A national registry to assess the value of cardiovascular magnetic resonance imaging after primary percutaneous coronary intervention pathway activation: a feasibility cohort study

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Scientific summary

National registry for CMR after PPCI pathway activation

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Scientific summary

Background

Cardiovascular magnetic resonance (CMR) is a non-invasive imaging technique that assesses heart structure and function with high spatial and temporal resolution. The use of CMR has increased in all subgroups of acute coronary syndrome (ACS) patients, including those who activate the primary percutaneous coronary intervention (PPCI) pathway. It is unknown if undergoing CMR influences patient management or reduces the length of hospital stay or the risk of major adverse cardiovascular events (MACEs) in these patients.

Objectives

- To determine whether or not it is feasible to set up a national registry linking routinely collected data from hospital information systems (HISs) for the index event (emergency angiography with or without PPCI) with hospital episode data [from Hospital Episode Statistics (HES) and Patient Episode Database Wales (PEDW), which collects equivalent information for the NHS Wales hospitals] and death registration data [from the Office for National Statistics (ONS)] for follow-up in the 12 months after the index event, in order to investigate the role of CMR in patients who activate the PPCI pathway.
- To describe resource use and associated costs of having CMR and to identify key drivers of cost-effectiveness for CMR.
- To identify an outcome measure representing a definitive change in clinical management, conditional on having undergone CMR, that would be credible to cardiologists and other stakeholders as an interim measure of the 'value added' by doing CMR.

Design

The study included three components to address the objectives listed in the preceding section:

1. Feasibility prospective cohort study – we established if we could implement patient consent, extract data about the index event from multiple HISs and link these data with hospital episode data for follow-up. We also quantified the proportion of patients who undergo CMR. We explored whether or not the cohort study could be set up using only hospital episode data.
2. Simple cost-effectiveness models – we developed economic decision models in two subgroups of patients who activate the PPCI pathway: (1) patients with multivessel disease and (2) patients with unobstructed coronary arteries. These subgroups were identified in the protocol (before commencing work on the study) as having the potential to benefit from CMR.
3. Formal consensus study – we defined important changes in management resulting from CMR and subgroups of patients to whom these changes relate. Potential changes in management were described from literature review and cardiologist expert opinion and were reviewed by a consensus panel and additional cardiologists (from across the UK). We determined whether or not changes in management defined as being important by formal consensus could be identified in hospital episode data in the 12 months following the index event, with the intention to formulate an 'interim' outcome measure representing a definitive change in clinical management that could be used for a future registry.

Setting

- Feasibility prospective cohort study: four 24/7 PPCI hospitals in England and Wales (two with and two without a dedicated CMR facility, both representing usual care in the NHS).
- Cost-effectiveness models: usual care (with or without CMR) in the NHS.
- Formal consensus study: secondary care (cardiology departments) across the UK.

Study population

Feasibility prospective cohort study

This comprised patients who activated the PPCI pathway and underwent an emergency coronary angiogram whether or not they received PPCI. We included patients if they were aged ≥ 18 years and underwent an emergency angiogram, defined as taking place within 2 hours of arrival at the hospital, unless specified otherwise by local protocols. We excluded patients if they were prisoners or lacked mental capacity to consent.

Cost-effectiveness models

- Model 1 (multivessel disease): patients who activate the PPCI pathway, have their index angiography and PPCI and are identified as having multivessel disease (commonly defined as stenosis of > 50% from the angiogram) in two or more coronary arteries.
- Model 2 (unobstructed coronary arteries): patients who activated the PPCI pathway, had their index angiography and were found to have unobstructed coronary arteries.

Formal consensus study

This comprised consultant cardiologists with CMR, interventional, echocardiography (ECHO), electrophysiology and heart failure expertise from across the UK.

Intervention(s)

Feasibility prospective cohort study

Cardiovascular magnetic resonance performed/not performed within 10 weeks of the index event (whether during the index admission or subsequently as an outpatient). All patients were assumed to receive standard ECHO as part of usual care.

Cost-effectiveness models

- Model 1 (multivessel disease): three different ischaemia testing methods; CMR versus stress ECHO versus pressure wire.
- Model 2 (unobstructed coronary arteries): CMR and standard ECHO versus standard ECHO alone.

Formal consensus study

For each statement, CMR was considered alongside standard or stress ECHO as appropriate.

Main outcome measures

Feasibility prospective cohort study

- Patient consent implemented at all four hospitals.
- Data linkage and extraction from multiple local HISs achieved for > 90% of consented patients at all four hospitals.
- Local data successfully linked with hospital episode data for > 90% of consented patients at all four hospitals.

