Cerebrotech Visor for detecting stroke

Medtech innovation briefing
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Summary

- The technology described in this briefing is the Cerebrotech Visor system. This uses bioimpedance measurements for early detection of stroke subtypes to allow appropriate management, including mechanical thrombectomy.

- The innovative aspects are that it uses an established physiological measurement for a new indication, it is portable and can be used in pre-hospital settings.

- The likely place in therapy is uncertain. It would most likely be used in a pre-hospital setting or in a hospital setting where immediate CT imaging is not available.

- The main points from the evidence summarised in this briefing are from 1 US cohort including a total of 248 adult patients in hospital. They show that the Visor system may be more accurate than diagnostic scales in diagnosing patients with severe ischaemic stroke.

- Key uncertainties around the evidence are that it is limited to a validation study, which was done in a setting with a different care pathway than the NHS.

- The cost of Cerebrotech Visor is £50,000 per unit (exclusive of VAT). The resource impact would be a potentially substantial additional cost to standard care. Any test which allows earlier management thereby reducing stroke-related disability could save costs, but there is no evidence on the Visor system to determine this.

The technology

Cerebrotech Visor (Cerebrotech Medical Systems Inc.) is a non-invasive, portable physiologic
monitor that uses a technology called Volumetric Impedance Phase-shift Spectroscopy. It is designed to detect differences in bioimpedance that may happen between the 2 halves of the brain in people who might have had an acute ischemic stroke. Cerebrotech Visor can also be used in people with cerebral oedema, but this is outside the scope of this briefing.

The device is designed to fit any head size and resembles a virtual reality headset. It is placed on the head and impedance readings are taken. It is thought that some stroke subtypes such as large artery occlusion would result in an asymmetry in the bioimpedance measurements which is proportional to the extent of brain injury.

The company has developed algorithms to identify different patterns of brain injury, including stroke. These are displayed as a Visor Score which measures the mean bioimpedance asymmetry. The mean bioimpedance asymmetry can differentiate between severe stokes (16.5%; 95% confidence interval [CI] 14.6 to 18.4) and small stokes (8.0%; 95% CI 6.9 to 8.0). A single reading generally takes less than 1 minute, after which the result is available. The device has rechargeable batteries and does not need routine maintenance. The company provide a loan replacement device if repairs are needed.

**Innovations**

The Visor system uses an established physiological measurement (bioimpedance) in a new way for the early detection of types of stroke which benefit from particular forms of management such as mechanical thrombectomy. It is portable, so can be used both before the patient arrives at hospital, and in emergency department settings.

**Current care pathway**

No standard methods for early differentiation of type of stroke are recommended or used in the NHS.

NICE’s guideline on stroke and transient ischaemic attack in over 16s recommends that people suspected of having a stroke, and who need brain imaging, have a CT scan. This is currently used to identify large artery occlusion, where mechanical thrombectomy treatment may be suitable. Around 40% of ischaemic strokes are caused by large artery occlusions (NHS England).

If imaging confirms a diagnosis of acute ischaemic stroke, then urgent thrombolysis (pharmacological treatments to dissolve the clot, usually within 4.5 hours of onset of symptoms) may be given to try to restore blood flow in the brain. NHS England has announced that it will
commission mechanical thrombectomy, which can substantially improve outcomes for people with large artery occlusions.

As well as pharmacological therapy or mechanical thrombectomy, people with acute ischaemic stroke will also have therapy to minimise brain damage, such as oxygen therapy, blood pressure control and blood sugar control.

The following NICE publications have been identified as relevant to this care pathway:

- Stroke and transient ischaemic attack in over 16s: diagnosis and initial management
- Stroke rehabilitation in adults
- Mechanical clot retrieval for treating acute ischaemic stroke
- Stroke and TIA
- Stroke

Population, setting and intended user

The place in treatment of the Visor system is uncertain. There is currently no standard pre-imaging triage test for stroke subtype. Visor could be used in a pre-hospital setting by paramedics or in an accident and emergency department without access to immediate CT imaging. It would be used in patients suspected of having a large vessel occlusion stroke as part of the patient selection process for mechanical clot removal.

