The accuracy of Influenza A (H1N1) “swine flu” laboratory testing: A systematic review of diagnostic test accuracy

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Abstract

Background

Influenza A (H1N1) recently became pandemic, highlighting the need for a cheap and accurate diagnostic test to diagnose this virus in a clinically relevant timeframe. The current reference standard (viral culture) requires a significant degree of technical expertise, laboratory time, resources and can take up to 10 days to obtain a result, during which time there could be a significant spread of infection. The objective of this systematic review was to obtain summary estimates of the diagnostic accuracy of currently available laboratory tests compared to viral culture for the diagnosis of Influenza A (H1N1) from respiratory samples.

Search Strategy

Diagnostic tests are still poorly indexed by major databases; therefore the search strategy was deliberately very broad and was conducted during May 2010. A range of databases of both published and Grey Literature were searched, using both Medical Subject Headings and text words. The reference lists of included studies and review articles were also searched for additional studies.

Selection Criteria

Studies that compared the diagnostic accuracy of any laboratory test (index test) compared to viral culture as the reference test were considered for inclusion. The inclusion criteria required each patient to undergo both the index and reference test, and for the tests to both be specific for influenza A (H1N1). Methodological quality was determined using the QUADAS checklist, a validated critical appraisal tool. No studies were excluded on the basis of poor methodological quality.

Search Results

The search identified 3843 potentially relevant studies. Of these 56 full text articles were retrieved for further analysis. Twenty nine relevant articles were assessed with the QUADAS checklist, with 24 being excluded on the basis of incongruence with the review objective or for containing insufficient detail. The remaining five studies examined the diagnostic accuracy of polymerase chain reaction (PCR), and were included in this systematic review.

Methodological Quality

The methodological quality of studies was assessed using the 14 item QUADAS checklist.

Data Extraction

Data was extracted from the included studies using both the QUADAS and STARD checklists. The checklists allowed an assessment of the quality and completeness of the conduct and reporting. Data was collected to determine the accuracy of the index tests. Patients were identified as being either H1N1 positive or negative on the basis of the viral culture results. The index test results were then compared for sensitivity and specificity.

Main Results

Five studies were included, containing a total of 1581 patients. Overall the methodological quality of the studies was moderate, however all suffered from incomplete reporting. Two notable areas of deficit were the reporting of reference test details and specific details related to the specificity of the index test. In addition to insufficient detail, the level of heterogeneity between the reference tests was unknown. As a result of these two factors, combining the test results in meta-analysis of data was not appropriate.

Two studies reported accuracy measures and when reported, the sensitivity and specificity of PCR was high. Although unable to generate a summary estimate of the overall accuracy of PCR, the results of this systematic review suggest that PCR using respiratory specimens appears to be highly sensitive and specific at identifying patients with H1N1.

Conclusions

There is limited evidence to suggest that polymerase chain reaction diagnostic tests are accurate in diagnosing H1N1. This systematic review highlights the need for better reporting and indexing of studies that examine the diagnostic accuracy of laboratory tests in general, and H1N1 specifically. This rapidly expanding area of research needs structure and consistency in order for its findings to be useful to health care clinicians and decision makers.

Student declaration

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution to Sarahlouise White and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

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Completion of this thesis would not have been possible without the support of Professor Alan Pearson and Dr Tim Schultz – thank you both so very much for your support.

Signed:

Dated: 31 July 2011