NICE advice

AcQMap for mapping the heart atria to target ablation treatment for arrhythmias

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is AcQMap. It is used for imaging and mapping the heart atria to target ablation treatment for arrhythmias.
- The **innovative aspects** are the analysis and display of global non-contact charge density data. This could allow for a more targeted approach to ablation therapy, reducing the risk of unnecessary excess tissue ablation.
- The intended **place in therapy** would be as an alternative to catheter ablation treatment of arrythmias using sequential bipolar contact mapping in people with heart arrhythmias, when drug treatment has not worked.
- The **main points from the evidence** summarised in this briefing are from 5 prospective studies including a total of 189 adults in tertiary care. One multicentre single-armed study shows that AcQMap is effective for targeted ablation treatment for atrial fibrillation.

- The **key uncertainty** around the evidence or technology is that there are no comparative studies showing long-term outcomes.
- The **cost** of AcQMap is around £5,720 to £7,285 per procedure (excluding VAT).

The technology

AcQMap (Acutus Medical) is an imaging and mapping system. It can be used to direct endocardial ablation treatment for stable and unstable arrhythmias, such as atrial fibrillation. It displays high-resolution 3D cardiac chamber reconstructions using ultrasound and cardiac electrical activity (measured using electrodes) as a propagation wavefront. 3D charge density maps can be overlaid on the cardiac chamber reconstruction.

The system can also be used with a novel algorithm, SuperMap, which is designed to be used to map stable or transient rhythms. It can distinguish between different morphologies and arrythmia cycle lengths in a single recording. The company claims that AcQMap can help identify arrhythmic regions of the heart, to guide targeted treatment with ablation, which cauterises or freezes areas of heart muscle.

The AcQMap System includes the AcQMap Console, which formats and transmits signals to the AcQMap Workstation for display and analysis using the AcQMap System Software. The AcQMap Workstation consists of a portable cart with a mounted desktop computer and USB keyboard and mouse for user input.

The AcQMap is used with an AcQMap 3D Imaging and Mapping Catheter. This catheter expands to form a 25 mm diameter spheroid cage and comprises 6 splines (arms), each of which houses 8 ultrasound transducers for anatomic reconstruction and 8 electrodes for recording biopotential signals. This catheter is inserted into the heart, through the AcQGuide Steerable Sheath, via a vein in the groin. The catheter allows non-contact mapping of the heart's electrical activity.

The AcQMap also needs an AcQMap Patient Electrode kit. This kit contains localisation dispersive electrodes, patient return electrodes, and body surface electrocardiogram (ECG) electrodes. The electrodes are placed on the body in designated locations based on colour coding and specific anatomical markers. They provide catheter-positioning information, a common reference between the person and AcQMap Console, and ECG monitoring information.

Patient patch connections are made directly to the front panel of the AcQMap Console along with the ECG cable. Ablation catheter and ablation generator connections are also made to the front panel, enabling signal acquisition by the AcQMap System.

Innovations

The company says that other 3D mapping systems are not able to collect global real-time activation data, which they believe are needed to effectively map atrial fibrillation. The device can remain in the heart during the ablation procedure to subsequently remap the arrythmia and look at the success of the ablation procedure. The SuperMap algorithm uses software that can identify multiple morphology and cycle length atrial tachycardias from a single moving non-contact recording. This technology could allow a more rapid and targeted approach to ablation therapy for atrial fibrillation and atrial tachycardia, reducing unnecessary ablation and so preserving atrial tissue.

Current care pathway

Atrial fibrillation can be treated with drugs including beta-blockers and rate-limiting calcium channel blockers. If drug treatment does not control symptoms or is unsuitable, people can be offered left atrial catheter ablation if they have paroxysmal atrial fibrillation; or left atrial catheter or surgical ablation for persistent atrial fibrillation. Mapping catheters can be inserted into the heart during the process to look at the electrical conduction and guide ablation.

