Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Lead-I ECG devices to detect atrial fibrillation.
Topic exploration report number:	TER173

Introduction and aims

Health Technology Wales researchers searched for evidence on Lead-I ECG devices to detect atrial fibrillation (AF). These have the potential to lead to earlier identification of patients at high risk of stroke and enable anticoagulation treatment to be started, reducing the risk of stroke. They may also allow quicker recording of ECGs in suspected AF and help to identify those with intermittent (paroxysmal) AF which may stop before a 12-lead ECG can be conducted.

Summary of evidence

A previous topic exploration by Health Technology Wales (*Use of AliveCor smart ECG monitors in the development of the new IP pharmacist role to improve the early detection of atrial fibrillation*) looked specifically for evidence on the use of AliveCor Kardia mobile device for detecting atrial fibrillation (AF) and reducing stroke incidence in “at risk” populations in the primary care setting. A Medtech innovation briefing published by NICE (MIB35) on the AliveCor Kardia mobile device was identified, which included a review of the evidence up to 2015. A small number of published and ongoing trials conducted subsequent to this date were also identified.

Published guidance

Diagnostics guidance was published by NICE in May 2019 (DG35) which looked for evidence of effectiveness in patients presenting to primary care with signs or symptoms of AF and an irregular pulse. No studies were identified in symptomatic patients with an irregular pulse so studies looking at asymptomatic populations were also included. Overall, the review found that there not enough evidence to recommend the routine adoption of lead-I ECG devices. NICE have also published a Medtech innovation briefing (MIB152) on remote ECG interpretation consultancy services for cardiovascular disease (July 2018).

Prior to this, Healthcare Improvement Scotland published guidance for primary care in 2014 on prevention of stroke in patients with atrial fibrillation. They recommend that use of a single-lead ECG recording at the time of symptoms can help in diagnosis but does not replace the need for a 12-lead ECG.

The NHS Wales Cardiac Network has published an all-Wales clinical pathway for AF diagnosis and management. Where an ECG is inconclusive and AF still suspected (paroxysmal), ECG monitoring should be organised for long enough to capture suspected episodes and it is recommended that clinicians "consider use of a commercial ambulatory ECG event-recording device".

Systematic reviews

The systematic review supporting the NICE guidance was published in December 2019. No other systematic reviews published since the NICE guidance that specifically looked at lead-I ECG devices were identified in this initial search.

A Cochrane Systematic Review of systematic screening for atrial fibrillation has been published (Moran et al. 2016) which did not specifically address lead-I ECG devices but may provide useful background information. The review found one study which reported that both systematic screening and opportunistic screening of individuals aged >65 years was more effective than routine practice. There was an incremental cost per additional case detected of GBP 337 and GBP 1514 for opportunistic and systematic screening respectively.

Economic evaluations

The review by NICE did not identify any published cost-effectiveness studies in the target population and a de novo model was produced. The model compared lead-I ECG devices with usual care for single time point testing of symptomatic patients presenting to primary care with an irregular pulse. All lead-I ECG devices were found to be more effective and more costly than usual care. The estimated ICERs for lead-I ECG devices ranged between £1,060 and £16,165, suggesting that all lead-I ECG devices were cost-effective in comparison to usual care. KardiaMobile was found to be the least costly and most effective of all of the lead-I ECG devices. Sensitivity analysis showed the model to be very sensitive to the proportion of patients with paroxysmal AF.

The NICE review also identified two economic evaluations (Welton et al. 2017; Jacobs et al. 2018) which suggested that lead-I ECG devices may be cost-effective for systematic, opportunistic screening of those aged ≥65 years during routine GP appointments.

The Health Economics Research Unit (HERU) (Tassie et al. 2016) developed a de novo model to assess the cost-effectiveness of opportunistic screening for AF in a high risk population using a hand-held single-lead ECG device compared to usual care. In the base case analysis, opportunistic screening was found to be less costly and more effective than usual care (no screening) over a 30-year time horizon.

In addition, the Health Information and Quality Authority (HIQA) published a HTA in 2015 of a national opportunistic screening programme for AF by pulse palpation and ECG in primary care. The estimated ICER was €20,271 per QALY.

