intravenous antibiotic therapy for young infants with febrile UTIs. This treatment option is feasible and may reduce significantly the number of hospital admissions for UTIs in this age group.

abstract

OBJECTIVE: The goal was to examine the feasibility of outpatient management for 1- to 3-month-old infants with febrile urinary tract infections.

METHODS: A cohort study was performed with all children 30 to 90 days of age who were evaluated for presumed febrile urinary tract infections in the emergency department of a tertiary-care pediatric hospital between January 1, 2005, and September 30, 2007. Patients were treated with intravenously administered antibiotics as outpatients in a day treatment center unless they met exclusion criteria, in which case they were hospitalized.

RESULTS: Of 118 infants included in the study, 67 (56.8%) were admitted to the day treatment center and 51 (43.2%) were hospitalized. The median age of day treatment center patients was 66 days (range: 33–85 days). The diagnosis of urinary tract infection was confirmed for 86.6% of patients treated in the day treatment center. *Escherichia coli* was identified in 84.5% of urine cultures; 98.3% of isolates were sensitive to gentamicin. Six blood cultures (10.3%) yielded positive results, 5 of them for *E coli*. Treatment with intravenously administered antibiotics in the day treatment center lasted a mean of 2.7 days. The mean number of visits, including appointments for voiding cystourethrography, was 2.9 visits. The rate of parental compliance with day treatment center visits was 98.3%. Intravenous access problems were seen in 8.6% of cases. Successful treatment in the day treatment center (defined as attendance at all visits, normalization of temperature within 48 hours, negative control urine and blood culture results, if cultures were performed, and absence of hospitalization from the day treatment center) was obtained for 86.2% of patients with confirmed urinary tract infections.

CONCLUSIONS: Ambulatory treatment of infants 30 to 90 days of age with febrile urinary tract infections by using short-term, intravenous antibiotic therapy at a day treatment center is feasible. *Pediatrics* 2009;124:16–22

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KEY WORDS
urinary tract infection, pyelonephritis, child, ambulatory treatment

ABBREVIATIONS
UTI— urinary tract infection
ED— emergency department
DTC— day treatment center
CSF— cerebrospinal fluid
OR— odds ratio
CI— confidence interval

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It is common practice to hospitalize very young infants with febrile urinary tract infections (UTIs) and to treat them with intravenously administered antibiotics. Children <3 months of age are of special concern, given their increased risk of developing bacteremia in association with UTIs.[1–3] Although it is a controversial issue,[4,5] some authors also consider young children to be at greater risk of developing renal scars after an episode of febrile UTI.[6,7]

Ambulatory treatment with intravenously administered antibiotics for children 3 months to 5 years of age with febrile UTIs has been shown to be safe, feasible, and satisfactory to parents.[8] To date, no description of ambulatory treatment with parenterally administered antibiotics for infants 1 to 3 months of age with UTIs has been reported. We hypothesized that specific challenges, namely, intravenous access problems and reluctance of emergency department (ED) physicians to send young infants with bacterial infections home during the first 24 to 48 hours of treatment, might be encountered with this approach in this age group. Our goal was to describe the feasibility of outpatient treatment with intravenously administered antibiotics in a day treatment center (DTC) for infants 1 to 3 months of age.

METHODS

A clinical protocol outlining treatment for infants 1 to 3 months of age with UTIs was implemented in 2005 at Sainte-Justine University Hospital Center, a tertiary-care pediatric center in Montreal, Canada. All children 30 to 90 days of age with a presumed diagnosis of febrile UTI in the ED were eligible for treatment according to the protocol. The decision to perform a lumbar puncture was made according to the clinical judgment of the ED pediatrician. Children who appeared nontoxic, who had normal renal function, and who met no other exclusion criteria received a single dose of intravenously administered gentamicin (5 or 2.5 mg/kg per dose, depending on the time of administration), a single dose of intravenously administered ampicillin, and 2 or 3 doses of orally administered amoxicillin, to be taken until the first visit at the DTC. That visit was scheduled within the next 24 hours, with daily visits until the end of intravenous treatment. Gentamicin was administered through peripheral intravenous access; the patency of the intravenous catheter was maintained with 50 U of heparin injected once daily. Parents were asked to measure the child's rectal temperature every 4 hours at home during intravenous treatment. Exclusion criteria for treatment in the DTC were as follows: age of <30 days, toxic appearance or dehydration, abnormal renal function, dubious parental compliance, history of urinary tract surgery, abnormal cerebrospinal fluid (CSF) findings (leukocyte count of >10 cells per μL or protein level of >0.40 g/L), or other serious medical conditions. Children who met any of these criteria were hospitalized.

