



Lumbar Puncture for All Febrile Infants 29-56 Days Old: A Retrospective Cohort Reassessment Study

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Objectives To determine the incidence of bacterial meningitis (BM) among all febrile infants 29-56 days old undergoing a lumbar puncture (LP) in the emergency department of a tertiary care children's hospital and the number of low-risk febrile infants with BM to reassess the need for routine LP in these infants.

Study design Retrospective cohort study using a quality improvement registry from July 2007-April 2014. Infants included were 29-56 days old with fever and who had an LP in the emergency department. Low-risk criteria were adapted from the Philadelphia criteria. BM was defined as having a bacterial pathogen isolated from the cerebrospinal fluid. A medical record review of one-third of randomly selected patients in the cohort determined the proportion who met low-risk criteria.

Results One of 1188 febrile infants (0.08%) had BM; this patient did not meet low-risk criteria. An additional 40 (3.4%) had positive cerebrospinal fluid cultures; all were contaminants. Subanalysis of one-third of the study population revealed that 45.6% met low-risk criteria; the most common reasons for failing low-risk classification included abnormal white blood cell count or urinalysis.

Conclusions In a cohort of febrile infants, BM is uncommon and no cases of BM would have been missed had LPs not been performed in those meeting low-risk criteria. (*J Pediatr* 2017;187:200-5).

Febrile is a common reason for young infants to seek care in the emergency department (ED). Febrile infants less than 56 days old are at increased risk for serious bacterial infection (SBI),¹⁻³ and clinicians are unable to consistently discriminate between a viral illness and SBI by physical examination alone.^{4,5} This led to the adoption of a conservative practice of routinely acquiring blood, urine, and cerebrospinal fluid (CSF) cultures, empirically treating with antibiotics and hospitalization.⁶ Subsequently, protocols were developed that defined subsets of febrile young infants at low risk for SBI; these patients, generally greater than 28 days old, were candidates for outpatient management, typically without antibiotics.⁷⁻⁹ The principle difference among protocols was whether CSF analysis was used as a low-risk criterion. Guidelines originating in Philadelphia and Boston recommended routinely performing the lumbar puncture (LP), whereas the Rochester protocol did not mandate CSF analysis.⁷⁻⁹

The lack of a universal approach has led to wide variation in clinical practice with respect to laboratory testing and patient disposition and inconsistent adherence to specific guidelines.¹⁰ Since publication of these protocols in the early 1990s, universal use of conjugate pneumococcal and *Haemophilus influenzae* (Hib) vaccines have changed the epidemiology of these infections and the incidence of *Listeria monocytogenes* has decreased.¹¹⁻¹³ Further, the routine acquisition of an LP may be contrary to the goals of value-based medicine by leading to false-positive CSF cultures, unnecessary hospitalizations, increased costs and durations of ED stays, pain for the patients, and parental anxiety.

In contrast, infants managed in a tertiary care referral center may warrant a more conservative approach because they likely have a higher incidence of SBI and bacterial meningitis (BM). The goal of this study was to reassess our standard practice of routinely performing LPs for all febrile infants 29-56 days old. The objectives of this study were to (1) determine the incidence of BM among all febrile infants undergoing an LP in the ED of a tertiary care referral center, (2) determine the ratio of contaminants to true pathogens among those with positive CSF cultures, (3) determine the proportion of study subjects who met low-risk criteria in the absence of CSF analysis, and (4) determine the number of infants meeting low-risk criteria who had BM.

Methods

This was a retrospective cohort study in the pediatric ED of an urban, tertiary care children's hospital with an annual patient volume of more than 90 000 visits.

BM	Bacterial meningitis
CSF	Cerebrospinal fluid
ED	Emergency department
Hib	<i>Haemophilus influenzae</i>
LP	Lumbar puncture
QI	Quality improvement
SBI	Serious bacterial infection

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Table I. Factors that define an infant at low risk for SBI

Past medical histories	Physical examination	Laboratory results
No chronic medical conditions No history of prematurity (<37 weeks gestation) No systemic antibiotics within 72 hours of visit	No skin or soft tissue infection such as omphalitis, mastitis, abscess, or cellulitis Not "irritable," "septic," "lethargic," or "toxic-appearing" No documented hypothermia (<36.5°F)	Peripheral WBC 5-15 000 per microliter Band/neutrophil ratio <0.2 in blood No hypoglycemia (<50 mg/dL) Standard urinalysis negative or small leukocyte esterase, negative nitrites, and <10 WBC/hpf or enhanced urinalysis <10 WBC/mm ³ and negative Gram stain Chest radiograph negative (if obtained)

hpf, high-power field; WBC, white blood cell count.

