ACE BRIEF FOR NEW AND EMERGING HEALTH TECHNOLOGIES

AcQMap for Patients with Cardiac Arrhythmia

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Contents

Summary of Key Points

- Cardiac arrhythmia comprises various heart rhythm abnormalities, with a prevalence of 1.5% to 5% in the US. Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and has a considerable impact on public health.
- Current catheter ablation treatments for cardiac arrhythmia are limited by time-consuming contact mapping techniques and a lack of strategies to target non-pulmonary vein (PV) targets, especially in patients with persistent arrhythmia.
- AcQMap (Acutus Medical) is a non-contact, charge-density mapping system that provides ultrasound-acquired anatomy and localised electrical assessment of cardiac activation across the whole heart chamber. It offers the potential for a high-resolution whole-chamber assessment of endocardial activation, enabling individualised ablation strategies.
- Overall, AcQMap was found to be generally safe with some evidence suggesting acute and long-term success rates compared to standard care.
    - AcQMap-guided ablation had comparable major adverse events to contact mapping.
    - Mixed findings for procedural outcomes such as procedure duration and radiation use were reported. Evidence limited to robotic ablations remained equivocal, while improved mapping efficiency was reported with use of the SuperMap algorithm. However, the clinical meaningfulness of the reported procedural outcomes is unclear.
    - Compared to contact mapping (propensity-score matched control), manual ablation guided by AcQMap showed good acute (24-hour) AF termination (73% vs. 10%, $p<0.001$) and 24-month freedom from AF or atrial tachycardia (68% vs. 46%, $p=0.04$) in patients with persistent AF.
    - Outcomes for AcQMap-guided ablation only demonstrated good acute success rate (81% to 98%), while 12-month freedom from arrhythmia ranged from 29% to 93.2%.
    - The ability of AcQMap to target non-PV targets was demonstrated in the RECOVER-AF trial. AcQMap-guided ablation in patients with persistent AF following a prior PV isolation procedure resulted in 91.5% of individuals remaining free from AF at 12 months.
- The healthcare system benefits and cost-effectiveness of AcQMap remain unclear.
- Key limitations of the evidence include a lack of direct comparative studies, especially randomised controlled trials, to compare AcQMap with contact-mapping strategies.
- The AcQMap system, comprising the workstation, console and cabling, costs £260,000 (S$443,066), while the AcQMap catheter, catheter sheath and patient electrode kit costs £4,550 (S$7,754) per procedure.
- Key implementation considerations include good clinical practice required for the use of the SuperMap algorithm and its cost.
- Local clinicians shared that AcQMap may have limited utility in the local setting due to the availability of efficient alternatives (e.g. multipoint contact-mapping catheters).

I. Background

Cardiac arrhythmia refers to the uncoordinated muscle contraction of the heart.[1] In a normal sinus rhythm, an electrical impulse originating from the sinoatrial node is conducted across the heart, including through the atrioventricular node, allowing the heart to contract efficiently.[1] Any deviation in this conduction pathway results in an arrhythmia that can be broadly classified, according to heart rate, into bradyarrhythmia or tachyarrhythmia, with further classification based on site of origin, means of transmission and symptoms.[1] Patients with cardiac arrhythmia may be asymptomatic or present with symptoms such as chest discomfort, syncope, palpitations or dyspnoea.[2]

In the US, the prevalence of arrhythmia is estimated to be 1.5% to 5% in the general population.[1] Among various rhythm abnormalities, atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and has a considerable impact on public health.[3] AF is associated with around a two-fold increased risk of all-cause death and increased morbidity, and is a frequent cause of hospitalisation, thromboembolic events and heart failure.[4,5] Further, AF presents a substantial economic burden, with an incremental associated cost of up to US$26 billion per year in the US.[5]