Costs

Technology costs

The Cerebrotech Visor costs £50,000 (excluding VAT) and has an expected lifespan of 5 years. The cost per patient would depend on the number of suspected stroke patients at a given site. The Cerebrotech Visor does not have any consumable costs.

Costs of standard care

The current standard of care does not involve the use of pre-hospital diagnosis other than standard triage of patients in emergency situations. All other aspects of the secondary care pathway would be the same.
Resource consequences

The use of Visor would be a potentially substantial additional cost to standard care. However the company will offer a discounted price which is cost saving or cost neutral compared with standard care. Any test which helped to identify patients with severe stroke earlier and where intervention reduced long-term disability could save costs. There is no evidence to suggest how likely this is with the Visor system.

The company states that 1 hour of training is needed to learn how to use the device. The device is not currently being used in the NHS.

Regulatory information

The Visor system is a CE marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

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

One prospective US study using data pooled from 3 study cohorts (Kellner et al. 2018) done in 248 patients is summarised in this briefing. All patients were assessed with the Visor system and at
least 1 pre-hospital stroke scale. Patients with stroke or brain pathology who were included had to have had neuroimaging within 30 minutes of the Visor reading (neuroimaging defined as CT, MRI or angiography).

Mean bioimpedance asymmetry was highest for patients with severe stroke compared with those with a minor stroke or healthy volunteers (16.5%, 8.0% and 5.0% respectively). The ability of Visor system to detect severe stroke amongst all stroke patients was higher than the pre-hospital scales calculated retrospectively from the National Institutes of Health Stroke Scale used in this study (table 1).

**Table 1 Summary of selected studies**

<table>
<thead>
<tr>
<th>Kellner et al. (2018)</th>
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<td><strong>Study size, design and location</strong></td>
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<td><strong>Prospective cohort study, USA</strong></td>
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<td><strong>Intervention and comparator(s)</strong></td>
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**Key outcomes**

Differentiation of patients with severe stroke from all strokes:

**Sensitivity:**
- Visor: 93% (95% CI 83 to 98)
- NIHSS: 79%
- PASS: 79%
- 3ISS: 75%
- CinPSS: 75%

**Specificity:**
- Visor: 92% (95% CI 75 to 99)
- NIHSS: 71%
- PASS: 75%
- 3ISS: 63%
- CinPSS: 71%

**Strengths and limitations**

Pooled data came from 3 cohorts with different selection criteria. Some brain pathologies may have been under-represented. This is a derivation study so data were maximised to refine a selection algorithm which has not been validated. Another potential limitation are radiowaves used in the device may be modified by metallic cranial implants. This was a company funded study.

**Abbreviations:**
- 3ISS, 3-Item Stroke Scale
- CI, Confidence interval
- CinPSS, Cincinnati Prehospital Stroke Severity Scale
- NIHSS, National Institutes of Health Stroke Scale
- PASS, Prehospital Stroke Severity Scale

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**Overall assessment of the evidence**

The evidence is limited to 1 validation study, the purpose of which was to evaluate the accuracy of the Visor system.

Confidence intervals for the sensitivity and specificity of the pre-hospital stroke scales were not reported so it is unclear if the Visor system is substantially better at diagnosing severe stroke.
However, the quoted sensitivity and specificities for Visor are higher than those for the stroke scales.

The study population was small and contained pooled data from 3 different cohorts with different inclusion criteria. Individuals with implanted medical devices or metal in the head or neck were excluded from this study. Certain stroke subtypes may have been over-represented from what would be seen in NHS practice. Validation of the results is needed in UK settings because the care pathway and diagnostic scales used in practice are different than those used in the study.

Recent and ongoing studies


- Electrical Bioimpedance Cerebral Spectroscopy detection of large vessel occlusion amongst patients with symptoms of acute stroke: MRC (Medical Research Council) Confidence in Concept project.