The DTC was open 7 days per week and was staffed by pediatric hospitalists. In the DTC, treatment was continued with once-daily dosing of intravenously administered gentamicin (5 mg/kg per day) until the child was afebrile for ≥24 hours and urine culture results were available. Oral amoxicillin treatment was discontinued when Gram-negative bacilli were identified in preliminary urine cultures. After gentamicin treatment was stopped, oral antibiotic therapy was continued for a total of 10 days. The choice of orally administered antibiotics was made on the basis of urine culture results. Children experiencing a first episode of UTI underwent renal ultrasonography and voiding cystourethrography before being discharged from the DTC. Repeat urine and blood cultures were performed only at the physician's request.

A retrospective cohort study was conducted to evaluate the application of this protocol between January 1, 2005, and September 30, 2007. During the study period, infants 30 to 90 days of age diagnosed with a first episode of presumed UTI in the ED were included in the study, provided they had a history of fever within 48 hours before the ED visit or a rectal temperature of >38°C in the ED.

Eligible patients admitted from the ED to the DTC or to a hospital ward were identified through review of the respective units' admission rosters. The charts of all children with an admission diagnosis of UTI or acute pyelonephritis were reviewed, to identify children meeting the inclusion criteria. The charts of all hospitalized patients 30 to 90 days of age with a discharge diagnosis of UTI or acute pyelonephritis also were reviewed. From this group of patients, we included children for whom UTI was the working diagnosis in the ED, although this specific diagnosis was not written on the admission roster. All medical charts were reviewed by 1 member of the research team (Dr Doré-Bergeron). Demographic data, laboratory results, and information on the clinical course and treatment were noted.

The diagnosis of UTI was deemed certain if urine cultures obtained through suprapubic aspiration showed Gram-negative bacteria (any amount) or $>10 \times 10^6$ colonies per L of Gram-positive bacteria or urine cultures obtained through bladder catheterization showed $>50 \times 10^6$ colonies per L of a single pathogen (excluding lactobacilli, corynebacteria, and coagulase-negative staphylococci) or $>10 \times 10^6$ colonies per L of *Pseudomonas* species. The diagnosis of UTI was deemed

probable if urine culture results were not consistent with these criteria but were deemed diagnostic of UTI by the treating physician. All cases of certain or probable UTI were considered as having a final diagnosis of UTI for the purposes of this study.

Descriptive statistics were calculated for the entire cohort. Univariate and multivariate analyses using logistic regression were performed to assess whether an infant's age was associated with successful implementation of the treatment protocol. The appropriateness of patient referral to the DTC or a hospital ward by ED practitioners was one of the outcome variables. The following covariates were used in the analysis for this outcome: child's age of ≤60 days, distance between home and the hospital of <20 km, ED physician's experience of ≤10 years, and time of day of ED assessment (child evaluated during the evening or night shift, as opposed to the day shift). Another outcome variable was created to reflect successful treatment in the DTC (defined as attendance at all visits, resolution of fever within 48 hours, negative control urine and blood culture results, if cultures were performed, and absence of hospitalization from the DTC). The following covariates were included in multivariate models involving this outcome: child's age of ≤60 days, distance between home and the hospital of <20 km, and type of bacteria found in urine cultures (*Escherichia coli* versus other bacteria). Maximal likelihood estimates of regression coefficients were used to estimate crude and adjusted odds ratios (ORs). Ninety-five percent confidence intervals (CIs) were calculated for all estimates reported. All analyses were performed by using SPSS 11.0.1 (SPSS Inc, Chicago, IL). This study was approved by the Sainte-Justine University Hospital Center institutional review board.