Current therapies for cardiac rhythm control, including antiarrhythmic drugs and catheter-based ablation procedures, are not optimally effective or safe.[5] To localise the origin of the arrhythmia for cardiac ablation procedures, patients undergo standard catheter endocardial mapping in the electrophysiology (EP) laboratory.[6] Such electro-anatomical mapping can be challenging with traditional sequential contact techniques, which requires time-consuming point-by-point manoeuvring of the catheter to trace the origin of an arrhythmic event and its activation sequence in the neighbouring areas.[6] The need for improved EP mapping is further highlighted by the limitations of the current pulmonary vein isolation (PVI) procedure, which is a cornerstone ablation strategy targeting the ectopic foci from the pulmonary veins (PV) initiating AF.[7] PVI is the most commonly used treatment strategy for paroxysmal AF. However, its low success rate in patients with persistent arrhythmia, together with limited empirical strategies to target non-PV triggers, underlines the need for an individualised and patient-specific approach to target localised areas of fibrosis or electrophysiological mechanisms.[7,8] It has been reported that beyond the scope of conventional contact mapping, such non-PV triggers can be targeted by non-contact mapping techniques.[9,10]

II. Technology

The AcQMap System (Acutus Medical) is an imaging and electrophysiological mapping system that can direct endocardial ablation treatment for stable and unstable arrhythmias, such as AF.[11] It comprises the AcQMap catheter, console and workstation (Figure 1). The AcQMap catheter is a single-use device that is introduced into the heart over a guidewire. It can be expanded to form a 25 mm diameter spheroid cage and comprises six splines, each housing eight ultrasound transducers for anatomic reconstruction and eight electrodes for recording biopotential signals.[11] A non-contact charge-density mapping system provides a dynamic, three-dimensional map of cardiac electrical patterns overlaid on ultrasound-acquired cardiac anatomy in under three minutes.[11,12] This provides a high-resolution whole chamber panoramic assessment of endocardial activation, offering an advantage over other non-contact mapping systems.[13]

Compared to traditional contact mapping, AcQMap allows visualisation of complex and temporally variable rhythm propagation, potentially uncovering mechanisms of complex arrhythmias and enabling individualised ablation strategies.[7,14] AcQMap allows a more rapid and targeted approach and has the potential to reduce unnecessary ablation procedures. As the device can be left in the heart during cardiac ablation, remapping can be performed to gauge the success of the ablation procedure.[11]

Figure 1. Illustration of the AcQMap system. Image adapted from https://www.dicardiology.com/content/fda-clears-second-generation-acqmap-3d-ep-imaging-and-mapping-catheter

The AcQMap system also requires a patient electrode kit. These electrodes are placed in designated locations on the body, providing catheter-positioning information.[11] The technology can also be used with the SuperMap algorithm to map stable or transient rhythms while distinguishing between different morphologies and arrhythmia cycle lengths in a single recording.[11] Further, AcQMap can also conduct traditional contact mapping activities using conventional EP catheters instead of the AcQMap catheters.[15]

III. Regulatory and Subsidy Status

The AcQMap system (AcQMap High Resolution Imaging and Mapping System and AcQMap 3D Imaging and Mapping Catheter) received regulatory clearance from the US Food and Drug Administration (FDA) in October 2017 and was approved by the Health Sciences Authority (HSA) in end 2022.[15-17] The SuperMap algorithm was cleared by the FDA in February 2020.[18]

IV. Stage of Development in Singapore

While AcQMap has been locally approved by HSA, local clinicians shared that non-contact mapping technologies, including AcQMap, are not used in local clinical practice (Personal Communication: Senior Consultant from National Heart Centre Singapore, 23 August 2023; Senior Consultant from National University Heart Centre Singapore, 6 September 2023).