Infants were included if they were 29-56 days of age, cared for in the ED between July 1, 2007, and April 20, 2014, had a rectal temperature of 38°C or higher measured either at home, in a physician's office, or in the ED, and had an LP and CSF analysis performed in the ED. Infants who had CSF collected from a ventriculoperitoneal shunt were excluded.

Data for this study were extracted from an existing clinical pathway quality improvement (QI) registry. The QI registry was created using data extracted from the electronic medical record and collated in a Database Warehouse using SAS (v9.2) software (SAS Institute, Cary, North Carolina). Patients were identified based on a qualifying date of birth and orders placed for an LP or CSF laboratory specimens. The following data were extracted: medical record number, encounter identification, date of birth, date and time of arrival to the ED, disposition from the ED (admission versus discharge), date and time of hospital discharge, and CSF results.

Two study investigators were assigned randomly to any patient with a positive CSF culture result and independently performed a manual review of those medical records to determine if the patient met low-risk criteria and if the organism was a true pathogen or a contaminant. Medical records were either electronic or scanned copies of paper records, depending on the year that the patient sought ED care. These data were abstracted and entered into a web-based data management tool (Research Electronic Data Capture) for analysis. Data collected included date and time of LP, highest documented fever, identification of CSF bacteria, and time (in hours) for growth of CSF bacteria. Additional data were collected for risk stratification, and an infant at low risk for SBI was defined as one meeting all criteria listed in **Table I**. The 2 investigators determined if the bacteria in the CSF represented a pathogen or a contaminant based on the specific organism, time to positivity, and detailed analysis of the patient's management by hospital physicians. In the event of a disagreement for any data point, a consensus was reached by the 2 investigators. In addition, crosscheck was performed between this database and microbiology laboratory records identifying all children of any age diagnosed with BM over the study period.

A secondary outcome was to determine the proportion of study subjects who met low-risk criteria (**Table I**). The low-risk criteria used in the study were a modification of the original Philadelphia criteria.¹⁴ During the 7-year study period, these data (along with CSF analysis) were used to define low-risk. The existing protocol was for patients judged to be low-risk

to be discharged home without antibiotics. For the study, we sought to determine if we could safely omit the CSF analysis in identifying low-risk infants.

The rate of low-risk subjects was estimated by performing a medical record review on a sample of approximately one-third ($n = 401$) of study infants randomly selected from the original QI registry. Based on previous work, we estimated that 35%-40% of subjects would meet low-risk criteria. An analysis before this study determined that a sample size of 400 subjects produced a 2-sided 95% CI with a width equal to 0.1, if 40% of the sample population was low risk. The data collected for this analysis were the same as those described for infants with a positive CSF culture; data were abstracted and entered into a web-based data management tool (Research Electronic Data Capture) for analysis. Each patient was randomly assigned to 2 study investigators who independently performed a manual review of the infants' medical records; any disagreements were reviewed and consensus determined by the study investigators.

Statistical Analyses

Demographic characteristics were summarized by standard descriptive summaries (eg, means and standard deviations were used for continuous variables and percentage for categorical variables). A χ^2 test was used to compare categorical variables of interest. The magnitude of association between these variables was approximated by calculating ORs and 95% CIs. $P \leq .05$ was considered statistically significant. All analyses were conducted using Stata version 13 (StataCorp, College Station, Texas).

This study was approved by the hospital's institutional review board. The requirement of informed consent/assent was waived.

Results

There were 1188 infants evaluated during the study period. The mean age was 43 days (SD 8) and 160 patients (13.5%) (95% CI 12.6-16.6) had known chronic medical conditions at the time of enrollment. The overall admission rate was 73.0% (95% CI 71.4-76.3). Additionally, during the 7-year study period, there was little variation in the rates of LP performance or hospital admission (**Figure**).

One infant (0.08%) (#41, **Table II**; available at www.jpeds.com) was diagnosed with BM but did not meet low-risk criteria. This patient was a 36-day-old infant born after

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