Combur9 urine reagent strips were sensitive and specific in diagnosing viral and bacterial meningitis


Objective
To evaluate the accuracy of urine reagent strips that measure cerebrospinal fluid (CSF) protein, glucose, and leucocytes in diagnosing bacterial and viral meningitis.

Design
Blinded comparison of urine reagent strip results with laboratory examination of CSF.

Setting
University-affiliated hospital in Safat, Kuwait.

Patients
234 children with suspected meningitis.

Description of Test and Diagnostic Standard
The CSF was washed off the reagent strip, Combur9 (Boehringer Mannheim), after 60 seconds, and the color change was read against the standards provided. The criteria for diagnosing bacterial meningitis were glucose concentration < 2.8 mmol/L, protein concentration > 0.5 g/L*, and any number of cells; or glucose concentration ≥ 2.8 mmol/L, protein concentration > 0.5 g/L*, and cell count ≥ 500 per μL. The criteria for diagnosing viral meningitis were glucose concentration 2.8 to 5.5 mmol/L, any amount of protein, and cell count 10 to 75 per μL. The laboratory examination of CSF, the diagnostic standard, was routine. The criteria for diagnosing bacterial meningitis were Gram stain or antigen detection or CSF culture positive; or positive blood culture with meningitis. The criteria for diagnosing presumed bacterial meningitis were negative CSF culture or antigen detection but other findings suggestive of bacterial meningitis. The criteria for diagnosing viral meningitis were clinical and laboratory features of viral meningitis; CSF, blood culture, and antigen-detection negative.

Main Outcome Measures
Sensitivity, specificity, and likelihood ratios.

Main Results
There were 60 viral, 57 bacterial, and 12 presumed bacterial cases of meningitis. Of the 60 viral cases, 2 were misdiagnosed by the strip as viral. Of the 60 viral cases, 2 were considered normal. None of the normal samples of CSF (105) were misdiagnosed; specificity of 100% (CI 98% to 100%). (The likelihood ratio of a positive test approaches infinity, and the likelihood ratio of a negative test was 0.03†.)

Conclusion
Combur9 urine reagent strips were sensitive and specific in diagnosing viral and bacterial meningitis.

Source of funding: In part, Boehringer Mannheim (Combur9 reagent strips).

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Commentary
Bacterial meningitis is among the most common life-threatening conditions in childhood. In many parts of the developing world, diagnostic facilities are unavailable, and physicians must act on clinical assessment alone. This important paper suggests that a simple reagent strip test that is relatively inexpensive (30¢ U.S. per test) can distinguish normal from infected CSF and can diagnose meningitis with a sensitivity of 97% and a specificity of 100%. The study involved 234 children with suspected meningitis. Of the 4 cases misdiagnosed by the strip, 2 of 69 bacterial cases were judged to be viral (and therefore might have adversely affected a clinical decision about therapy) and 2 of 60 cases of viral meningitis were considered normal (a less significant error from the therapy standpoint).

An independent observer was used to assess the strip results, but no data are presented on the precision of that observer’s assessment. Other studies of strip tests suggest that the accuracy and precision of these tests may vary widely, especially under field conditions (1, 2). Their effective shelf-life in developing countries is another concern.

The article does not give details about the selection process of the children in the study or about the clinical and bacteriological details of the cases. Therefore, it is difficult to know how far the findings may be generalised to other populations of children, and this certainly needs further study.

Nonetheless, this valuable study should act as a stimulus to physicians in developing countries to rigorously evaluate the reagent strips in various settings and to confirm or refute the role of the strips as a highly cost-effective diagnostic tool for bacterial meningitis.

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doi: 10.1136/ebm.1996.1.57

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