- CMR requested and carried out for ≥ 10% of patients activating the PPCI pathway in CMR hospitals.
- Whether or not the registry could be compiled from hospital episode data rather than from multiple HISs.

Cost-effectiveness model

The main outcomes were key drivers of cost-effectiveness for CMR in patients with (1) multivessel disease (model 1) and (2) unobstructed coronary arteries (model 2).

Formal consensus study

- Identification, through formal consensus, of the important changes in management resulting from CMR and the subgroups of patients to whom these changes relate.
- Identification of relevant subgroups of patients in the data sets obtained (local HISs and follow-up hospital episode data).
- Ascertainment of the consequences of important changes in management from hospital episode data.

Data sources

Feasibility prospective cohort study

- Index procedure: local HIS at each participating hospital –
  - basic demography [local Patient Administration System (PAS)/British Cardiovascular Intervention Society – Central Cardiac Audit Database (BCIS-CCAD)]
  - clinical characteristics on presentation at the index admission, peri- and post-procedural (PPCI) characteristics (local catheter laboratory database/BCIS-CCAD)
  - ECHO and CMR reports (local imaging databases)
  - biochemistry (local biochemistry databases)
  - medications on discharge (one hospital only).
- Follow-up: hospital episode data. We requested inpatient, outpatient, accident and emergency and critical care data sets.

Cost-effectiveness models

Data were sourced from a literature review for model parameter estimates and *NHS Reference Costs* (Department of Health and Social Care. *NHS Reference Costs 2015 to 2016*. London: Department of Health and Social Care; 2016) for unit costs.

Formal consensus study

For the formal consensus study, data were sourced from a literature review and cardiologist expert opinion. In-hospital data were sourced from local HIS data and follow-up data were sourced from HES data.

Results

Feasibility prospective cohort study

- Consent using conventional methods was successfully implemented (across all hospitals, consent rates were 59–74%); 2462 patients were screened (May 2013–September 2014) but only 1670 participants (68%) were recruited.
- Hospitals submitted varying numbers of requested data: clinical data (for ≥ 82% of patients across all hospitals), biochemistry data (three hospitals, for ≥ 98% of patients), ECHO data (three hospitals, for 34–87% of patients) and medications data (for 97% of patients in one hospital). Imaging data (ECHO and CMR data from one hospital) were submitted as free-text reports extracted from radiology databases.

- HIS data were linked with hospital episode data for 99% of all consented patients. We identified an admission that matched the index admission within ± 1 day for 93% and 97% of consented patients.
- At the two CMR hospitals, 14% and 20% of patients received CMR.
- We identified 98% of patients who underwent PPCI and 85% of patients who had an emergency angiogram but no PCI in hospital episode data. We could identify CMR exposure in hospital episode data for only 29% (55/189) of patients who had a CMR in our cohort.

Cost-effectiveness models

- In both model 1 (multivessel disease) and model 2 (unobstructed coronary arteries), the difference in quality-adjusted life-years (QALYs) between CMR and no CMR was very small (0.0012, 95% CI –0.0076 to 0.0093 and 0.0005, 95% CI –0.0050 and 0.0077, respectively) (the 'current' comparator for model 1 is stress ECHO; the 'current' comparator for model 2 is standard ECHO). The diagnostic accuracy of the ischaemia tests was the key driver of cost-effectiveness in sensitivity analyses for both model 1 and model 2.

Formal consensus study

- There was consensus that CMR leads to clinically important changes in management in five patient subgroups, namely those with: (1) out-of-hospital cardiac arrest, (2) unobstructed coronary arteries, (3) left ventricular (LV) thrombus, (4) multivessel disease and (5) PPCI with CMR markers indicating poor prognosis.
- Patients with unobstructed arteries and PPCI patients could be identified from both the local HIS data set and hospital episode data. Patients with an out-of-hospital cardiac arrest and PPCI patients who developed a LV thrombus could not be identified from the local HIS data set, but could be identified in hospital episode data. Patients with multivessel disease could be identified only from the local HIS data set, not from hospital episode data.
- We identified the following changes in management in hospital episode data: new diagnoses and procedures (those that resulted in hospital admission and were recorded in outpatient visits) and the frequency of outpatient appointments related to cardiac events. We could not identify changes in medications because there were no medication data in the hospital episode data.

Limitations

Feasibility prospective cohort study

We could not identify all eligible patients from local HISs. The conventional consent model failed to capture a sizeable proportion of the eligible population, but we could not identify and test a more efficient model of obtaining consent. The study population did not include patients presenting with a broader diagnosis of ACS but not requiring emergency coronary angiography (e.g. those with non-ST elevation myocardial infarction), who may also benefit from CMR.