☐	Yet to emerge	☐	Established
☒	Investigational / Experimental (subject of clinical trials or deviate from standard practice and not routinely used)	☐	Established *but* modification in indication or technique

☐	Nearly established	☐	Established *but* should consider for reassessment (due to perceived no/low value)

V. Treatment Pathway

Local treatment strategies for patients with cardiac arrhythmia depend on the type, cause and characteristics of the disease (Personal Communication: Senior Consultant from National Heart Centre Singapore, 23 August 2023; Senior Consultant from National University Heart Centre Singapore, 6 September 2023). Patients may be treated with one or a combination of the following (see Figure A1 in Appendix A):

- Pharmacotherapies, generally as a first-line treatment, including rate control drugs (e.g. beta-blockers), rhythm control drugs (e.g. anti-arrhythmic drugs) or stroke prevention therapies (e.g. anti-coagulants)
- Non-invasive therapies, including vagal manoeuvres or cardioversion
- Surgery or other procedures, including implantation of pacemakers or defibrillators, EP study with ablation or maze surgery.

AcQMap can provide an alternative to existing mapping catheters in the EP laboratory to guide treatment of cardiac arrhythmia. In particular, experts consulted by NICE shared that depending on its effectiveness, AcQMap may either replace or be used alongside standard care for AF ablation.[11]

VI. Summary of Evidence

This assessment was conducted based on the Population, Intervention, Comparator and Outcome (PICO) criteria presented in Table 1. Literature searches were conducted in international health technology assessment (HTA) databases, Cochrane library, PubMed and Embase. Eight studies were included in the key evidence base including: one HTA report from the National Institute for Health and Care Excellence (NICE; MIB246, 2021) comprising five single-arm studies,[11] five comparative studies[19-23] and two additional single-arm studies.[24,25] Of the five comparative studies, four[19-21,23] involved comparisons with a matched control group, while one study[22] had a within-patient design where both EP mapping with AcQMap and contact mapping were performed on the same patient. The two single-arm studies are the RECOVER-AF trial,[24] which served as both a pre-market study in Canada and post-market study in Europe, and a real-world study.[25] The study design and characteristics of the key evidence sources are presented in Tables B1 and B2 (Appendix B).

Table 1: Summary of PICO criteria

Population	Patients with cardiac arrhythmia
Intervention	AcQMap system
Comparator	Current standard electrophysiology procedures, including contact mapping
Outcome	Safety, clinical- and cost-effectiveness

Safety

Based on seven studies,[11,19-21,23-25] the AcQMap system was found to be generally safe. Across two studies[20,23] comparing catheter ablation guided by AcQMap and by contact mapping, no between-group differences were reported for procedural complications (3.4% *vs.* 3.3%) or major complications (Table 2). This finding was corroborated by five additional studies[11,19,21,24,25] that reported on safety outcomes of AcQMap only, where a low rate of major adverse events (AEs) was demonstrated across a heterogenous population (Table 2). Common major AEs reported included stroke, cardiac tamponade and hemiparalysis, all of which were adjudicated to be related to the ablation procedure. Notably, experts consulted by NICE shared that the AEs reported for AcQMap-guided ablation are similar to those observed for other catheter ablation procedures.[11]

Table 2: Summary of safety outcomes

Study	Population (n)	Key outcome
Comparative outcomes		
Shi et al. (2021)[23]	Patients with persistent AF (n=120)	No major complications occurred in both groups
Gagyi et al. (2022)[20]	Patients with AF or AT (n=238)	Procedural complications: AcQMap-RMN *vs.* CARTO-RMN (3.4% *vs.* 3.3%, p=1.0)
Outcomes for AcQMap-guided ablation only		
Willems et al. (2019)[11a]	Patients with persistent AF scheduled for de novo catheter ablation (n=129)	● 98% (126/129) of patients MAE free ● No MAEs related to use of the system ● 6 (4.6%) procedure-related MAEs reported
Liebregts et al. (2021)[25]	Patients with persistent AF or atypical flutter (n=21)	● 2 patients (10%) with major complications attributable to radiofrequency ablation ● No major complications attributed to the mapping system
Betts et al. (2023)[24]	Patients receiving retreatment for AF (n=103)	● No MAEs reported ● 6 procedure-related AEs and 1 device-related AE
Gagyi et al. (2023)[21]	Patients with AT undergoing de novo or redo ablation (n=70)	● Post-procedural complications in 2 patients (2.9%)
Gagyi et al. (2023)[19]	Patients with AT and PACs (n=31)	● 1 procedure-related AE

[a] Study reviewed in NICE MIB246 (2021)[11].

