Clinical Question

Does point-of-care testing (POCT) for lipids improve the risk stratification and management of cardiovascular disease compared to standard practice?

ADVANTAGES OVER EXISTING TECHNOLOGY

Requiring less than 5 minutes to perform, cholesterol and triglycerides tests can be carried out during the consultation for the screening and diagnosis of hypercholesterolaemia, as well as CVD risk assessment, and the long-term monitoring of patients already on treatment. Patients could be given their results immediately, providing more accurate categorisation in the QRISK® (www.qrisk.org) or Framingham (www.framinghamheartstudy.org) risk scores and allow appropriate management decisions.

DETAILS OF TECHNOLOGY

Two point-of-care Cholesterol Reference Method Laboratory Network certified devices are available in the UK to measure total and high density lipoprotein (HDL) cholesterol:

1. Cholestech LDX® System (Alere, UK). Several test cassettes are available that perform one or more of: total cholesterol (2.6–12.9 mmol/l), HDL (0.4–2.6 mmol/l), triglycerides (0.5–7.3 mmol/l), total cholesterol/HDL ratio, estimate of low density lipoprotein (LDL), and very low density lipoprotein (VLDL), as well as glucose.

2. Professional CardioChek PA (Polymer Technology Systems, Inc., Indiana, US; BHR Pharmaceuticals Ltd., Nuneaton, UK). Handheld device that performs a range of tests depending on the test strip selected: lipid panel and single testing for glucose, ketone, total cholesterol (2.6–10.3 mmol/l), HDL cholesterol (0.6–2.2 mmol/l), triglycerides (1.3–12.8 mmol/l), and calculated LDL cholesterol.

Measurements are taken from a fingerstick blood sample applied to a cassette or strip, that is inserted into a reader, and results are available in 2–5 minutes.

PATIENT GROUP AND USE

- Patients requiring primary prevention of cardiovascular disease.
- Management of patients with pre-existing cardiovascular disease.
- NHS Health Check for adults aged 40–74 years.
- Patients with a history of familial hypercholesterolaemia.

IMPORTANCE

Cardiovascular disease (CVD) is the main cause of death in the UK, accounting for over 180,000 deaths in 2009: 1 in 3 of all deaths (www.heartstats.org). Lipid lowering therapy (usually a statin) is used in all patients with a history of cardiovascular disease and lipid tests are monitored annually. Assessment of CVD risk for primary prevention is recommended by the National Institute for Health and Clinical Excellence for all patients over the age of 40 years and includes lipid measurement.

PREVIOUS RESEARCH

Accuracy compared to existing technology

The CardioChek and Cholestech LDX devices were evaluated by the UK NHS Purchasing and Supply Agency in 2005.¹ For CardioChek, comparing 106 patients’ samples with laboratory results gave correlation coefficients of 0.86 for total cholesterol (coefficient of variation [CV] = 12%), 0.74 for HDL cholesterol (CV = 22%), and 0.98 for triglycerides (CV = 14%). For Cholestech, comparing 119 patients’ samples with laboratory analysis, the correlation coefficients were 0.97 for total cholesterol (CV = 5%), and 0.95 for HDL (CV = 5–10%). The accuracy of Cholestech LDX measurements of total cholesterol (TC), calculated low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglycerides was compared to laboratory
analyses, giving correlations of 0.91, 0.88, 0.77, and 0.93, respectively (all P<0.01). A study of point-of-care testing (POCT) in Ireland using Cholestech LDX validated the use of this device. However, one study of the accuracy of Cholestech in hyperlipidemic individuals over the age of 70 showed that the portable measurements systematically overestimated triglycerides (0.3 g/L; P<0.001) and HDL-C (0.015 g/L; P = 0.03), while LDL-C concentrations were underestimated (0.043 g/L; P = 0.046). A study comparing CardioChek PA and Cholestech LDX with a standard venous blood sample tested in a laboratory, showed that the Cholestech LDX analyser demonstrated slightly better reproducibility than the CardioChek PA analyser when compared with laboratory gold standard analysis; however, the study was limited by the small sample size (n = 34) with no known risk factors, and did not prove superior accuracy of either device. In a comparative study of 100 samples, correlation coefficients between the POCT and laboratory methods were >0.9 for Cholestech and >0.84 CardioChek. This translates into machines that are fairly accurate. However, at levels near decision thresholds of diagnosis and treatment, the machines may overestimate triglycerides and HDL, and underestimate LDL.

Impact compared to existing technology

References


Funding
The Centre for Monitoring and Diagnosis Oxford (MaDOx) is funded by the National Institute for Health Research, UK programme grant ‘Development and implementation of new diagnostic processes and technologies in primary care’.

Competing interests
The authors have declared no competing interests.

Provenance
Freely submitted; externally peer reviewed.

Acknowledgements
The authors would like to thank Richard Stevens and Nia Roberts for helpful discussions. This article presents independent research commissioned by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0407-10347). The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health.

Discuss this article
Contribute and read comments about this article on the Discussion Forum: http://www.rcgp.org.uk/bjgp-discuss