NICE advice

Helge for detecting haemolysis

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Helge. It is a point-of-care test to detect haemolysis in blood samples.
- The **innovative aspects** are that it detects haemolysis in whole blood at the point of care when the samples are collected. This provides quality assurance of the samples and helps clinicians' decision making for patient care.
- The intended **place in therapy** would be as an additional intervention to current standard care for detecting haemolysis in blood samples.
- The **main points from the evidence** summarised in this briefing are from 2 cross-sectional studies. Of these, 1 included 1,270 blood samples and the other study included 1,671 people presenting to the emergency department. They show that Helge could detect haemolysis in blood samples, reporting a sensitivity of 80% and a specificity of 99% compared with the laboratory test. Of samples collected by different methods, the haemolysis incidence was 21.3% using a peripheral venous catheter, 2.4% using a butterfly needle and 1.6% using a straight needle. Risk of haemolysis assessed by nurses during blood sample collection was correlated to ease of blood sample collection (observed blood flow).

- **Key uncertainties** around the evidence are that there is no gold standard point-of-care reference test or cut-off threshold to detect haemolysis and compare with the Helge system. There are only 2 studies on the technology and neither of these are from the UK. This means evidence is limited and may not be generalisable to the NHS.
- The **cost** of the Helge system is based on a subscription model. This includes all costs for training, disposables, and the readers (updates and maintenance). Depending on the number of readers and projected use, the price is between £500 and £1,000 per reader per month (excluding VAT). The costs of routine testing in the laboratory are £3.71 (phlebotomy test) and £1.10 (biochemistry test). There are no specific costs for haemolysis.

The technology

Helge (Hemcheck) is used for photometric haemolysis detection. The system analyses free haemoglobin in plasma or serum. It is intended for testing in whole blood at the point of care when a sample is being taken to inform a diagnosis.

The Helge system is designed to find haemolysed blood samples directly at the point of care and provide quality assurance of the samples. Helge has 2 different disposable tests: s-test for blood gas syringes and v-test for test tubes. When blood is collected using a gas syringe or a test tube, a small amount of blood is dispensed into the disposable test. This separates whole blood to plasma or serum. The disposable test with the sample is then placed onto a reader (Helge H10 reader) to see whether the blood sample is haemolysed. The haemoglobin concentration is measured in an interval between 0 g/litre and 10 g/litre and translated to a haemolytic index. The user can define which values of a haemolytic index (between 0 and 555) should be considered positive for haemolysis. The cut off is adjustable using software settings in the system.

Innovations

Helge is a point-of-care technology that can test blood samples for haemolysis without the need for centrifugation. This could avoid potential errors caused by haemolysed blood samples. The company notes that there is currently no point-of-care technology that can detect haemolysis in blood gas analysis. It claims that Helge can provide fast test results that improve patient care.

Current care pathway

Haemolysis happens when red blood cells burst and release the blood cell content into the plasma. Haemolysis may happen inside or outside the body. Haemolysis inside the body is a result of a

number of medical conditions, such as genetic disorders or autoimmune disorders. Outside the body, haemolysis is triggered by improper or mishandled procedures during sampling collection and transportation. For example, when collecting a blood sample, squeezing a finger too hard can cause haemolysis. Haemolysis has been recognised as the most common pre-analytical artefact found in laboratory blood samples. Blood is usually re-collected if the blood sample is haemolysed.

There are no NICE guidelines for testing haemolysis. The British Committee for Standards in Haematology is currently producing a guideline on autoimmune haemolytic anaemia.

Population, setting and intended user

Helge is intended to detect haemolysis in whole blood samples. It enables healthcare professionals to test blood for haemolysis at the patient's side. This provides information for clinical decisions at the point of care and also avoids taking unnecessary blood samples.

The system would be used by nurses and phlebotomists in the NHS. It would most likely be used in intensive and emergency care settings.

Costs

Technology costs

The cost of the technology is based on a subscription model that includes all costs for training, disposables, and the readers (updates and maintenance). Depending on the number of readers and projected consumption rate per reader, the price is between £500 and £1,000 per reader per month (excluding VAT).

Costs of standard care

The costs for standard laboratory blood tests are £3.71 for the phlebotomy test and £1.10 for every separate biochemistry test, such as urea and electrolytes tests (reference cost 2018/19). There is no specific cost for haemolysis, but a haemolysed blood sample would have to be repeated.

Resource consequences

The technology has been launched in the UK but has not yet been used in the NHS.

The potential barrier to using the technology in the NHS is the cost. The company indicated that Helge costs more than a standard test for haemolysis in the laboratory. But it could be resource

releasing if it leads to improved lead time and reduction in unnecessary blood tests. The estimate of the cost of repeating haemolysed specimens was based on an average of 60 admissions per day. This was £4,355 per month, plus additional time and equipment costs (Jacobs et al. 2012). The costs for additional length of stay for patients with rejected samples (those that could not be processed in the laboratory) were about £7.01 per hour or £168.17 per day, excluding investigative and treatment costs (Bodansky et al. 2017). Using the technology in the NHS would not need any change to facilities or infrastructure. The company noted the technology is easy to use and training is needed to do the tests and interpret the results.

Regulatory information

Helge is a CE-marked class I (In Vitro Diagnostic Directive general category, or In Vitro Diagnostic Regulation class A) medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Two studies are summarised in this briefing, that are considered the most relevant to the technology. They include 1 cross-sectional study (full text) and 1 comparative study (conference abstract). The selected studies include 1,270 blood samples (Duhalde et al. 2019, full text) and 1,671 people (Duhalde et al. 2019, abstract) who presented to emergency department.