Primary and ongoing studies

This preliminary search of the evidence base identified studies which had been included in the NICE diagnostics guidance (May 2019) and a number of ongoing studies. This suggests that there may be new primary evidence available which has been published since the NICE guidance.

Lead-I ECG device is a digital health technology and was determined to be a *Tier 3b* technology according to the Evidence Standards Framework for Digital Health Technologies**.** This technology is within the classification of *Diagnose* and it is recommended that high quality randomised controlled studies or studies done in a setting relevant to the UK health and social care system with a relevant comparator, or a well-conducted meta-analysis of randomised controlled studies, is used to demonstrate effectiveness of the technology.

Areas of uncertainty

A second proposal has been submitted for use of the KardiaMobile device to support social distancing in line with new COVID-19 regulations. The Medtech innovation briefing produced by NICE (MIB152) did not include KardiaMobile and more evidence may be available in this area now.

Conclusions

Whilst the evidence review for the NICE guidance (DG35) was intended to be limited to symptomatic patients in the primary care setting, it was widened to asymptomatic patients and is relatively recent. However, the de novo health economic model produced was limited to symptomatic patients in primary care. HERU developed a model for opportunistic screening of AF, which suggested that opportunistic screening with a hand-held single-lead ECG device might be cost-effective in comparison to no screening.

Overall there has been a significant amount of evidence published in this area. However, there may be benefits to developing a health economic analysis which is wider than that previously undertaken by NICE or HERU.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland *Use the global site search; hand search Scottish Health Technologies Group publications and work programme*	No relevant evidence identified.
Health Technology Assessment Group *Use global search*	No relevant evidence identified.
Health Information and Quality Authority *Search publications using keywords*	https://www.hiqa.ie/hiqa-news-updates/hiqa-publishes-economic-evaluation-national-screening-programme-atrial HTA of a national opportunistic screening programme for atrial fibrillation in primary care in 2015 – pulse palpitation followed by ECG, no reference to lead-I ECG.
UK guidelines and guidance	
SIGN *Use the global search*	https://www.sign.ac.uk/sign-152-arrhythmias https://www.sign.ac.uk/assets/af_publication.pdf
NICE *Check for guidelines, technology appraisals, diagnostics, interventional procedures, and medical technologies guidance*	https://www.nice.org.uk/guidance/cg180 https://www.nice.org.uk/guidance/dg35 https://www.nice.org.uk/advice/mib177/chapter/Summary https://www.nice.org.uk/advice/mib35 https://www.nice.org.uk/advice/mib152
Secondary literature and economic evaluations	
ECRI *Requires a log-in to access the member search*	https://www.ecri.org/search-results/member-preview/hdjournal/pages/evaluation-alivecor-kardiaband-smartphone-ecg/
EUnetHTA *Check for ongoing or published assessments, both of which can be accessed here:* https://www.eunethta.eu/rapid-reas/ *Also carry out a quick search of the EUnetHTA site.*	No relevant evidence identified.
Cochrane library	https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009586.pub3/full?highlightAbstract=single%7Cecg%7Csingl%7Clead

Search the site and check the Cochrane Reviews and Other Reviews tabs for relevant results	
PubMed (Ovid not available) *Check for systematic reviews, meta-analyses, economic evaluations.*	https://www.ncbi.nlm.nih.gov/pubmed/31869370 https://www.ncbi.nlm.nih.gov/pubmed/31933471
Primary studies	
Cochrane library *Only include primary studies if there is insufficient secondary evidence*	Multiple found
PubMed (Ovid not available)	Multiple found
Ongoing primary or secondary research	
PROSPERO database *Check for recent systematic review protocols.*	No new relevant evidence identified.
Clinicaltrials.gov *Only include if insufficient secondary evidence and primary studies found. Check for ongoing studies that have recently closed or are due to complete in the next 6-12 months.*	Multiple
Other	
(insert source searched, or list any evidence provided by the topic proposer)	

Date of search:	April 2020
Concepts used:	Kardia mobile; imPulse; MyDiagnostick; Zenicor-ECG; electrocardiogram device; lead-I ECG; single lead ECG; atrial fibrillation