RESULTS

A total of 129 infants were eligible for the study. Eleven patients were excluded because they were already receiving antibiotics at the time of their ED visit. Of the remaining 118 patients, 56.8% were sent to the DTC from the ED to complete their treatment and 43.2% were hospitalized. Patient flow throughout the study is summarized in Fig 1.

Most patients were evaluated in the ED during the evening or night shift (79.7%), by a physician with ≤10 years of experience (55.6%). More than one third of patients (36.4%) lived >20 km from the hospital. Eighty-seven percent of infants (102 of 118 infants) treated for presumed UTIs in the ED were referred to the appropriate setting (DTC or hospital ward). Two infants were sent to the DTC when they should have been hospitalized because of abnormal lumbar puncture results, according to the protocol's criteria. The CSF analyses for these 2 patients showed mildly elevated protein levels (0.44 g/L and 0.48 g/L) and white blood cell counts of 11 cells per μL and 5 cells per μL; their blood and CSF culture results remained negative. Fourteen infants were hospitalized, although the information available in their charts did not indicate a reason for hospitalization (Table 1). Adherence of ED physicians to patient referral to the appropriate setting (DTC or hospital ward) was somewhat lower for younger infants, but this association was not statistically significant (crude OR, comparing ≤60-day-old children with older children: 0.5 [95% CI: 0.2–1.5]). This finding was unchanged with adjustment for the distance between home and the hospital, the experience of the ED physician, and the time of day at which infants were seen in the ED (adjusted OR: 0.4 [95% CI: 0.1–1.5]). No significant association was found between these other covariates and appropriate treatment setting referral.

A final diagnosis of UTI was made for 86.6% of patients sent to the DTC. Characteristics of these infants are presented in Table 2. The diagnosis was deemed certain for 82.8% of patients and probable for 17.2%. Ninety-eight percent of bacteria identified in urine

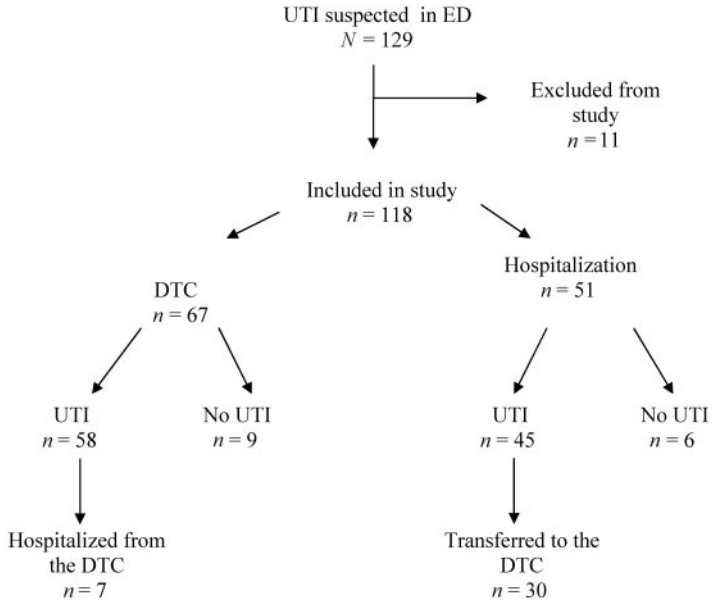

FIGURE 1
Patient flow through the study.

TABLE 1 Reasons for Hospitalization From ED ($N = 51$)

Variable	*n* (%)
Abnormal CSF findings	11 (21.6)
Toxic appearance/dehydration	16 (31.3)
Underlying medical problem	5 (9.8)
Abnormal creatinine levels	1 (2.0)
Parental refusal	4 (7.8)
No reason specified	14 (27.5)

cultures were sensitive to gentamicin. Seven patients (12%) underwent lumbar punctures in the ED; all CSF cultures yielded negative results. Six patients had bacteremia. Five of the 6 infants with bacteremia underwent follow-up blood cultures, all of which yielded negative results.