Abbreviations: AE, adverse event; AF, atrial fibrillation; AT, atrial tachycardia; MAE, major adverse event; PAC, premature atrial contraction; RMN, robotic magnetic navigation.

Effectiveness

Procedural outcomes

Overall, the evidence showed mixed findings of procedural outcomes for AcQMap. Comparative evidence limited to ablation with robotic magnetic navigation (RMN) showed that AcQMap-guided ablations were generally more time consuming and had a higher fluoroscopy use. In two studies[20,21] comprising patients with AF or atrial tachycardia (AT), procedure duration and fluoroscopy dose were higher in the AcQMap-RMN group than for the CARTO-RMN (contact mapping) group (Table 3). One study[20] attributed these findings to an initial learning curve for AcQMap use, showing that AcQMap-RMN procedures performed later in the study had significantly shorter duration (191.7 *vs.* 135.5 min, p<0.01) and lower fluoroscopy doses (310.1 *vs.* 134 mGy, p<0.01) than earlier procedures. However, no difference in procedural outcomes was reported between the last 30 AcQMap-RMN procedures and the CARTO-RMN group (see Figure C1 in Appendix C).[20]

In contrast, another study[19] conducted by the same group found no difference in procedure duration and radiation use between AcQMap-guided RMN ablation and the historical control group (Table 3). However, it is unclear what method of ablation and EP mapping were used in the historical controls.

Table 3: Procedural outcomes of AcQMap *vs.* contact mapping-guided robotic ablation

Study	Population (n)	Procedure duration (min)[a]			Fluoroscopy dose (mGy)		
		AcQMap-RMN	CARTO-RMN	p-value	AcQMap-RMN	CARTO-RMN	p-value
Gagyi et al. (2022)[20]	Patients with AF or AT (n=238)	172.5 ± 52.6	129.6 ± 47.7	<0.01	181.0 (110.5 to 320.0)[b]	132.0 (68.5 to 220.5)[b]	0.02
Gagyi et al. (2023)[21]	Patients with AT undergoing de novo or redo ablation (n=125)[c]	174 ± 61.8	147.5 ± 51.1	0.01	152.0 (84.3 to 299.5)[b]	132.5 (32.1 to 270.5)[b]	0.10
Gagyi et al. (2023)[19]	Patients with AT and PACs (n=31)[d]	155.3 ± 46.6	157.4 ± 33.6	0.80	17.1 ± 9.4[e]	16.9 ± 7.6[e]	0.90

[a] Values presented as mean ± S.D.
[b] Values presented as median and interquartile range (IQR).
[c] Includes 67 patients in the AcQMap-RMN group and 58 patients in the historical control (CARTO-RMN) group.
[d] Population excludes historical data obtained from a German catheter ablation registry.
[e] Values reported as total fluoroscopy time (minute).
Abbreviations: AF, atrial fibrillation; AT, atrial tachycardia; IQR, interquartile range; PAC, premature atrial contraction; RMN, robotic magnetic navigation.

It has also been reported that procedural outcomes improved when the SuperMap algorithm was used with AcQMap . One small study (n=19) showed that the SuperMap algorithm allowed faster generation of diagnostic activation maps (394 ± 219s *vs.* 611 ± 331s, p<0.0005) with a higher density of electrogram points (7351 ± 5054 *vs.* 3620 ± 3211, p<0.0005) than contact mapping.[22] Similarly, a single-arm study (n=7) reviewed by NICE reported fast mean procedure time of 56.4 minutes with SuperMap, although it was limited by the small sample size.[11]

