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Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices: a systematic review and cost-effectiveness analysis

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Scientific summary

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices: a systematic review and cost-effectiveness analysis

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Scientific summary

Background

Heart failure (HF) is a clinical syndrome caused by any structural or functional cardiac disorder that impairs the heart's ability to function efficiently and pump blood around the body. The most common symptoms of HF are breathlessness, fatigue and oedema. Conditions that can cause HF include coronary heart disease, high blood pressure, heart rhythm or valve abnormalities and conditions affecting the heart muscle (cardiomyopathies and myocarditis).

Around 920,000 people in the UK were living with HF in 2018, with an estimated 200,000 new diagnoses each year. HF mainly affects people over the age of 65, with an average age of diagnosis of 77, and risk increases significantly with age. Around 1 in 35 people aged 65–74 years have HF, which increases to 1 in 15 of people aged 75–84 years, and to just over 1 in 7 people of those aged above 85 years.

The National Institute for Health and Care Excellence (NICE) guidelines for diagnosis and management of chronic HF in adults recommend that monitoring of people with chronic HF should include a clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status and nutritional status, a review of medication and an assessment of renal function. The European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic HF add that HF management may involve in-person service models or home-based telemonitoring, and that the COVID-19 pandemic has highlighted some of the potential advantages of the latter. While care is usually followed up by HF clinics, suitable patients may be followed up by community HF nurses or a general practitioner (GP) with a special interest in HF – a clinical expert commented that there is no standard HF service model.

Patients who have cardiac implantable electronic devices (CIEDs) due to HF or who are at risk of HF may have a remote monitoring system incorporated in the device. The remote monitoring system includes a predictive algorithm for HF. The system can send alerts, and/or the stored data can be reviewed. There is additional cost to access and use the remote monitoring system. The decision question is whether the algorithm-based remote monitoring of HF risk data in people with CIEDs represent a clinical and cost-effective use of NHS resources and should be recommended for use.

Four relevant remote monitoring algorithms were identified for consideration:

- CorVue algorithm with integrated CIED [Abbott Laboratories (Abbott Park, IL, USA)]
- HeartInsight algorithm with integrated CIED (BIOTRONIK, Berlin, Germany)
- HeartLogic algorithm with integrated CIED (Boston Scientific, Marlborough, MA, USA)
- TriageHF algorithm with integrated CIED [Medtronic plc (Medtronic plc, Dublin, Ireland)].

Objectives

To determine the clinical and cost-effectiveness of the four remote monitoring algorithms for detecting HF in people with CIEDs.

Methods

Systematic review

The systematic review was conducted following the general principles recommended by the Centre for Reviews and Dissemination (CRD) guidance.

A comprehensive range of databases and sources of grey literature were searched for the identification of studies relating to the use of algorithm-based remote monitoring of HF risk data in people with CorVue, HeartInsight, HeartLogic or TriageHF CIEDs. The bibliographic databases searched were MEDLINE and EMBASE (via Ovid), the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), the Cochrane Database of Systematic Reviews (CDSR) and the Cochrane Central Register of Controlled Trials (CCRCT) (via the Cochrane Library) and the Database of Abstracts of Reviews of Effects (DARE) (via the CRD). International CTRIs, such as the US ClinicalTrials.gov; EudraCT; the World Health Organization's International Clinical Trials Registry Platform (ICTRP); and ScanMedicine, a multinational open access clinical trial database, were searched for the identification of ongoing clinical trials. Additionally, we searched for health technology assessment (HTA) reports in the international HTA database (INAHTA) and for protocols of systematic reviews in International Prospective Register of Systematic Reviews (PROSPERO) and International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY), both international registers of systematic reviews. Finally, we searched for pre-print manuscripts in medRxiv, a pre-print server for health sciences. We performed backwards and forwards citation chaining to identify potentially relevant studies cited or citing the included studies. Company submission documents and company websites were also searched for additional relevant studies.

Data extraction of the study characteristics and outcome data was done by one reviewer and checked by another reviewer. The risk of bias was assessed using Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS–I), whereby clinical outcomes were reported in non-randomised intervention studies; and Prediction model Risk Of Bias Assessment Tool (PROBAST), whereby prognostic outcomes, including sensitivity and specificity, were reported. The Cochrane risk of bias tool was not used because none of the included studies were randomised controlled trials (RCTs).

Due to diversity across the studies, meta-analysis was not performed, and the evidence was synthesised narratively and in tabular format.

