

Diagnostic accuracy of genetic markers and nucleic acid techniques for the detection of *Leptospira* in clinical samples: a meta-analysis

ABSTRACT

Background: Leptospirosis is often difficult to diagnose because of its nonspecific symptoms. The drawbacks of direct isolation and serological tests have led to the increased development of nucleic acid-based assays, which are more rapid and accurate. A meta-analysis was performed to evaluate the diagnostic accuracy of genetic markers for the detection of *Leptospira* in clinical samples. Methodology and principle findings: a literature search was performed in Scopus, PubMed, MEDLINE and non-indexed citations (via Ovid) by using suitable keyword combinations. Studies evaluating the performance of nucleic acid assays targeting leptospire genes in human or animal clinical samples against a reference test were included. Of the 1645 articles identified, 42 eligible studies involving 7414 samples were included in the analysis. The diagnostic performance of nucleic acid assays targeting the *rrs*, *lipL32*, *secY* and *flaB* genes was pooled and analyzed. Among the genetic markers analyzed, the *secY* gene showed the highest diagnostic accuracy measures, with a pooled sensitivity of 0.56 (95% CI: 0.50-0.63), a specificity of 0.98 (95% CI: 0.97-0.98), a diagnostic odds ratio of 46.16 (95% CI: 6.20-343.49), and an area under the curve of summary receiver operating characteristics curves of 0.94. Nevertheless, a high degree of heterogeneity was observed in this meta-analysis. Therefore, the present findings here should be interpreted with caution. Conclusion: The diagnostic accuracies of the studies examined for each genetic marker showed a significant heterogeneity. The *secY* gene exhibited higher diagnostic accuracy measures compared with other genetic markers, such as *lipL32*, *flaB*, and *rrs*, but the difference was not significant. Thus, these genetic markers had no significant difference in diagnostic accuracy for leptospirosis. Further research into these genetic markers is warranted.