The clinical evidence with its strengths and limitations are summarised in the overall assessment of

the evidence.

Overall assessment of the evidence

The evidence for Helge is limited in quantity and quality. The studies were done in Sweden and so the generalisability of the evidence to the NHS may be limited.

The primary outcomes include diagnostic accuracy and the incidence of haemolysis detected using Helge compared with routine haemolysis detection tests in the laboratory. Available studies report the diagnostic accuracy and the incidence of haemolysis in the blood samples. However, there are no data on subsequent clinical outcomes and the resource impact of the test.

Duhalde et al. (2019, full text)

Study size, design and location

A cross-sectional study done in Sweden of 1,270 blood gas samples from people presenting to the emergency department as part of routine care.

Intervention and comparator

The point-of-care method (Helge) was used to detect haemolysis. The comparator was routine haemolysis method in the hospital laboratory.

Key outcomes

Haemolysis was defined as more than 50 mg/100 ml free haemoglobin in plasma. This was present in 7.9% (n=100) of all study samples. The point-of-care method identified haemolysed samples with a sensitivity of 80% and a specificity of 99% compared with the routine method. The positive and negative predictive values were 89% and 98%, respectively.

Strengths and limitations

The haemolysis detection was done immediately after blood gas analysis. There is no gold standard reference test; the study defined haemolysis as more than 50 mg/100 ml free haemoglobin in plasma. Two study authors had a conflict of interest (1 author is the founder of the company and the other author is employed by the company).

Duhalde et al. (2019, abstract)

Study size, design and location

A cross-sectional study in Sweden of 1,671 people who attended the emergency department.

Intervention and comparator

Helge was used in the intervention group. The comparator was routine haemolysis method in the hospital laboratory.

Key outcomes

Of all samples included, haemolysis was detected in 7.9% of people in the intervention group and 12.3% people in the control group. Of samples collected by different methods, haemolysis incidence was 21.3% using: peripheral venous catheter, 2.4% using butterfly needle and 1.6% using straight needle. Risk of haemolysis assessed by nurses during blood sample collection correlated to observed blood flow: 35.9% in slow flow samples, 15.7% in fast flow samples, and 8.0% in normal flow samples. Nurses' haemolysis rates varied between 2.7% and 18.6%.

Strengths and limitations

The abstract reported the point-of-care method for detecting haemolysed samples in the emergency care setting. Strengths and limitations are not assessed because limited information was reported in the abstract.

Sustainability

The company claims that the use of Helge can reduce the need for repeat tests, and so potentially reduce usage of some materials such as needles, vacuum tubes, syringes and reagents. As a point of care test, Helge can avoid transportation of samples to the lab. There is no published evidence to support these claims.

Recent and ongoing studies

The company noted that a recent study has been completed, but there is very limited information available. A Hemcheck press release about the recently completed study has more information.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three experts were aware of the technology, none had used it in their clinical practice.

Level of innovation

All expert commentators agreed that the technology is novel. One commentator noted Helge is innovative in its concept and in current practice, large clinical chemistry analysers generally incorporate spectrophotometric haemolysis checks. Another expert suggested that there is a high haemolysis rate in blood samples taken in emergency departments. Knowing about haemolysis early would mean that samples can be taken and repeated quickly, reducing delays and improving patient flow. None of the experts were aware of any similar technology to do these tests at point of care.

Potential patient impact

One expert thought that the technology would allow the detection of unsuspected haemolysis in blood gas or electrolyte samples. This could avoid incorrect potassium readings that can result in patient harm through inappropriate treatment. The expert indicated that the rate of moderate to severe haemolysis in blood gas samples is about 6% and most blood gas analysers do not incorporate haemolysis checks. Therefore, the technology would be of particular value to patients having blood gas analysis when haemolysis checks are generally not currently available. Another expert considered the potential benefits of Helge in the emergency department. This could include, for instance, avoiding false conclusions about hyperkalaemia by checking for haemolysis in blood gas (or other point-of-care) samples.

For blood tube samples, 2 experts thought that Helge would allow earlier identification of haemolysis and an earlier opportunity to take a fresh blood sample. This would improve the turnaround time of test results and reduce the number of tests being run without a valid result in the laboratory. One expert thought this could speed up clinical decision making in the emergency department, reducing patient waits and improving flow of patients. This expert considered that people with hyperkalaemia and people with suspected acute coronary syndromes having troponin testing (when the troponin assay is affected by haemolysis) would be most likely to benefit from this technology.

One expert indicated that there were very few benefits to patients in using the technology and stated that Helge may cause unnecessary rejection of samples.

Potential system impact

Reduced delays to final blood results by recognising haemolysed blood in blood tube samples is a key benefit to the healthcare system. For blood tube samples, 1 expert thought that there would be a saving in reagent costs. This would happen if any samples in which haemolysis was detected at point of care were not sent to the laboratory.

General comments

All commentators thought Helge would be an additional intervention to current standard care for detecting haemolysis in blood samples. The experts noted that the technology is not yet used in the NHS, and there is very limited evidence on the clinical and cost effectiveness. The barriers to using the test in the NHS could be the cost of the technology and potential issues with patients agreeing to use Helge.

Expert commentators

The following clinicians contributed to this briefing:

- Richard Body, professor/honorary consultant in emergency medicine, University of Manchester/Manchester University NHS Foundation Trust. Director of the Diagnostics & Technology Accelerator (DiTA).
- Anne Dawnay, consultant clinical biochemist, clinical biochemistry, Barts Health NHS Trust. Did not declare any interests.
- Maurice O'Kane, consultant chemical pathologist, Western Health and Social Care Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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