Economic review

A broad search for cost-effectiveness studies was undertaken in the following sources: MEDLINE and EMBASE (Ovid), CDSR and CCRCT (the Cochrane Library), CRD, DARE and HTA database and NHS Economic Evaluation Database (NHS EED), the international HTA database and NIHR Journals Library. Whenever appropriate to the database, we used a validated Scottish Intercollegiate Guidelines Network (SIGN) search filter for the identification of cost-effectiveness studies.

Additionally, in August 2023, we performed focused searches for resource utilisation, quality-adjusted life-year (QALY) and utility values to populate the economic model. We searched MEDLINE and EMBASE via Ovid and used two validated economic filters for cost-of-illness studies and quality-of-life studies. We also searched specialist sources such as Cost-effectiveness Analysis Registry (CEA Registry), Research Papers in Economics (RePEC) and ScHARRHUD (School of Health and Related Research Health Utilities Database at the University of Sheffield).

Economic modelling

A de novo two-state Markov model (with alive and dead states) was used to estimate the cost-effectiveness of algorithm-based remote monitoring of HF risk data in people with CIEDs. The model structure captured the key costs and outcomes associated with cardiac remote monitoring (CRM). Patients in the alive state experienced a number of hospitalisations per year, made a number of clinic visits (scheduled and unscheduled) and were at risk of dying. CorVue, HeartInsight, HeartLogic and TriageHF were modelled separately, and outcome differences for one device were not assumed to apply to another device. QALYs gained was the measure of benefit for the economic evaluation.

Results

Clinical effectiveness

Eighty-one reports comprising 42 studies of clinical effectiveness were included in the systematic review. Eight studies evaluated CorVue, 1 published study evaluated HeartInsight, 19 studies evaluated HeartLogic and 14 studies evaluated

TriageHF. Of the included studies, the great majority were single-arm cohort designs (retrospective and prospective). No RCTs were identified, and five studies provided some comparative data (CorVue; *n* = 1, HeartLogic; *n* = 3, TriageHF; *n* = 1).

The greatest amount of evidence for prognostic accuracy was identified in studies assessing the TriageHF algorithm (*n* = 10). Of these, the area under the curve (AUC) was reported in three studies assessing worsening HF (AUC= 0.75), mortality (AUC = 0.61) and hospital admissions (AUC = 0.81). Sensitivity for high risk status for HF-related events (e.g. hospitalisations) showed great variability (range = 37.4 to 87.9%). Specificity also varied (range = 44.4–90.2%). A similar amount of evidence was identified for prognostic accuracy outcomes evaluating HeartLogic (*n* = 8). Validation studies for HeartLogic to predict HF events (hospitalisations and clinical visits) reported sensitivity as adequate to high (range = 66–100%); similarly, specificity was adequate to high (range = 61–93%). False positive rates were generally low in the seven studies reporting this outcome; conversely, one study reported a high false positive rate (26 of 38 alerts). In comparison to HeartLogic and TriageHF, there was limited evidence for CorVue (*n* = 5) and HeartInsight (*n* = 1) overall and for prognostic outcomes. The CorVue algorithm demonstrated inadequate sensitivity for HF events, defined as hospitalisations (range = 20–68%). Specificity was only reported in two studies at 70% and 77%. The low predictive accuracy was also accompanied by a high false positive rate. The one published study for HeartInsight algorithm had 65.5% sensitivity and 86.7% specificity for first postimplant HF hospitalisations. Additionally, 54.8% sensitivity and 86.5% specificity for HF hospitalisation, outpatient intravenous intervention (IVI) or death. False positive rates were low.

Reported clinical outcomes included HF events, mortality and adverse events (morbidity). Twelve studies reported HF events for three algorithms (HeartLogic, *n* = 7; CorVue *n* = 3, TriageHF *n* = 2). Only one of these studies was comparative, with data showing less HF events when the HeartLogic algorithm was utilised. For non-comparative evidence using HeartLogic, there was evidence that when IN alert compared to OUT of alert related to increased risk of HF events occurring. Similarly, TriageHF showed an increased risk of HF events when in high or medium risk status. No comparative evidence was generated for CorVue, and only numerical data were presented. No evidence was identified for HeartInsight. There was limited evidence for HF-related deaths. Three HeartLogic studies demonstrated an increased risk of death when IN alert compared to OUT of alert. One study assessing differences between unplanned HF hospitalisations and medical admissions for TriageHF reported more deaths occurring during HF hospitalisations. Only two studies reported adverse events (HeartInsight *n* = 1, HeartLogic *n* = 1).

