NICE National Institute for Health and Care Excellence

NICE guidance

KardiaMobile for detecting atrial fibrillation

Medical technologies guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB232.

1 Recommendations

1.1 KardiaMobile is recommended as an option for detecting atrial fibrillation (AF) for people with suspected paroxysmal AF, who present with symptoms such as palpitations and are referred for ambulatory electrocardiogram (ECG) monitoring by a clinician.

Why the committee made these recommendations

Detecting atrial fibrillation in people with suspected paroxysmal AF usually involves wearing a continuous ECG monitor, such as a Holter monitor. KardiaMobile is a portable ECG recorder that can help detect AF.

Clinical evidence shows that significantly more people had AF detected using the KardiaMobile single-lead device compared with a Holter monitor.

Cost modelling shows that KardiaMobile is cost saving compared with Holter monitor by an average of £13.22 per patient over 2 years in people presenting with symptoms such as palpitations. KardiaMobile is cost saving because of a reduction in diagnostic costs including the cost of the device. For more information on the cost impact to the NHS, see the NICE resource impact summary report.

2 The technology

Technology

2.1 KardiaMobile is a portable electrocardiogram (ECG) recorder for detecting atrial fibrillation (AF). It is available as a single-lead or 6-lead (KardiaMobile-6L) ECG recorder. The single-lead device has 2 electrodes on the top surface. The person places 2 fingers on each electrode to take their ECG. KardiaMobile-6L has 3 electrodes: 2 on the top surface and 1 on the bottom which is placed on the left leg. People must keep still and must keep touching the electrodes for at least 30 seconds for a complete recording to be taken.

2.2 KardiaMobile works with a compatible smart mobile device to run the Kardia app. While taking a reading, the ECG recording is sent wirelessly to the mobile device where it can be viewed in the app. The app shows the ECG trace and the classification as either normal, possible AF, tachycardia, bradycardia or unclassified. Traces may also be classified as unreadable if the ECG data cannot be interpreted because of possible interference. ECG data can be saved as a PDF file and emailed to healthcare professionals.

Innovative aspects

2.3 KardiaMobile is easy to use. It is compact and can be used anywhere, at any time of the day, to record an ECG. ECG recordings can be made available to healthcare professionals as soon as they are taken rather than at the end of a specified monitoring period.

Intended use

2.4 The KardiaMobile heart monitor and Kardia app is intended for adults to detect abnormal heart rhythms. This guidance focuses on using KardiaMobile for detecting AF in adults referred for ECG monitoring. KardiaMobile would be

prescribed by a healthcare professional for people who are experiencing arrhythmia symptoms more than 24 hours apart. The healthcare professional will advise on the frequency and length of use. The instructions for use state that all interpretations of ECG recordings should be reviewed by a healthcare professional and used to support clinical decision making.

Relevant pathway

2.5 The section on detection and diagnosis in NICE's guideline on atrial fibrillation recommends that people with suspected AF have manual pulse palpations to detect an irregular pulse. If an irregular pulse is then detected, a 12-lead ECG is done. If an irregular pulse is undetected by a 12-lead ECG recording then an ambulatory monitor, event record or other ECG technology should be done whether or not the person has symptoms.

Costs

2.6 The cost of a single-lead KardiaMobile device is £82.50 (excluding VAT) The Kardia app is free of cost.

For more details, see the website for KardiaMobile.

3 Evidence

Clinical evidence

The main clinical evidence comprises 27 studies including 5 randomised controlled trials

3.1 There were 27 studies relevant to the decision problem in the scope:

- 5 randomised controlled trials (RCTs)
- 7 diagnostic accuracy studies
- 1 case-control study
- 13 single-arm observational studies
- 1 case report.

3.2 Of the 27 included studies, 16 studies were peer reviewed, including 4 UK studies (Bray et al. 2021, Dimarco et al. 2018, Reed et al. 2021, Reed et al. 2019), one of which is an RCT (Reed et al. 2019). The included studies covered 6 population groups:

- people with palpitations
- people with a history of atrial fibrillation (AF), who have had treatment (ablation, cardioversion, or medical therapy) to restore sinus rhythm and used KardiaMobile to identify recurrence
- people with diagnosed AF to assess AF burden
- people with transient AF after surgery or hospitalisation whose heart rhythms reverted back to sinus rhythm before discharge and used KardiaMobile to identify recurrence
- people after stroke or transient ischaemic attack who were monitored using

KardiaMobile

- mixed population including people with known or suspected AF.

All published evidence is on the single-lead KardiaMobile device. For full details of the clinical evidence, see section 4 of the assessment report in the supporting documentation.