The clinical course for patients with confirmed UTIs treated in the DTC is presented in Table 3. Fever resolution occurred within 48 hours after treatment initiation for 98.3% of patients. Minor problems with intravenous access, including failure to establish intravenous access (gentamicin was administered intramuscularly) and the need to replace the intravenous line during the course of therapy, were encountered for 5 patients (8.6%). Parental compliance with scheduled visits was excellent (98.3%).

Seven patients were hospitalized from the DTC. One child had concomitant gastroesophageal reflux severe enough to justify hospitalization. Another infant was found to have right hydronephrosis and was admitted for completion of the investigation. Five of the 6 children with bacteremia also were hospitalized, not because of clinical deterioration but simply because of the positive blood culture results. These infants all had uneventful hospital stays. The only patient with bacteremia who was not hospitalized also had an uneventful course. He received 2 days of intravenous antibiotic therapy for *E coli* bacteremia, followed by oral antibiotic treatment.

Treatment was considered successful for 86.2% of patients treated in the DTC. Seven of the 8 "treatment failures" were considered failures because of hospital admission. The overall success of treatment was lower for young infants, but this result was not statistically significant (crude OR, comparing ≤60-day-old children with older infants: 0.2 [95% CI: 0.1–1.1]). This result was unchanged with adjustment for the distance between home and the hospital and the type of bacteria found in urine cultures (adjusted OR: 0.2 [95% CI: 0.1–1.1]). The difference in overall success rates between the 2 age groups was attributable to the frequency of hospitalization for infants ≤60 days of age (5 of 22 infants), compared with older infants (2 of 36 infants); rates of family compliance with appointments and times to resolution of fever were comparable in the 2 groups.

A final diagnosis of UTI was made for 88.2% of patients hospitalized from the ED. Characteristics of these patients are summarized in Table 2. Treatment with intravenously administered antibiotics lasted a mean of 3.8 days (SD: 4.0 days), and the mean length of hospitalization was 3.9 days (SD: 4.6 days). Seven patients (15.6%) had minor intravenous access problems. Thirty children (66.7%) were transferred to the DTC to finish their course of intravenous antibiotic therapy or to undergo renal imaging.

TABLE 2 Characteristics of Infants With Final Diagnoses of UTI Treated in DTC or Hospital ($N = 103$)

Variable	DTC ($N = 58$)	Hospital ($N = 45$)
Male, *n* (%)	37 (63.8)	33 (73.3)
History of renal anomaly, *n* (%)	1 (1.7)	4 (8.9)
Age, median (range), d	66 (33–85)	52 (31–86)
Age distribution, *n* (%)		
30–37 d	3 (5.2)	8 (17.8)
38–45 d	5 (8.6)	6 (13.3)
46–53 d	8 (13.8)	10 (22.2)
54–61 d	9 (15.5)	7 (15.6)
≥62 d	33 (56.9)	14 (31.1)
Temperature in ED, mean ± SD, °C	38.3 ± 0.7	38.7 ± 0.8
Predominant bacteria in urine culture, *n* (%)		
Escherichia coli	49 (84.5)	39 (86.7)
Klebsiella spp	4 (6.9)	3 (6.7)
Proteus mirabilis	1 (1.7)	
Citrobacter spp	1 (1.7)	
Serratia marcescens	1 (1.7)	
Enterococcus		1 (2.2)
Streptococcus spp (not *Streptococcus pneumoniae* or group B)		1 (2.2)
Other	2 (3.4)	1 (2.2)
Blood culture results, *n* (%)	58 (100)	43 (95.6)
Negative	52 (89.7)	40 (93.0)
E coli	5 (8.6)	2 (4.7)
S pneumoniae	1 (1.7)	
Klebsiella spp		1 (2.3)
Absolute white blood cell count, mean ± SD, 10^9 cells per L	17.1 ± 6.0	15.4 ± 5.6
Serum creatinine level, mean ± SD, mmol/L	28.4 ± 6.0	33.4 ± 10.8