For the patient-reported outcome measures, one single prospective cohort evaluating the TriageHF algorithm provided outcomes for health-related quality of life by using the 6-minute walk test (6MWT) and Minnesota Living With Heart Failure Questionnaire (MLWHF). There was a decrease in walking distance at 8 months follow-up and no statistically significant change in the MLWHF from baseline to follow up at 8 months.

Cost-effectiveness

There was no comparative evidence on hospitalisation, mortality and follow-up visits or length of stay (LOS) for CorVue or HeartInsight. CorVue and HeartInsight were cost-increasing when a conservative assumption of no difference in hospitalisation, mortality, follow-up visits (scheduled/unscheduled) was made. Threshold analysis for these two devices showed that even a very small reduction in the incidence rate of hospitalisation would make them cost-effective.

HeartLogic had some evidence on LOS, and hospitalisation rates and the cost-effectiveness estimates showed it to be dominant (i.e. less costly and more effective than the comparator). TriageHF also had some evidence on hospitalisation rates, and was also dominant. The studies supplying the hospitalisation and LOS evidence were either at serious or critical risk of bias due to confounding.

Due to the high cost of hospitalisation, the remote monitoring services (RMS) devices for these technologies only need to reduce the hospitalisation rates by small percentage for them to become cost-effective. The lack of hospitalisation outcome evidence for CorVue or HeartInsight means it is not possible to produce cost-effectiveness estimates for these technologies. The cost-effectiveness estimates of HeartLogic and TriageHF are based on evidence that is at risk of bias. There was also limited evidence on healthcare contact outcomes.

Discussion

The majority of the evidence base for all algorithms is derived from single cohort (prospective and retrospective) studies and provide mixed results. Only five included studies reported comparative evidence.

The available evidence for the HeartLogic algorithm showed adequate to high sensitivity and specificity for the prediction of HF events (i.e. hospitalisations). False positive rates were low.

TriageHF accuracy measures varied substantially between low and high sensitivity and specificity. False positive rates were only reported in one study and were relatively low.

Evidence for the accuracy of CorVue showed low sensitivity, and specificity was generally not reported. False positive rates were high in most studies.

One study evaluating the clinical effectiveness of HeartInsight was identified. It was a development and validation study and reported adequate sensitivity and specificity for HF events. False positive rates were moderate in this single study. No comparative evidence was identified for the use of HeartInsight.

There was a paucity of data for some of the outcomes listed in the protocol, including patient-reported outcome measures for health-related quality of life and satisfaction and adherence to treatment. In addition, mortality and adverse events were not widely reported. Lastly, there was limited reporting for the software failure rate.

The assumptions around parameters may not be applicable to all populations or subgroup and may not reflect real-world experience. Limited device-specific comparative evidence on outcomes mean that the cost-effectiveness findings in this report need to be interpreted with caution. Further research and comparative evidence on effectiveness might be needed to confirm cost-effectiveness.

Conclusions

The evidence for HeartLogic and TriageHF showed a potential to be of use in clinical practice; however, there are important uncertainties due to a lack of comparative evidence. HeartLogic had the highest and most consistent accuracy measures (i.e. sensitivity of ≥ 70%); the data suggest that being IN alert is linked to greater risk of HF events; however, these estimates were generally derived from composite outcomes (e.g. hospitalisations and outpatient visits). TriageHF showed similar accuracy, but with further degree of variation, for detecting such HF events when in a high risk status; however, these estimates were more commonly reported from single end-point studies. HeartInsight reported comparable accuracy to HeartLogic and TriageHF (sensitivity of 65%); however, this was only based on one published study, therefore it is uncertain whether further studies will replicate these findings. CorVue prognostic accuracy data varied substantially (i.e. sensitivity reported to be as low as 20%). For all technologies, most studies were judged to be at high risk of bias, which reduces certainty about the evidence.

All remote monitoring algorithms only needed to reduce hospitalisations by a small amount for them to be cost-effective given the evidence on incremental healthcare visits use compared to no remote monitoring algorithm. Better quality and adequately powered evidence on both hospitalisations and healthcare contacts (visits, calls), which also records time spent reviewing remote monitoring data, would help inform the cost-effectiveness of the remote monitoring algorithms.

Suggested priorities for further research

Further studies on the effectiveness of remote monitoring should be prospectively designed and compare outcomes for people with a CIED and remote monitoring algorithm to people with a CIED with no remote monitoring algorithm.

In addition, inclusion of relevant patient-reported outcome measures, and patient involvement to capture the patient voice and preferences, would facilitate a more complete evaluation of the technologies' benefits.

Study registration

This study is registered as PROSPERO CRD42023447089.

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This article

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