Evidence shows that monitoring with KardiaMobile increases AF detection

3.3 Three RCTs including 1 UK trial (Goldenthal et al. 2019, Koh et al. 2021, Reed et al. 2019) found that significantly more people in the KardiaMobile monitored group had AF detected compared with those who had standard care, which included 24-hour Holter monitoring. This was supported by the results from an observational study (Yan et al. 2020).

Evidence suggests that the KardiaMobile algorithm has a high diagnostic accuracy per electrocardiogram (ECG) recording

3.4 Four peer reviewed studies (Hermans et al. 2021, Lowres et al. 2016, Selder et al. 2019, William et al. 2018) reported on the diagnostic accuracy of AF detection using the KardiaMobile algorithm compared with clinical interpretation of the KardiaMobile ECG as the reference standard. Its sensitivity ranged between 92% and 99% per recorded ECG, with specificity between 92% and 98%. However, the external assessment centre (EAC) highlighted that diagnostic accuracy was reported on a per ECG recording and not a per person basis. Also, these 4 studies had 4 different patient populations with a pre-test probability of AF between 4.8% and 35.6%. The EAC also noted that KardiaMobile is not intended to be used to confirm the presence of AF as a standalone test but to help detect AF. All interpretations should be reviewed by healthcare professionals for clinical decision making. It is expected that false positives and negatives are likely to be captured by the clinical reviews.

Evidence shows that using KardiaMobile reduces time to AF detection but there is no direct evidence for clinical outcomes after AF diagnosis

3.5 Reed et al. (2019) showed that people using KardiaMobile had their symptomatic cardiac arrhythmia detected significantly earlier than those having standard care (9.9 days compared with 48.0 days, p=0.0004). This finding was supported by 1 observational study (Yan et al. 2020) which also reported that KardiaMobile significantly reduced the time to AF detection when compared with standard care. There was no direct published evidence to show that using KardiaMobile improves clinical outcomes (such as reduction in stroke) after a diagnosis of AF.

KardiaMobile is easy to use and is associated with an improvement in quality of life

3.6 The evidence from 12 studies and a patient survey reported that KardiaMobile was easier to use compared with other ECG monitors such as Holter monitors. People felt that KardiaMobile would be useful in self-monitoring at home and improving their ability to access the care they needed. Two RCTs (Caceres et al. 2020, Guhl et al. 2020) showed that people who used KardiaMobile had a significant improvement in AF-specific quality-of-life scores compared with people in the control groups. The EAC noted that both trials used additional interventions, and the effect of KardiaMobile alone on quality of life may be difficult to interpret.

The rate of unclassified ECG outputs varied in the studies but is falling because of software updates

3.7 Evidence reported that there were a proportion of ECG traces that did not fit the current KardiaMobile algorithm classifications, ranging from 9.6% to 27.6%. These outputs are presented as unclassified. However, the company stated that software updates are improving the classification algorithm, and the number of unclassified outputs is reducing. Also, around 0.6% to 1.9% of KardiaMobile outputs were unreadable. This often happens when an ECG trace has

interference and cannot be interpreted by the Kardia app; however, a proportion of these can be interpreted by a clinician.

Cost evidence

Published cost evidence includes 2 UK studies representing NHS costs

3.8 Three published studies reported the economic impact of KardiaMobile:

- a cost-effectiveness analysis done alongside a UK RCT compared the cost per symptomatic rhythm diagnosis using KardiaMobile in addition to standard care with standard care alone (Reed et al. 2019)
- a UK budget impact analysis (York Health Economics Consortium et al. 2018)
- a US single-arm study estimated the cost saving using data from a patient survey (Praus et al. 2021).

  All studies reported that KardiaMobile was cost saving. Two studies reported that the main driver for the saving was a reduction in healthcare appointments.

The company presented a cost model showing that monitoring with KardiaMobile is cost saving

3.9 The company developed a de novo model comparing KardiaMobile with Holter monitoring and the Zio patch. The model included people aged 64 and over with known or suspected AF who were referred for ambulatory ECG monitoring in a secondary care setting. The model assessed the costs associated with diagnosing and managing AF. Overall, the company's base case showed that using KardiaMobile could save between £320 and £380 per person over 5 years because of the cost of the technology, reductions in repeat testing, referrals to secondary care and stroke events.

For full details of the cost evidence, see section 9 of the assessment report in the supporting documentation.

The company's cost model was updated to address the limitations presented by the EAC

3.10 The EAC was unable to validate the company's original model, and highlighted limitations and errors in some of the parameters and assumptions used. The complexity of the model meant that inconsistencies could not be investigated and corrected. There was a lack of robust evidence to support the need for such complex time dependencies in the diagnostic phase of the model, and this approach required several additional assumptions. The EAC considered that the diagnosis phase could have been modelled more simply. Overall, the EAC considered the model to be overly complex, not transparent and not verifiable. It also did not agree with underlying structural assumptions, parameter choice or their implementation in the model.

3.11 The company submitted an updated cost model, which was modified and simplified to address the EAC's comments. Furthermore, various scenario analyses and probabilistic sensitivity analyses were done to explore uncertainties of the cost impact. The model was informed by 6 comparative studies including 1 UK study (Reid et al. 2019) and the results showed that using KardiaMobile resulted in cost saving in 2 studies of people with palpitations, and in 3 studies of people who were monitored for recurrent AF but was cost incurring in a study for monitoring AF. The EAC was, however, unable to validate the company model without further clarifications from the company (see Appendix B - EAC commentary), limiting the certainty in the results presented.

Additional cost modelling by the EAC showed KardiaMobile to be cost saving for detecting AF in people presenting with undiagnosed palpitations

3.12 The EAC initially did a simple cost calculator to explore the expected costs of using KardiaMobile to detect and treat AF over a 1-year time horizon. It then went

on to develop a new cost model that better captured the clinical pathway of using KardiaMobile for detection and ongoing monitoring of AF, compared with Holter monitoring in the NHS. The additional analyses included people presenting with undiagnosed palpitations and people who need to monitor AF recurrence after treatment. The base case results of the additional analyses showed a saving of £13.22 per person over 2 years when KardiaMobile was used for detecting AF in people presenting with undiagnosed palpitations but an additional £85.91 cost per patient over 10 years when KardiaMobile was used for monitoring AF recurrence detection in a population at low risk of having a stroke (CHA2DS2-VAScC score of 1).

4 Committee discussion

Clinical-effectiveness overview

Evidence supports using KardiaMobile for improved detection of atrial fibrillation in people with suspected paroxysmal atrial fibrillation

4.1 The committee noted considerable evidence from 6 comparative studies, including 3 randomised controlled trials that showed improved atrial fibrillation (AF) detection using the single-lead KardiaMobile. The clinical experts agreed that monitoring with KardiaMobile could increase infrequent AF event detection because it could record an AF event whenever symptoms are presented. The external assessment centre (EAC) advised that the evidence base was strongest in people with undiagnosed palpitations and people with a history of AF who need to monitor their AF recurrence. The experts noted that, in clinical practice, KardiaMobile has been most commonly used in people presenting with palpitations for detecting infrequent AF events. The committee concluded that the population groups in the evidence base reflected the use of the KardiaMobile device in a wide range of relevant clinical contexts, but it considered the most persuasive clinical cases were symptomatic people with suspected paroxysmal AF.

KardiaMobile single-lead device is an option for detecting AF but there is no evidence on the 6-lead device

4.2 The committee noted that all the evidence on the clinical effectiveness of KardiaMobile was on the single-lead device. It was advised that the single-lead device is commonly used in clinical practice to detect AF, and the use of the 6-lead device is limited in the NHS. The clinical experts agreed that the 6-lead device provides heart rhythm from multiple angles, and it could have incremental benefits in some people to detect other arrhythmias when a good quality

electrocardiogram (ECG) trace is available. For AF detection, the committee and experts concluded that the single-lead device is suitable in most patients.

Evidence on using KardiaMobile for people after AF is diagnosed would be valuable, including the clinical consequences

4.3 The clinical experts advised that AF is a chronic condition. After AF is diagnosed, people are likely to be on medications such as anticoagulation or rhythm control drugs to reduce the risk of stroke and control symptoms for a long time. The experts noted that KardiaMobile could improve medication management; for instance, some medications can only be used when the normal heart rhythm is restored. However, no direct evidence was available on the clinical benefits of KardiaMobile after diagnosis of AF. For example, there was no evidence for the association between early AF detection and reduction in longer-term outcomes such as stroke events. The committee understood the limitations of the evidence base and concluded that more research would be of value that explores the use of KardiaMobile after AF diagnosis, including the impact of using KardiaMobile on clinical outcomes.

NHS considerations overview

KardiaMobile is easy to use and to access which means it is well suited for ambulatory monitoring

4.4 Evidence from published studies and patient experts shows that KardiaMobile is easier to use compared with other ECG monitors such as the Holter monitor. People with experience of using KardiaMobile found the device to be accessible at symptom onset and that it allowed improved access to care when needed. It has been well accepted across people of different age groups if they have a compatible mobile device. The committee concluded that KardiaMobile is a convenient device that people can use at home to monitor their heart rhythms.

Patient selection will improve the care pathway and should be

guided by clinical judgement

4.5 Patient selection is important and should be guided by clinical judgement. The clinical experts emphasised that devices need to be offered to people on an individual basis guided by clinical assessment of individual circumstances. Key factors to consider include risk of developing AF, age, comorbidities, and the availability of primary and secondary care resources to interpret ECG traces. Furthermore, other factors such as the compatibility of mobile devices and patient preference also need to be considered. They noted that widespread use of KardiaMobile in the NHS without careful patient selection may place extra demand on local services. The committee concluded that healthcare professionals should assess individuals and indications when considering whether to prescribe KardiaMobile.

