Reviewer’s report

Title: Diagnosis of tuberculosis in an Indian population by an indirect ELISA protocol based on detection of Antigen 85 complex: a prospective cohort study

Version: 4 Date: 27 March 2007

Reviewer: Marcus B Conde

Reviewer’s report:

General
I still think there are some methodological concerns to be considered.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. AFB smear of sputum is a diagnostic method with good sensitivity for detecting M.tb among patients with cavitary disease. However, because the low sensitivity in patients with noncavitary TB and in those unable to expectorate spontaneously most reports evaluating new tests (including serologic test) for TB diagnosis should focus on TB patients who do not have a mycobacteriological diagnosis. However, the gold standard method used for the evaluation of a new diagnosis test is a crucial point of the MS. It must be very well described, besides reliable and reproducible. Although I assume that the clinical diagnosis might be used in this circumstance, the description of the criteria used in this MS must be much improved. I think authors should inform in the text:
   • the positive predictive value of respiratory symptoms for the TB diagnosis in the setting of the study (if possible)
   • which specific symptoms were considered for TB diagnosis and if they were considered all together or not (for instances, only low-grade fever during one month was considered TB?)
   • which radiographic evidence was considered suggestive of TB?
   • how the radiographic evaluation has been done (double blind)?
   • what is definition used by the authors for chronic cough or even chronic symptoms (3 weeks?4 weeks?)
   • which ultrasound evidence is considered suggested of TB?
   • I think authors should evaluate separately pulmonary TB and extra pulmonary in this context
   • authors must inform if patients with clinical diagnosis were not able to provide sputum or were all culture/afb negative?
   • how many samples of sputum were collected for patients with clinical diagnosis?
   • which anti-TB treatment was used?
   • patients with clinical diagnosis took anti-TB drug under DOT? Did they take another Medicine or just anti-TB drug?
   • the expression “clinical improvement” is vague and must be better described.
   • actually, “clinical improvement” is not enough for a TB clinical diagnosis and I suggest “clinical AND radiographic improvement”

2. The cut off value is calculated using ROC curve or mean +/- 2 SD. I am not sure if is appropriated using mean +/- 1 SD. I suggest authors use ROC curve for calculation of sensitivity and specificity and inform the CI 95% of both.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests