TITLE: Point-of-Care International Normalized Ratio Testing Versus Plasma-Based Testing: Comparative Accuracy and Reliability

DATE: 26 April 2010

RESEARCH QUESTION:

What is the comparative accuracy and reliability of point-of-care international normalized ratio (INR) testing versus plasma-based testing?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 3, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between August 2006 and April 2010. No filters were applied to limit the retrieval by study type. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS:

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment (HTA) reports and systematic reviews are presented first. These are followed by randomized controlled trials (RCTs).

This report is an update to a CADTH HTA published in February 2007. The current report includes articles published about point-of-care (POC) INR since August 2006, which was the final search date of the previous report.
The literature search identified two health technology assessments, one systematic review, and two randomized controlled trials on the comparative accuracy and reliability of POC INR testing versus plasma-based testing. No meta-analyses or controlled clinical trials were identified. Additional articles of potential interest, including observational studies, are provided in the appendix.

OVERALL SUMMARY OF FINDINGS:

Two HTAs were identified by the literature search. An HTA published by the Ontario Health Technology Advisory Committee\(^2\) concluded that patient self-testing, as well as general practitioner (GP) and nurse use of POC INR devices, were as effective as laboratory-based INR testing for the outcomes of thromboembolic events, major hemorrhages, and all-cause mortality. It also stated that POC INR testing might produce better long-term oral anticoagulation control, resulting in greater patient satisfaction and quality of life. An HTA published by the Belgian Federal Health Care Knowledge Centre\(^3\) concluded that POC testing for INR is beneficial for patient outcomes, especially when self-managed by the patient, because it reduces thromboembolic events. For POC testing by GPs or by health professionals in anticoagulation clinics, the report stated that there was no evidence that it affected patients’ clinical outcomes compared with usual care.

A 2010 systematic review\(^4\) assessed any POC testing, including INR, in a general practice setting. Although the abstract did not state outcome findings specific to INR, it did state that there were no significant differences between POC and laboratory testing in terms of clinical effectiveness for any of the clinical conditions studied.

Two RCTs were identified. One trial\(^5\) compared POC testing using CoaguChek S and XS INR with hospital laboratory monitoring. The study results showed good agreement between POC and laboratory testing for the lower values (2.0 to 3.5 INR units), but more disagreement in the values above 3.5 units. The authors concluded that POC testing was reliable and safe, but required monitoring with external quality control. An RCT set in 53 Australian general practices,\(^6\) assessed clinical effectiveness of any POC testing, including INR. The trial results indicated that POC testing was non-inferior to laboratory testing for patients in the target range. However, the conclusions state that POC INR did not provide same or better clinical effectiveness than laboratory testing. The abstract did not explain the discrepancy between these statements.

Overall, the studies included in this report indicate that POC INR testing provides similar clinical outcomes to laboratory testing, with the exception of INR results in the upper ranges.
REFERENCES SUMMARIZED:

Health technology assessments


Systematic reviews and meta-analyses


Randomized controlled trials


Controlled clinical trials

No literature identified
APPENDIX – FURTHER INFORMATION:

Observational studies


