



Measuring the accuracy of a point system to diagnose tuberculosis in children with a negative smear or with no smear or culture

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Abstract In Brazil, a scoring system was adopted to diagnose tuberculosis in childhood. This study determined the accuracy in diagnosing tuberculosis in children with either a negative smear or with no smear or culture conducted in a reference center in João Pessoa Paraíba – Brazil. It is a phase III validation study, using a cross-sectional design. The study population consisted of 167 patients attending the outpatient clinics suspected of having tuberculosis. The reference standard for the diagnosis of tuberculosis was a blind and independent review of the medical records, radiology and tuberculin test by two experts. Of the 167 patients, 60 were considered to have tuberculosis (by the reference standard diagnostics). The results for the scoring system with the cut-off of 30 points were: sensitivity 78.57% (95%-CI: 65.56–88.41%), specificity 69.16% (95%-CI: 59.50–77.73%), positive predictive value (PPV): 57.14% (95%-CI: 45.35–68.37%), negative predictive value (NPV): 86.05% (95%-CI: 76.89–92.58%), likelihood ratio (+): 2.55, pre-test probability: 34.36%, and post-test probability (+): 57.14%. This supports the current recommendation for the use of this scoring system in Brazil and similar sites with the cut-off of 30 points. However, as the discriminatory power of the point scoring system may vary across settings, it would be advisable to replicate this phase III study in different settings.

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1. Introduction

The diagnosis of tuberculosis in children remains a challenge. Symptoms are non-specific and, in the early phases of the disease, up to 50% of the

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children may be asymptomatic [1,2]. In spite of the advances in tuberculosis diagnosing, no test is highly accurate in children [3]. The presence of acid-fast bacilli on sputum smear microscopy—the standard diagnostic criteria for adults—is rare in childhood. Recently, there has been an increasing interest in defining diagnostic criteria for patients with negative smear and culture [4]. In Brazil, a scoring system was adopted to diagnose tuberculosis in childhood in 2002 [5]. In childhood, bacteriology is positive in only 5% of cases and culture in 25% [6]. Diagnosis in children therefore must be based on clinical and radiological findings, tuberculin test results, epidemiological links, and response to treatment using algorithms or personal experience [6,7].

Diagnostic scoring systems for the diagnosis of tuberculosis were developed, but none are used routinely. All scores have limitations [8–10]: low sensitivity [11,12]; inclusion of smear or culture or histopathology as a criteria [10,11,13], or response to antibiotic therapy or anti-tuberculosis treatment as a step to diagnosis, and postponing the diagnosis of tuberculosis [10,14]. The scoring system adopted in Brazil in 2002 to diagnose childhood tuberculosis in children and adolescents aged 15 years or less has rarely been evaluated [15–18] and was tested retrospectively, mainly with hospitalized patients, which has clear limitations [9,15,17]. The study reported in this paper aims to identify the accuracy of the scoring system proposed by the Ministry of Health to diagnosis tuberculosis in children aged 15 years or less with negative smear and culture attending outpatient clinics.

2. Methods

The study was conducted during the period 2003–2005, in a Reference Center for infectious diseases in João Pessoa Paraíba – Brazil. It is a phase III validation study, according to the Sackett and Haynes (2002) classification [19], using a cross-section design. In phase III studies, all individuals enrolled are suspected of having the disease and the investigation is carried out to verify if the test (the scoring system) distinguishes those with and without the target disorder. It was a delayed-type cross-sectional study in which the follow-up procedure was aimed at retrospectively assessing the health status at time zero, as a substitute for establishing the reference standard diagnosis of tuberculosis immediately at time zero itself [20].

Children and adolescents were considered suspects of tuberculosis according to the guidelines of the Ministry of Health [5]. In short, tuberculosis suspects were those children and adolescents who

had been symptomatic for more than 15 days or who had contact with a respiratory symptomatic patient.

The reference standard for the diagnosis of tuberculosis was a blind and independent review of the medical records, radiology and tuberculin test by two experts in childhood tuberculosis disease. There was an independent assessment of the scoring and the reference standard. The experts were blind with regard to the result of the scoring for each patient, and the interviewer responsible for the application of the score was blind to the diagnosis established by the experts. Experts and the investigator responsible for the application of the score were not informed as to the diagnosis given by the attendant physician or if patients had started treatment for tuberculosis. Disagreement between the two experts was solved by a third expert who would review all discordant diagnoses. Two experts were specialists in pulmonology (by the Brazilian Society of Pulmonology and Tisiology), and one in pediatric infectious diseases (by the Brazilian Pediatric Society) and had experience in attending patients at the hospital and at the outpatient pediatric infectious disease and pediatric pulmonology clinics. Children were classified as positive by the reference standard if, after a period of six months, they had the diagnosis of tuberculosis by two (of three) experts. The steps for selection and follow-up of patients are summarized in Fig. 1.

Smear microscopy for acid-fast bacilli and culture for *Mycobacterium tuberculosis* was requested of all patients. A total of 68 patients were able to expectorate voluntarily and had the smear microscopy and culture performed, four of them had a positive smear and none had a positive culture. The four patients with a positive smear were excluded from the study.

The sample included 163 patients aged less than 15 years attending the outpatient clinics suspected of having tuberculosis disease. A total of 56 cases were diagnosed as tuberculosis disease according to the reference standard. The data were collected in a standard questionnaire applied by the investigator to the patient or caregiver. Sensitivity, specificity, predictive values, likelihood ratios and pre- and post-test probability were calculated for two score cut-off points: 30 and 40 points. All children in the study were followed up for 6 months, with complete treatment for those diagnosed with TB disease by the attending physician. None of the patients included in the study had, nor developed during the follow-up period, any sign or symptom of extra-pulmonary tuberculosis; lymph node, pleural, or other organs or systems

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