The study took longer than anticipated to complete after the end of recruitment because our application for hospital episode data coincided with the moratorium on all data requests imposed by NHS Digital (formerly known as the Health and Social Care Information Centre). During this time, data availability/quality is likely to have changed/improved given the rapidly evolving NHS information technology (IT) systems/platforms. New diagnostic tests for detecting ischaemia (e.g. pressure wire), directly competing with CMR, were also introduced during the time frame of the study and were rapidly adopted by many cardiologists. These changes to usual care weakened the importance of the research question that we described at the outset – the comparison of CMR versus standard ECHO/stress ECHO (usual care at the start of the study) – but highlighted the importance of different research questions.

Cost-effectiveness models

There is uncertainty around the majority of parameter estimates in both models. Many estimates were based on single studies with small sample sizes. Some of these studies were conducted outside the UK, where patient pathways differ. In the base-case analyses, CMR and pressure wire were treated as reference standards and both were assumed to have 100% sensitivity and specificity. This assumption may not be true and, if not, this will influence findings because the diagnostic accuracy of the ischaemia tests was found to be the key driver of cost-effectiveness.

Individual patient data on resource use from hospital episode data were not available in time to be used in the cost-effectiveness analyses. Therefore, we estimated resource use associated with each of the patient pathways, so, although the standard care pathways have been costed, it is likely that we have underestimated the variability between individual patients and their actual patient pathways. Finally, there was also uncertainty about the utility estimates used in the cost-effectiveness models because we did not find good-quality primary data.

Formal consensus study

The number of panel members in our expert panel was lower than the recommended 8–12 members for a consensus panel. We extended the survey to other UK cardiologists to compensate for this and prevent the possibility of introducing bias (given the self-selected nature of the panel). We did not include different stakeholder groups in the consensus panel because the technical wording of the statements would not have been easily understood by non-cardiologists. Therefore, we cannot be certain that the changes in management that were identified are relevant to other stakeholders (e.g. commissioners and patients).

Conclusions

Feasibility prospective cohort study

We did not identify all patients who were eligible for the study; for example, patients with unobstructed arteries (i.e. those who had an emergency angiogram but did not receive PPCI) were difficult to identify from catheter laboratory databases. We successfully consented patients but obtaining individual, opt-in consent would not be feasible for a national registry. We explored several consent models (i.e. opt out on procedural consent form, standard consent at discharge) but none was implemented because of logistic difficulties. Linkage of data from HIS with hospital episode data was feasible, but data from HIS are not uniformly available/exportable. Information about whether or not participants had had CMR in CMR hospitals was successfully obtained from HIS, although some referrals for CMR were for research rather than clinical purposes. It is feasible to identify important changes in management in the five patient subgroups in hospital episode data.

Cost-effectiveness models

For each of the base-case models, the differences in QALYs between strategies were very small; therefore, the results were largely driven by the differences in costs, although these were also modest. Sensitivity analyses around the two models identified the diagnostic accuracy of the ischaemia tests as the key driver of cost-effectiveness.

Formal consensus study

We defined five subgroups of patients who activate the PPCI pathway for whom there was consensus that CMR changes patient management in a clinically important way. All subgroups could be identified in either the local HIS data set, hospital episode data or both. Some, but not all, important changes in management could be identified in follow-up HES/PEDW data. The main constraints on identifying important changes in management were (1) outpatient hospital episode data were poorly coded with respect to the diagnosis, (2) medication data were not available at baseline or follow-up (preventing inspection of/prescription of changes in medication after the index event) and (3) data about diagnostic investigations were poorly coded in both acute care and outpatient data sets.

Future work

- Identify/test a more efficient method of obtaining consent.
- Some limitations of our study are now historic and others are being addressed. Therefore, it is recommended to test the feasibility of conducting the study using national data sets [HES/BCIS/Diagnostic Imaging Dataset (DID), Clinical Practice Research Datalink (CPRD) for medications], which are likely to be able to capture all of the eligible population, without the need for individual patient consent; MACEs could be used as the outcome.
- Cost-effectiveness models suggest that it is important for the NHS to have a definitive answer about the relative diagnostic accuracy of CMR versus pressure wire, despite the fact that the pressure wire is rapidly superseding CMR across catheter laboratories.
- A feasible registry is a goal worth pursuing, offering a test bed for the rapid evaluation of changes in practice in this expensive and fast-moving area of clinical care (often driven by commercial interest).

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