DISCUSSION

Our study shows that ambulatory treatment for 30- to 90-day-old infants with febrile UTIs, using short-term, parenteral antibiotic therapy, is feasible. Almost all treatment failures were attributable to hospital admissions from the DTC. In most instances, pa-

TABLE 3 Clinical Course of Infants With UTIs Treated in DTC ($N = 58$)

No. of visits at DTC, mean ± SD	2.9 ± 1.0
Full parental compliance with scheduled visits, *n* (%)	57 (98.3)
Compliance with guidelines for intravenous antibiotic administration, *n* (%)[a]	41 (80.4)
Antibiotic treatment stopped after 24 h without fever[a]	49 (96.1)
Antibiotic treatment stopped once antibiotic susceptibility of isolate known[a]	47 (92.2)
Duration of intravenous antibiotic therapy in DTC, mean ± SD, d	2.7 ± 1.1
Duration of fever after initiation of antibiotic therapy, *n* (%)	
<24 h	53 (91.4)
24–47 h	4 (6.9)
≥48 h	1 (1.7)
Intravenous access-related problems, *n* (%)	5 (8.6)
Hospitalization during course of treatment at DTC, *n* (%)	7 (12.1)
Time between first and last DTC visits, mean ± SD, d[a]	9.3 ± 5.6
Child well clinically at last DTC visit, *n* (%)[a]	51 (100.0)
Successful treatment in DTC, *n* (%)	50 (86.2)

[a] Excluding 7 patients who were hospitalized during the course of treatment in the DTC.

tients were admitted because of positive blood culture results and were not in clinically unstable condition. We did not study long-term results (eg, rate and extent of renal scarring) for the group of patients treated in the DTC. If these patients had been hospitalized, however, they would have been treated with a similar antibiotic regimen in the hospital. In this context, and given the excellent compliance of parents with follow-up care, comparable long-term results could be expected with the 2 approaches (ambulatory versus in-hospital intravenous treatment).

Outpatient parenteral management of acute infections such as febrile UTIs has several advantages, compared with intravenous antibiotic therapy given during traditional hospitalization. It is much less costly for the hospital[8] and for families[9] and, because of a much shorter length of stay within the hospital setting, may decrease the risk of nosocomial infections. More than one half of our 30- to 90-day-old infants with a final diagnosis of UTI were treated in the DTC without being hospitalized. This approach thus seems applicable for a large proportion of cases, despite the patients' young age. Since the end of the study period, this protocol has continued to be applied in our institution; ~40 more 1- to 3-month-old infants have been treated for febrile UTIs in the DTC and, to our knowledge, no significant complications related to the ambulatory treatment have been observed in this group of patients.

According to Dayan et al,[10] outpatient therapy for young infants with UTIs can be advocated only if renal ultrasonography and voiding cystourethrography can be completed in a timely manner. In this study, the rate of parental compliance with appointments for ultrasonography and voiding cystourethrography was almost 100%, similar to rates we observed previously for children 3 months to 5 years of age who were treated in the same setting.[8] This rate is much higher than that reported in a 2005 population-based study from the state of Washington.[11] Our exceptionally high compliance rate is probably attributable to several factors, some of which are directly related to the close follow-up monitoring at the DTC.[8]