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

- NICE's guideline on atrial fibrillation: management
- NICE's interventional procedures guidance on percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation
- NICE's interventional procedures guidance on percutaneous radiofrequency ablation for atrial fibrillation

Population, setting and intended user

The AcQMap System is intended to treat cardiac arrhythmias, particularly atrial fibrillation or atrial tachycardia, that need endocardial catheter ablation. This would be done in a

tertiary care setting by cardiologists with expertise in electrophysiology and ablation procedures.

The AcQMap System is contraindicated for some people, including those with:

- implanted prosthetic, artificial, or repaired cardiac valves in the chamber being mapped
- a permanent pacemaker or implantable cardioverter-defibrillator leads in the chamber being mapped
- hypercoagulopathy, or for whom anticoagulation therapy during an electrophysiology procedure is unsuitable
- active systemic infection
- inferior vena cava embolic protection filter devices.

Some or all of these contraindications would also be applicable to other invasive heart electrophysiology procedures.

Costs

Technology costs

The company estimates total costs per procedure of:

- £5,670 to £7,285 for atrial fibrillation
- £5,720 to £6,405 for right atrial tachycardia
- £5,690 to £6,585 for left atrial tachycardia.

This takes into account equipment not manufactured by the company including ablation catheters, decapolar coronary sinus catheters and irrigation tubing.

The AcQMap catheter, catheter sheath, and patient electrode kit cost £4,550 per procedure.

The AcQMap System also needs a single-use unipolar reference, which can be 1 of 2

options:

- AcQRef, another sheath featuring an integrated ring electrode at £150 to £252 (excluding VAT), or
- a fixed quadripolar catheter estimated at £60 to £90 (excluding VAT).

The AcQMap System, which includes a workstation, console and cabling, costs £260,000 (excluding VAT). The company says that the anticipated in-service lifetime is 7 to 10 years.

Costs of standard care

The standard care equivalent for AcQMap is complex percutaneous transluminal ablation of heart at £3,800 to £5,300 per procedure (NHS reference cost 2018 to 19, EY30A and B).

Resource consequences

The company says that the AcQMap System is currently used in 7 NHS sites in England, which are doing 1 to 8 cases a month. This technology would be used instead of other systems used to map or identify regions of the heart for ablation.

There is an upfront cost of buying the system, which includes the workstation and console needed to use the technology.

The company claims the technology will reduce the need for repeat procedures, leading to more efficient use of hospital resources including catheter lab time, general anaesthetic availability and disposable consumables used in each procedure.

The company provides free support for all procedures. It also provides a free 2-day face-to-face training course, which covers system set up and use, map collection and data review. Attendees need to complete a logbook of 5 to 10 procedures before being signed off as proficient. Also included for free in the training are travel and accommodation, space rental, staff costs and hardware and disposables used.

Regulatory information

AcQMap is a CE marked class IIb medical device.

The following manufacturer field safety notices or medical device alerts for this technology have been identified. In April 2020 there was a US Food and Drug Administration (FDA) device recall for the AcQGuide Flex Steerable Introducer and a US FDA recall for the AcQGuide Mini Fixed-Curve Introducer. The recalls were from the company and related to the manufacturing process potentially leaving foreign material particulates on the finished device. The company says that this fault has now been resolved.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Heart arrhythmias are more prevalent in older people and in men. Sex and age are protected characteristics under the 2010 Equalities Act.

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

Five prospective studies are summarised in this briefing. In total, there were 189 people included in these studies.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

One of the studies has an appropriate sample size and relevant long-term outcome measures. It was also done partly in the UK, so it's relevant to the NHS. The other 4

studies are limited by their purpose: testing a new algorithm in a small group of people, comparing the accuracy of non-contact with contact mapping technologies without ablation, and assessing the characteristics of persistent atrial fibrillation. Although these studies are useful to the evidence base, they do not provide evidence on long-term treatment outcomes. Further data are needed to directly compare this new technology with standard care.