Specialist commentator comments

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

None of the specialists had used this technology before; 2 said they were familiar with scientific principles behind the device and 1 was planning to use the device in a clinical trial.

Level of innovation

All the commentators said the device is innovative when used in the pre-hospital setting where immediate imaging is not available. One commentator noted CT imaging would still be needed when the patient arrived in secondary care before having mechanical thrombectomy. Another noted that the only alternative is the use of clinical assessment scales with poor specificity and these are not in use in the UK. Two experts said advanced systems are available, which use mobile stroke units in ambulances or ultrasound or microwave diagnosis but neither are technically or financially feasible in the NHS.
Potential patient impact

Two commentators said using the Visor system to triage patients before hospital and directing them for care in a regional centre may have a big effect. In regional centres, CT angiography can confirm diagnosis and mechanical thrombectomy can be used. Mechanical thrombectomy has been shown only to be beneficial within 6 hours of the start of symptoms. Another commentator felt the subgroup of eligible patients for such treatment with endovascular procedures was relatively small. A further commentator said the device would be an addition to pre-hospital clinical scores for diagnosis of large vessel occlusion. One specialist noted that this could be life saving for a small group of patients with a proximal large vessel occlusion where mechanical thrombectomy can avoid disability. They also said that such treatments are very time dependent and if this device added complexity or delay in getting a patient to the CT angiogram, which is still needed, any benefits may not be realised. One specialist commented that there are still not enough clinical data to decide which patient groups might benefit from this device.

Potential system impact

The commentators agreed that this device has no effect on the secondary care pathway but could have a role in pre-hospital triage of patients. One specialist said earlier and more precise recognition of patients who need access to a regional stroke centre could reduce patient disabilities by reducing transfer times and mean better use of ambulance and staff time, avoiding transferring patients who are wrongly diagnosed. Another commentator felt that the effect was still unclear based on the current evidence, especially in the detection of anterior compared with posterior large artery occlusions.

Two specialists felt this device would add costs to the current pathway as all of the current secondary care measures would still be needed. Two felt there were potential savings to offset the upfront costs in faster appropriate treatments reducing morbidity and disability in patients.

General comments

Two commentators noted there were still uncertainties in the clinical evidence. In particular, with diagnostic accuracy in specific stroke populations, such as false negatives in very early stroke or posterior or brain stem stroke. All commentators noted training in an appropriate setting would be important, especially because staff rotation in emergency settings can be high. One commentator said studies looking at patient treatment pathways would be useful as screening tools that rely on physical examination are not routinely used in the UK. Another commentator felt that testing against current rating tools would be important.
The scale of the benefitting population was unclear. Two specialists said the device could be used on all suspected stroke patients, with 1 noting this is 3% of ambulance workload (about 85,000 patients). They added that a subset of these patients could benefit from triage with the device (in the region of 40,000 to 60,000 patients). Another expert said the 10,000 patients who might be eligible for mechanical thrombectomy could potentially benefit. A fourth commentator felt, although this is a rapidly developing field, the numbers potentially benefitting from mechanical thrombectomy could be very small.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Terry Quinn, chief scientist office and Stroke Association senior clinical lecturer and honorary consultant physician, Institute of Cardiovascular and Medical Sciences, Glasgow Royal Infirmary. Did not declare any interests.

- Dr Christopher Price, clinical reader, Institute of Neuroscience, Newcastle University UK. Chief investigator of a trial funded by the MRC (Medical Research Council) to evaluate this device in the NHS. This may result in a clinical journal publication.

- Professor Daniel Lasserson, professor of ambulatory care, Institute of Applied Health Research, fellow of the Institute of Global Innovation, College of Medical and Dental Sciences, University of Birmingham. Did not declare any interests.

- Professor Alastair Buchan, professor of stroke medicine and consultant neurologist, Radcliffe Department of Medicine, University of Oxford. Senior medical science advisor and co-founder of Brainomix, a company that develops electronic ASPECTS (e-ASPECTS), an automated method to evaluate ASPECTS in stroke patients.

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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