Bacteremia associated with UTIs is mostly observed in patients <6 months of age,[1] particularly those <2 months of age, whose risk of bacteremia is between 4.0% and 22.7%.[1,2,10,12,13] In most instances, it is not possible to distinguish children with UTIs with bacteremia from children with UTIs without bacteremia at the time of presentation, on the basis of criteria such as level and duration of fever.[1,3] The standard recommendation for empirical treatment of Gram-negative bacteremia in infants is still parenteral antibiotic therapy.[14] For these reasons, 1- to 3-month-old children with febrile UTIs are usually treated with intravenously administered antibiotics as inpatients.[10,15–17] Administration of short-term, intravenous antibiotic therapy in an ambulatory setting does not allow 24-hour on-site monitoring, as is the case for traditional hospitalization. However, the antibiotic treatment itself can be delivered effectively in an ambulatory setting, by using once-daily dosing of intravenously administered gentamicin.[18] If appropriate intravenous antibiotic therapy is initiated, then infants <3 months of age with UTIs are likely to have an uncomplicated clinical course[10]; this is also true of children with bacteremia.[1–3,10] All of these arguments favor ambulatory intravenous treatment as described in this study. This would not be the case if complications were common or if the likelihood of disease progression was significant despite adequate initial treatment.

Since 1999, 3 multicenter, randomized, clinical trials have addressed the issue of orally administered versus intravenously administered antibiotics for children with febrile UTIs.[19–21] The conclusions of those 3 trials were similar, that is, treatment with orally administered antibiotics (cefixime,[19] co-amoxiclav,[20] or ceftibuten[21]) is as effective as parenteral therapy followed by oral treatment. However, Neuhaus et al[21] did not include infants <6 months of age. Hoberman et al[19] included 13 patients 4 to 8 weeks of age, but only 4 were treated with orally administered antibiotics; all were initially admitted to the hospital for monitoring of their progress. Montini et al[20] studied ~200 patients between 1 and 6 months of

age, but no information was provided concerning the specific distribution of patients within this age category; all children were admitted to the hospital to start therapy, including those receiving orally administered antibiotics. A recent Cochrane review concluded that children with acute pyelonephritis can be treated effectively with orally administered antibiotics.[22] Given the currently available data, however, the authors of the review were unable to perform subgroup analyses distinguishing infants, children, and adolescents. Until more data on the safety of oral treatment for young infants become available, outpatient treatment with parenterally administered antibiotics is an interesting alternative.

The number of children who underwent lumbar puncture before treatment in the DTC was small. There is no clear consensus on indications for performing lumbar punctures for 1- to 3-month-old febrile infants who appear to be well.[14] Several decision rules have been developed in attempts to identify young children at low risk for serious bacterial infection.[23–26] The Boston[25] and Philadelphia[26] criteria require CSF analysis; the Rochester criteria[23,24] do not. Performing lumbar puncture when empirical antibiotic treatment is to be given to a young infant who has fever without an obvious source is a common practice.[14,27] However, the benefits of lumbar puncture for young infants with a presumed diagnosis of febrile UTI, rather than infants with fever without an identified source, have not been assessed. Culture-proven bacterial meningitis is very uncommon in infants <1 to 3 months of age with diagnosed UTIs (<1% of cases)[1,10,28,29] and, to our knowledge, has not been reported for children >60 days of age. Sterile pleocytosis seems more common[13,28]; this phenomenon may render more difficult the interpretation of CSF anomalies in infants with UTIs. During the wait for additional data, the decision to perform a lumbar puncture on the basis of clinical assessment findings seems justifiable for 30- to 90-day-old children with presumed febrile UTIs,[29] especially in experienced hands. Systematic lumbar puncture for children <60 days of age is another option.

Our study was performed in a pediatric tertiary-care hospital. All infants were initially assessed by ED pediatricians. The infants were monitored on a daily basis by pediatric hospitalists until symptoms improved and culture results were obtained. The DTC team also included pediatric nurses who were well trained in the delivery of parenteral antibiotic therapy on an ambulatory basis. Results might have been different in another context.

CONCLUSIONS

Ambulatory treatment for 30- to 90-day-old infants with febrile UTIs, by using short-term intravenous antibiotic therapy in a DTC, is a feasible alternative to hospitalization for more than one half of patients. Excellent parental compliance can be achieved in this setting, which allows close medical supervision. During the wait for more evidence on the safety of oral antibiotic therapy for very young infants with UTIs, this approach may reduce significantly the number of hospital admissions for UTI treatment in this age group.

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