Clinical outcomes

Findings from two comparative studies[20,23] suggested that AcQMap-guided ablation may be an effective strategy for treating persistent AF and AT up to 24 months. In patients with persistent AF, PVI followed by AcQMap-guided catheter ablation resulted in significantly higher acute (24-hour) AF termination (73% *vs.* 10%, p<0.001) and 24-month freedom from AF or AT (68% *vs.* 46%, p=0.04) than empirical PVI and posterior wall electrical isolation guided by contact mapping (Table 4).[23] Similar findings were reported for ablation using RMN, where compared to contact mapping (CARTO 3), AcQMap-guided robotic ablation resulted in significantly lower recurrence of persistent AF (36.6% *vs.* 75%, p=0.04) and AT (17.1% *vs.* 38.7%, p=0.04) at 12 months (Table 4).[20]

Table 4: Summary of comparative clinical outcomes of AcQMap *vs.* contact mapping

Study	Population (n)	Comparison arms	Clinical endpoint	Outcome

Shi et al. (2021)[23]	Patients undergoing de novo ablation for perAF (n=120)[a]	AcQMap *vs.* CARTO (PSM control)	Acute success rate	73% *vs.* 10% (p<0.001)
			Single-procedure freedom from AF/AT at 24 months[b]	68% *vs.* 46% (p=0.043)
Gagyi et al. (2022)[20]	Patients with AF or AA (n=238)[c]	AcQMap-RMN *vs.* CARTO-RMN (age- and sex-matched control)	Recurrence of perAF at 12 months	36.6% *vs.* 75% (p=0.04)
			Recurrence of PAF at 12 months	6.6% *vs.* 12.5% (p=0.58)
			Recurrence of AT at 12 months	17.1% *vs.* 38.7% (p=0.05)

[a] Includes 40 patients with perAF with PVI + AcQMap-guided ablation and a propensity score-matched control group of 80 patients who underwent de novo empirical PVI + PWI ablation guided by conventional contact mapping.

[b] In the absence of antiarrhythmic medications following a single procedure.

[c] Includes 147 consecutive patients mapped with AcQMap-RMN and an age and sex-matched cohort of control patients mapped with the CARTO-RMN system.

Abbreviations: AA, atrial arrhythmia; AF, atrial fibrillation; AT, atrial tachycardia; PAF, paroxysmal atrial fibrillation; perAF, persistent atrial fibrillation; PSM, propensity score matching; PVI, pulmonary vein isolation; PWI, posterior wall electrical isolation; RMN, robotic magnetic navigation.

One study reviewed by NICE[11] and four other studies[19,21,24,25] reported clinical outcomes for AcQMap only (Table 5). Across a heterogenous population (e.g. AF or AT) and treatment type (e.g. de novo or redo ablation), with varying timeframes for achieving sinus rhythm, AcQMap-guided ablation demonstrated good acute success rates (81% to 98%). Freedom from arrhythmia at 12 months ranged from 29% to 93.2%.[11,19,21,24,25] The lowest rate was reported by a real-world study[25] (n=21) and postulated to be due to the selection of patients with therapy-resistant arrhythmias and limited user experience with the AcQMap system.

Table 5: Summary of clinical outcomes of AcQMap only

Study	Population (n)	Acute success rate	12-month freedom from arrhythmia
Willems et al. (2019)[11a]	Patients with persistent AF scheduled for de novo catheter ablation (n=127)	98%[b]	72.5% (95% CI, 63.9% to 80.3%)[c]; 93.2% (95% CI, 87.1% to 97%)[d]
Liebregts et al. (2021)[25]	Patients with persistent AF or atypical flutter (n=21)	81%[e]	Afl: 57% PerAF: 29%
Betts et al. (2023)[24]	Patients receiving retreatment for AF (n=103)	NR	67%[c]; 75.7%[d]
Gagyi et al. (2023)[21]	Patients with AT undergoing de novo or redo ablation (n=70)[f]	94%[g]	80.6%
Gagyi et al. (2023)[19]	Patients with ATs and PACs (n=31)	96.8%[h]	80.6%

[a] Study reviewed in NICE MIB246 (2021)[11].

[b] Acute success defined as procedural conversion to sinus rhythm within 12 hours of the index procedure.

[c] Single-procedure freedom at 12-months on or off anti-arrhythmic drugs.

