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Point-of-care testing for the analysis of lipid panels:

primary care diagnostic technology update

Clinical Question

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

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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 $P<0.01$).[2] A study of point-of-care testing (POCT) in Ireland using Cholestech LDX validated the use of this device.[3] 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; $P = 0.046$).[4]

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,[5] 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.[6] 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

A recent Australian multicentre cluster randomised controlled trial of POCT in GP practices involving patients with established hyperlipidaemia, established type 1 or type 2 diabetes, or taking anticoagulant therapy, showed that for all tests except INR (international normalised ratio) and HDL cholesterol, the POCT had the same clinical effectiveness as pathology laboratory testing.[7] The same study also showed that access to POCT was associated with the same or better medication adherence.[8] A survey of GPs and patients showed that cholesterol POCT was strongly supported, citing factors such as convenience and efficiency.[9] A randomised trial of pharmacy-based cholesterol risk management involving 54 community pharmacies and 675 patients at high risk for cardiovascular events showed that in 57% of intervention patients versus 31% in usual care,[10] the primary endpoint of a complete fasting cholesterol panel by the GP, or prescription of new cholesterol-lowering medication or an increase in dosage was reached.

Cost-effectiveness and economic impact

A randomised controlled trial with 4968 patients in 53 general practices across Australia,[11] found a non-significant increase in per-patient direct costs for the POCT group, although there were also cost savings in terms of patient and family-incurred costs (travel and time seeking health care). The main cost contributors were due to increased pharmaceutical costs and hospitalisations (not statistically significant) in the POCT group. The study is limited by reporting its measure of effectiveness in terms of 'proportion of patients within the therapeutic range', rather than life-years or QALYs. POCT is more effective than standard laboratory testing but also more costly; the incremental cost-effectiveness ratio (in terms of incremental cost per patient maintained within the therapeutic range) is reported to be $AUS 10 082 (£4567), requiring a decision as to whether this cost is justified in terms of the value placed on the measure of effectiveness used in this analysis.

A US review of POCT cholesterol monitors described their possible role in pharmacies[12] and suggests that they offer several potential advantages including ease of use, portability, increased patient access, low cost, fewer physician or laboratory visits, and instant results.

Further research is required to determine whether it provides a cost-effective alternative to standard laboratory practice in the UK.

Relevant guidelines

Department of Health. *NHS Health Check: vascular risk assessment and management best practice guidance*. London: TSO, 2009.

National Institute for Health and Clinical Excellence. *Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease*. NICE clinical guideline 67. London: NICE, 2008.

Methodology

Standardised methodology was applied in writing this report, using prioritisation criteria and a comprehensive, standardised search strategy and critical appraisal. Full details of this are available from madox.org.

Additional resources

Department of Health. *Putting prevention first- vascular checks: risk assessment and management — next steps guidance for primary care trusts*. NHS Health Check

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