Willems et al. (2019)

Study size, design and location

Prospective multicentre non-randomised trial including 127 people with persistent atrial fibrillation who were scheduled for de novo catheter ablation in Europe (including the UK) and Canada.

Intervention and comparator(s)

The intervention was the AcQMap System. There was no comparator.

Key outcomes

Acute procedural efficacy was shown in 125 adults (98%). At 12 months, single-procedure freedom from atrial fibrillation on or off anti-arrhythmic drugs was 72.5% (95% confidence interval [CI] 63.9% to 80.3%). After 1 or 2 procedures, freedom from atrial fibrillation was 93.2% (95% CI 87.1% to 97.0%). However, 6 major adverse events were reported including 1 stroke, 2 cardiac tamponades, 1 air embolism causing ventricular fibrillation, 1 femoral arteriovenous fistula and 1 lymphocele.

Strengths and limitations

This study was not randomised and received funding from the company. However, the study included a large group of people and was conducted partly in the UK. The study also followed up procedural effectiveness for 12 months.

Ramak et al. (2020)

Study size, design and location

Prospective study of 7 people with atrial tachycardia evaluating the safety and feasibility of the new mapping algorithm, SuperMap, in Belgium.

Intervention and comparator(s)

The intervention was the AcQMap System. There was no comparator.

Key outcomes

The new algorithm enabled mapping of stable and transient rhythms and identified arrhythmogenic areas in all participants. Acute ablation was successful. The study showed the procedure time was fast with a mean total procedure time of 56.4 minutes (range 12.1) and a mean fluoroscopy time of 13.6 minutes (range 9.49). There were no procedural complications.

Strengths and limitations

This retrospective study had a small cohort size, which limits the conclusions that can be drawn. It showed that the new SuperMap algorithm was safe and effective in the post-atrial fibrillation ablation atrial tachycardia group studied.

Shi et al. (2020a)

Study size, design and location

Prospective study of 20 people with persistent atrial fibrillation who had an electrophysiological study then radiofrequency catheter ablation guided by non-contact dipole density mapping in the UK.

Intervention and comparator(s)

The intervention was non-contact (using AcQMap) and contact unipolar electrogram pairs recorded simultaneously from multiple locations. There was no comparator.

Key outcomes

This study aimed to validate the accuracy of non-contact electrograms against contact electrograms in the left atrium during sinus rhythm and atrial fibrillation. Seven hundred and ninety-six electrogram pairs in sinus rhythm and 969 electrogram pairs in atrial fibrillation were compared from 20 adults with persistent atrial fibrillation. The study found that the non-contact dipole density mapping system provided comparable reconstructed atrial electrogram measurements to contact mapping in sinus rhythm or atrial fibrillation in the left atrium when the anatomical site of interest is less than 40 mm from the mapping catheter.

Strengths and limitations

The study compared the accuracy of the electrogram measurements between contact and non-contact mapping methods. However, although the study said that participants had catheter ablation guided by non-contact dipole density mapping after the electrophysiological study, the outcomes of this procedure were not described.

Shi et al. (2020b)

Study size, design and location

Prospective study of 25 people with persistent atrial fibrillation who had catheter ablation guided by non-contact charge density mapping in the UK.

Intervention and comparator(s)

The intervention was non-contact (using AcQMap) and contact unipolar electrogram pairs recorded simultaneously from multiple locations. There was no comparator.

Key outcomes

This study aimed to identify activation patterns in the left atrium during persistent atrial fibrillation using charge density mapping. The study analysed 144 atrial fibrillation segments with 1,068 activation patterns. It found that localised irregular activation was the most common pattern of activation, found in 63% of participants during atrial fibrillation. Ninety-six per cent of participants showed continuous and changing patterns of activation. The authors noted that the clinical implications of individualised ablation

strategies need to be determined.

Strengths and limitations

The study showed the variability in activation patterns in people with persistent atrial fibrillation using non-contact mapping methods. However, although the participants identified needed a catheter ablation procedure, there were no clinical outcome data for this.