[d] Freedom at 12-months on or off anti-arrhythmic drugs after two procedures.

[e] Acute success defined as conversion to sinus rhythm at the end of the procedure.

[f] Outcomes based on AcQMap-RMN guided ablation.

[g] Acute success defined as non-inducibility of the treated arrhythmia.

[h] Acute success defined as the absence of tachyarrhythmias during a waiting time 15 to 30 minutes after the last ablation application.

Abbreviations: AF, atrial fibrillation; Afl, atrial flutter; AT, atrial tachycardia; CI, confidence interval; NR, not reported; PAC, premature atrial contraction; PerAF, persistent atrial fibrillation; RMN, robotic magnetic navigation.

Further, two studies[23,24] demonstrated the clinical utility of AcQMap in targeting non-PV foci following a previous PVI ablation that targets PV triggers. In the RECOVER-AF trial,[24] AcQMap-guided ablation in patients with persistent AF following a prior PVI ablation resulted in 91.5% of individuals remaining AF-free at 12 months. Similarly, Shi et al. (2022)[23] demonstrated a stepwise increase in acute AF termination with each consecutive ablation of additional non-PV sites with AcQMap (see Figure C2 in Appendix C).

Healthcare system benefits

No evidence was identified regarding healthcare system benefits of AcQMap. As reported by NICE, the company claims that the technology can lead to more efficient use of healthcare resources (e.g. catheter lab time, general anaesthetic availability and disposable consumables) by reducing the need for repeat ablation procedures.[11]

Cost-effectiveness

The cost-effectiveness of AcQMap compared to standard care remains unclear. Manour et al. (2017)[26] have reported cost savings for restoring sinus rhythm in a single ablation procedure compared to repeated ablations for AF. This suggests possible economic benefits may be realised if AcQMap-guided ablation could reduce the number of repeated ablation procedures. Further investigation is required.

Ongoing trials

Four ongoing trials were identified from the ScanMedicine database (NIHR Innovation Observatory), including two registry and two technical studies (Table 6). Of interest, the two registry studies will report on acute ablation success and long-term patient outcomes with the AcQMap system at three years, and are estimated to be completed in 2029.

Table 6: Summary of ongoing trials

Trial (Study ID)	Estimated Enrolment	Brief description	Estimated completion date
DISCOVER (NCT03893331)	1,000	A registry to provide clinical data regarding the commercial, real-life experience with the AcQMap System across Europe and UK.	September 2029
Discover-US (NCT04431544)	1,000	A registry to provide clinical data regarding the commercial, real-life experience with the AcQMap System in the US.	August 2029
Shape vs Substrate in AF (NCT05993104)	80	A three-phase case-only study to investigate the relation between geometric abnormality and abnormal electrical activity using AcQMap to determine the feasibility of geometric assessment in catheter ablation procedure.	September 2026
CASDAF-HD (NCT04229472)	35	A non-randomised controlled trial to investigate the mechanisms involved in arrhythmia propagation using Abbott Advisa HD grid and AcQMap.	March 2024

Summary

Overall, AcQMap-guided ablation was generally safe with a low rate of major AEs that was comparable to ablation guided by contact mapping. Mixed findings for procedural outcomes were reported: evidence limited to ablations with RMN remained equivocal, while improved mapping efficiency was reported with use of the SuperMap algorithm. However, the clinical meaningfulness of the reported procedural outcomes is unclear. Compared to contact mapping (propensity score matched control), AcQMap-guided ablation showed significantly better acute success (73% *vs.* 10%, p<0.001) and 24-month freedom from AF or AT (68% *vs.* 46%, p=0.04) in patients with persistent AF. Findings for AcQMap-guided ablation only demonstrated a good acute success rate (81% to 98%), while 12-month freedom from arrhythmia ranged from 29% to 93.2%. Additionally, in the RECOVER-AF trial, 91.5% of patients with only a prior PVI remained AF-free at 12 months following AcQMap-guided ablation, suggesting the ability of AcQMap to target non-PV targets. Currently, the healthcare system benefits and cost-effectiveness of AcQMap remain to be investigated.