KardiaMobile outputs should be reviewed by a healthcare professional for clinical decision making

4.6 The committee noted that one of KardiaMobile's advantages over some other technologies is that it is a portable device that provides real-time ECG traces and heart rhythm classification. Despite this, the EAC confirmed that clinical interpretation of all recorded ECGs is needed, in line with the device instructions for use, to limit the effect of false negative and false positive results. The clinical experts added that expertise in interpreting ECG traces is essential to ensure the accuracy of AF diagnosis. Also, the experts added that a considerable proportion of unreadable and unclassified ECG recordings would be interpretable by experienced healthcare professionals to inform clinical decision making. The committee concluded that ECG data generated by KardiaMobile should be reviewed by an experienced healthcare professional before a diagnosis is made.

People need a smart device compatible with the KardiaMobile app and must stay still while taking an ECG recording

4.7 People need a smart device compatible with the KardiaMobile app. The company provides a list of compatible smart devices. The clinical experts said that in their experience, most people have access to a smart device, and alternative

ambulatory monitors are offered if a person does not have a compatible device. The clinical experts also noted that KardiaMobile may not be suitable for people who cannot stay still or have problems holding the device; for example, people with tremors may have difficulty with recording an accurate trace.

Training is important to minimise unreadable ECG recordings when using KardiaMobile

4.8 The clinical experts highlighted the issue of unreadable ECG traces. They explained that the way people use the device is likely to affect the quality of ECG recordings. In clinical practice, healthcare professionals often provide support for people to set up the device, allowing them to also advise on effective use. There are also self-help videos that explain how to use the device. The clinical experts noted that a lack of experience using the device may lead to unreadable ECG recordings. The committee concluded that training is important to make sure people use the device correctly and minimise possible interference while taking the recording.

Cost-modelling overview

The company's cost model estimated KardiaMobile to be cost saving compared with other ECG monitors

4.9 The committee understood that the company's original cost model was complex. The model was simplified during consultation. Data from 6 comparative studies was used to estimate the cost impact using KardiaMobile for 2 separate cohorts: 1) undiagnosed people presenting with palpitations and 2) people with previously diagnosed AF at risk of AF recurrence. The committee noted that the results from the company's cost model showed that KardiaMobile is cost saving for each cohort compared with Holter monitor over a 5-year time horizon. The committee considered that some assumptions and parameters, such as 100% diagnostic accuracy for KardiaMobile, may be unlikely or may not fully reflect clinical practice. The committee concluded that the company's modified model was relevant to the decision problem, but still featured limitations, and considered the

EAC's additional cost modelling a more appropriate basis for its decision making.

The EAC's additional cost modelling suggests that KardiaMobile is likely to be cost saving in people with suspected AF presenting with palpitations

4.10 The committee felt that the EAC's original approach using a cost calculator did not capture the cost impact of using KardiaMobile. The EAC was therefore asked to develop a new cost model, to evaluate using KardiaMobile to detect AF in people presenting with undiagnosed palpitations and people being monitored for AF recurrence. From these further analyses, the committee accepted that KardiaMobile is slightly cost saving compared with standard care for patients with undiagnosed AF (people with symptomatic palpitations). This saving is driven by a reduction in diagnostic costs because the cost of KardiaMobile is lower than that of Holter monitor. The clinical experts explained that the benefits of KardiaMobile in this population are likely to be realised because KardiaMobile is better at detecting infrequent AF events compared with Holter monitor. The committee concluded that there are likely to be cost benefits using KardiaMobile in symptomatic patients with suspected paroxysmal AF.

The care pathway for monitoring AF recurrence is complex and varied and more information is needed

4.11 For people who need to monitor AF recurrence, including those who have had an ischaemic stroke or a transient ischaemic attack without current evidence of AF, the results of the EAC's analysis show that KardiaMobile is likely to be cost incurring. This was driven by an increase in using anticoagulation for preventing strokes. The committee understood that the model included only a small selection of patients who are at low risk of developing strokes (CHA2DS2-VAScC score of 1) and that medication was the only intervention included in the model. Expert advice suggested that clinical management of patients being monitored for AF recurrence is complex and varied widely because of patients' comorbidities and their medical and treatment history. In clinical practice, there is no clear care pathway for monitoring AF recurrence. The committee accepted the

limitations of the current model and concluded that more information is needed about the care pathway for AF recurrence monitoring and its associated resource use.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

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Update information

July 2023: This guidance was withdrawn between December 2022 and July 2023. During this time the supply of KardiaMobile to the NHS was paused while the company worked towards meeting the Digital Technology Assessment Criteria (DTAC). These criteria have now been met and accepted by NHS England and supply has resumed.

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Accreditation

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