Chierchia et al. (2021)

Study size, design and location

Prospective study of 10 people with persistent atrial fibrillation who needed a repeat ablation procedure (after a pulmonary vein isolation procedure) guided by non-contact charge density mapping in Belgium.

Intervention and comparator(s)

The intervention was the AcQMap System. A further procedure using the CARTO 3D mapping system and PentaRay catheter was done in the same study group.

Key outcomes

All included participants had left atria mapping with both technologies. The study found that low voltage areas mapped with bipolar voltage mapping (using CARTO 3D mapping) in sinus rhythm and during coronary sinus pacing only partially overlap in persistent atrial fibrillation. Localised complex conduction cores from global non-contact mapping during persistent atrial fibrillation partially co-localise with low voltage areas. The authors suggested that using bipolar voltage mapping may not be the most appropriate method for identifying ablation areas in people with persistent atrial fibrillation. After an ablation procedure, atrial arrhythmia did not recur in 60% of participants during a 16-month follow-up period.

Strengths and limitations

The study was limited by a small sample size. Although there was procedure follow up,

there was no clear evidence on whether atrial fibrillation recurrence was a result of the AcQMap mapping system. The authors said a key limitation of their study was that mapping with the 3D CARTO mapping system was not done in atrial fibrillation.

Sustainability

The AcQMap System, which includes the AcQMap Workstation, console and cabling, are reusable. Other equipment needed, including the AcQMap catheter, sheath, and patient electrode kit, are single use.

Recent and ongoing studies

- AcQMap objectively visualize the etiology of recurrent AF following a failed AF ablation (RECOVER AF). ClinicalTrials.gov identifier: NCT03368781. Status: completed. Indication: recurrent atrial fibrillation. Devices: AcQMap Imaging and Mapping System. Date: 29 October 2020. Countries: UK, Belgium, Canada, Germany, Czech Republic and the Netherlands.

- AcQMap global registry of procedural and long-term clinical outcomes (AcQMap Registry) (DISCOVER). ClinicalTrials.gov identifier: NCT03893331. Status: recruiting. Indication: ablation of arrhythmias. Devices: AcQMap System. Date: 15 February 2025. Countries: UK and the Netherlands.

- AcQMap US registry of procedural and long-term clinical outcomes (Discover-US). ClinicalTrials.gov identifier: NCT04431544. Status: recruiting. Indication: ablation of arrhythmias. Devices: AcQMap System. Date: 15 November 2025. Country: US.

- Pulmonary vein isolation plus left atrial slow zone mapping and ablation (PLASZMA). ClinicalTrials.gov identifier: NCT04512794. Status: not yet recruiting. Indication: atrial arrhythmias. Devices: AcQMap High Resolution Imaging and Mapping System. Date: 1 December 2022. Country: US.

- Biatrial global high-density electroanatomical mapping of atrial fibrillation (BiMap-AF). ClinicalTrials.gov identifier: NCT03812601. Status: active, not recruiting. Indication: atrial fibrillation. Devices: AcQMap. Date: November 2021. Country: UK.

- Characterising the stable and dynamic left atrial substrate in atrial fibrillation (CASDAF-HD). ClinicalTrials.gov identifier: NCT04229472. Status: not yet recruiting. Indication: atrial fibrillation. Devices: Abbott Advisor HD grid, AcQMap. Date: March 2022. Country: UK.

Expert comments

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

All 6 experts were familiar with the technology and 3 had used it before.

Level of innovation

All experts said that the technology is innovative because it allows non-contact mapping, instead of contact mapping, to treat arrhythmias. Three said it was faster than collecting contact data sequentially from multiple sites in the cardiac chamber. Four experts said that the ability to map the entire cardiac chamber simultaneously was particularly beneficial for unstable rhythms, such as atrial fibrillation, which have not been reliably mapped using standard technology. One expert noted that this type of global non-contact mapping can provide mechanistic information about the arrhythmia, which can help guide treatment.

