The evaluation of tests for neonatal sepsis is important because the infection may present a very serious threat to the baby. There is an urgent need to know whether the baby has sepsis to institute treatment as quickly as possible. Confirmation of the diagnosis may take time, and diagnostic tests are used to obtain a rapid indication of the infection status. These tests are not perfect. Some real cases of infection will produce negative test results, whereas some babies without infection will test positive. The potential usefulness of the test will depend, above all, on the clinical condition of the baby. If the baby is really very sick, the test will not give very much additional information. Similarly, if the baby is evidently well, a clinical examination will be sufficient and a positive test result would not dramatically increase the probability that the baby is infected. It is in situations in which the clinical picture leaves the physician in doubt about the infection status that a diagnostic test is likely to be most useful. Thus, the result of a diagnostic test must be evaluated in the light of the clinical condition of the baby.

Extensive literature exists on single laboratory tests or combinations of tests, as well as tests used together with risk factors and/or clinical signs, to diagnose neonatal sepsis. In many instances, the results of the evaluations have been conflicting. There are several possible explanations for the divergent results, and the purpose of this review is to update readers on the topic and raise issues that should be addressed in the future.

**Basic Physiology of Neonatal Infection**

Throughout pregnancy and until the membranes rupture, the fetus is relatively protected from the microbial flora of the mother by the chorioamniotic membranes, the placenta, and poorly understood antibacterial factors in amniotic fluid (1). However, there ...
Neonatal sepsis is a leading cause of morbidity and mortality. Current laboratory tests cannot accurately discriminate endangered neonates. What is new: The diagnostic odds ratio of presepsin is 170.28 and the area under the curve is 0.9751.


All neonates with clinical suspicion of neonatal sepsis according to WHO criteria [11] admitted at NICU and premature Unit were enrolled. Neonates with history of use of antibiotics before enrolment for more than 72 hours and those with body weight less than 1 kilogram were excluded from the study. Sample size and sampling procedure. Sample size was estimated using Buderer formula [12]; using anticipated sensitivity and specificity of 95% and neonatal sepsis prevalence of 40% [3]. The minimum sample size obtained was 305 neonates. Chiesa C, Panero A, Osborn JF, Simonetti AF, Pacifico L: Diagnosis of neonatal sepsis: a clinical and laboratory challenge. Clin Chem. 2004, 50 (2): 279–287. https://doi.org/10.1373/clinchem.2003.025171


Subjects

SUBJECT AREAS

Pediatric Clinical Chemistry

Analysis of the reliability of laboratory tests in the diagnosis of neonatal sepsis must therefore take account of the fact that postnatal age may dramatically affect the interpretation of what constitutes the normal (and equally important the abnormal) value of a laboratory test (60). Virtually all published guidelines stress the need for reference values. The clinical need for highly sensitive CRP assays was first recognized in neonatal pediatric practice (71), and their recent development holds promise for a further increase in the diagnostic accuracy of neonatal infection. However, before introduction of the new tests into routine neonatal practice, the CRP reference intervals to be established by the newly developed assays need to be compared with the traditional ones.