Two experts said that this technology could replace, or be used alongside, standard care for atrial fibrillation ablation, depending on further evidence of its effectiveness. Two thought it would only be used alongside standard care. One expert said that AcQMap may become standard care for some people with persistent atrial fibrillation who are likely to have a poor outcome from pulmonary vein isolation alone.

Potential patient impact

Two experts said that AcQMap-guided ablation could be more effective than current treatment for persistent atrial fibrillation, and reduce the number of ablation procedures needed. However, they said that evidence is needed from randomised controlled trials to prove its effectiveness compared with standard care. One expert noted that people with very complex atrial arrhythmias may benefit more from using this specific technology than anyone with atrial fibrillation, but further evidence is needed to show this. One commented

that, for more challenging atrial fibrillation (such as persistent atrial fibrillation, or atrial fibrillation that has recurred after previous pulmonary vein isolation ablation), the AcQMap System offers a greater chance of a successful ablation procedure than current standard care. The expert also noted that for atrial tachycardias, particularly those that are non-sustained or with multiple foci, the technology offers the chance of faster procedures with a higher success rate. Another expert thought that this device gives the opportunity to treat non-sustained atrial tachycardias that cannot be mapped with other systems, and identify possible sites for atrial fibrillation initiation and perpetuation.

One expert commented that AcQMap could allow more personalised treatments and reduce procedure time. Three noted that the technology can improve success rates and reduce the need for further procedures. This could mean less scar tissue and a better clinical outcome. One expert suggested fewer heart failures could mean fewer hospitalisations and deaths. They also said that, if there was less atrial fibrillation refractory to rhythm control measures, that could also lead to fewer hospitalisations.

Potential system impact

Five experts said that if the technology is effective, it could lead to less ablated tissue, fewer redo procedures and potentially quicker procedures. One said that if fewer procedures were needed, the technology could be cost saving. However, another expert said the cost case depends on whether randomised controlled trial or registry data show that the technology improves procedural success and reduces the need for further medical treatment. Two said that the technology would cost more than standard care using electro-anatomical mapping systems because extra consumable equipment is needed, including the AcQMap mapping catheter. One expert thought the technology could be cost neutral in the future. Five experts thought that only limited changes to facilities were needed to adopt the technology and that it could be adopted in any department currently doing ablation for complex cardiac arrhythmias. The only change needed was to purchase the core equipment and the consumables. Four experts said that training is needed. Two of these said that, because the technology is similar to existing technology, experienced cardiac electrophysiologists would have a relatively short learning curve. Three experts mentioned that support from experienced users for the first cases is beneficial. Two said that the company provides ongoing technical support.

General comments

Four experts said that the adverse events seen in the AcQMap data so far are similar to what would be expected for other catheter ablation procedures. Five noted the current lack of randomised controlled trial data comparing the technology to standard care. However, 1 expert said that most technologies in this field are assessed using single-arm studies. One said that longer-term outcome data are also needed.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Justin Lee, consultant cardiologist, Northern General Hospital. Received support for attending conference and educational meetings from Medtronic, Servier, Bayer and Pfizer. Dr Lee received support for travel costs for attending training from Acutus Medical.
- Dr Kim Rajappan, consultant cardiologist, John Radcliffe Hospital. Dr Rajappan has been involved in research and received honoraria for speaking about competing technologies made by Abbott and Biosense Webster.
- Dr Tom Wong, consultant electrophysiologist and cardiologist, Royal Brompton and Harefield NHS Foundation Trust. Dr Wong has received an educational grant from Acutus Medical.
- Professor Tim Betts, consultant cardiologist, John Radcliffe Hospital. Professor Betts has received speaker fees for educational lectures and honoraria for training new users.
- Dr David R Tomlinson, consultant cardiologist and electrophysiologist, Derriford Hospital, Plymouth. Did not declare any interests.
- Dr Muzahir Tayebjee, consultant cardiologist and electrophysiologist, Leeds General Infirmary. Dr Tayebjee has received research grants from Medtronic, Abbott Medical and Biosense Webster.

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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