However, these findings should be interpreted with caution. While comparative evidence with matched controls is available, further validation of the findings with randomised controlled trials (RCTs) would be beneficial to establish the effectiveness of AcQMap compared to standard care. Further, intermittent (24 to 48 hours) monitoring for arrhythmia during follow-up in some studies[23,24] may potentially miss sporadic AF episodes.

VII. Estimated Costs

The AcQMap System, comprising the workstation, console and cabling, was reported by NICE to cost £260,000 (S$443,066)[a] excluding tax. In addition, the AcQMap catheter, catheter sheath and patient electrode kit cost £4,550 (S$7,754)[a] per procedure.[11]

VIII. Implementation Considerations

In adopting AcQMap for local use, there may be a need to adhere to good clinical practice as the SuperMap algorithm involves artificial intelligence (AI). As outlined in the Ministry of Health's Artificial Intelligence in Healthcare Guidelines, it would be necessary to exercise clinical governance and oversight over the use of the SuperMap algorithm. This includes assessing risk to anticipate software failure, ensuring its performance in the local setting and evaluating for cybersecurity vulnerabilities.[27]

Moreover, there are indications that cost may be a barrier to adoption. Experts consulted by NICE shared that AcQMap would cost more than standard care due to the need for additional consumable equipment including the AcQMap mapping catheter, although others thought the technology may be cost neutral in the future.[11] Locally, cost has also been cited as a factor in the low uptake of non-contact mapping technologies (Personal communication: Senior Consultant from National University Heart Centre Singapore, 6 September 2023).

In addition, it was reported by NICE that the technology is not expected to require major changes to infrastructure or facilities. Experts consulted by NICE opined that only limited facilities changes are required and the technology can be adopted in any practice that is performing ablation for complex cardiac arrhythmias.[11] Of note, a local clinician shared that there may be a learning curve and clinicians will need a certain volume of cases per year to

[a] Based on the Monetary Authority of Singapore exchange rate as of 8 September 2023: £1=S$1.7041. Figures were rounded to the nearest dollar.

maintain familiarity (Personal communication: Senior Consultant from National Heart Centre Singapore, 13 October 2023).

IX. Concurrent Developments

While non-contact multielectrode catheters that allow the development of high-density maps have been widely commercialised, AcQMap is the only non-contact mapping catheter currently known to provide real-time anatomy combined with high-resolution charge density maps of electrical activation.

X. Additional Information

Local clinicians shared that AcQMap may be used as an alternative to current mapping systems for non-sustained arrhythmias (e.g. non-sustained ventricular tachycardia, which is a common but asymptomatic arrhythmia most often diagnosed during cardiac monitoring), with one clinician highlighting the limited use for AcQMap in the local setting. While it may be useful, if proven, to map single beat arrhythmias, the local availability of multipoint contact mapping catheters such as PentaRay (Biosense Webster, Inc.) and Advisor HD Grid (Abbott Medical) have enabled fairly rapid mapping, thereby reducing the potential benefits of non-contact mapping catheters. Although unstable arrhythmias like ventricular tachycardia may not respond well to technologies like multipoint contact mapping catheters, alternative methods such as the anatomical substrate-based approach can still achieve favourable outcomes without requiring non-contact mapping. Notably, despite non-contact mapping technologies being locally available since the 2000s, they are not widely used due to technical challenges and cost, further pointing to their limited utility in the local context (Personal communication: Senior Consultant from National University Heart Centre Singapore, 6 September 2023; Senior Consultant from National Heart Centre Singapore, 13 October 2023).

Moreover, it was shared that the benefits of targeting non-PV sites for AF ablation remains controversial, thus rendering the advantage of AcQMap unclear (Personal communication: Senior Consultant from National University Heart Centre Singapore, 6 October 2023).

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Appendix

Appendix A: Clinical pathway for the treatment of cardiac arrhythmia

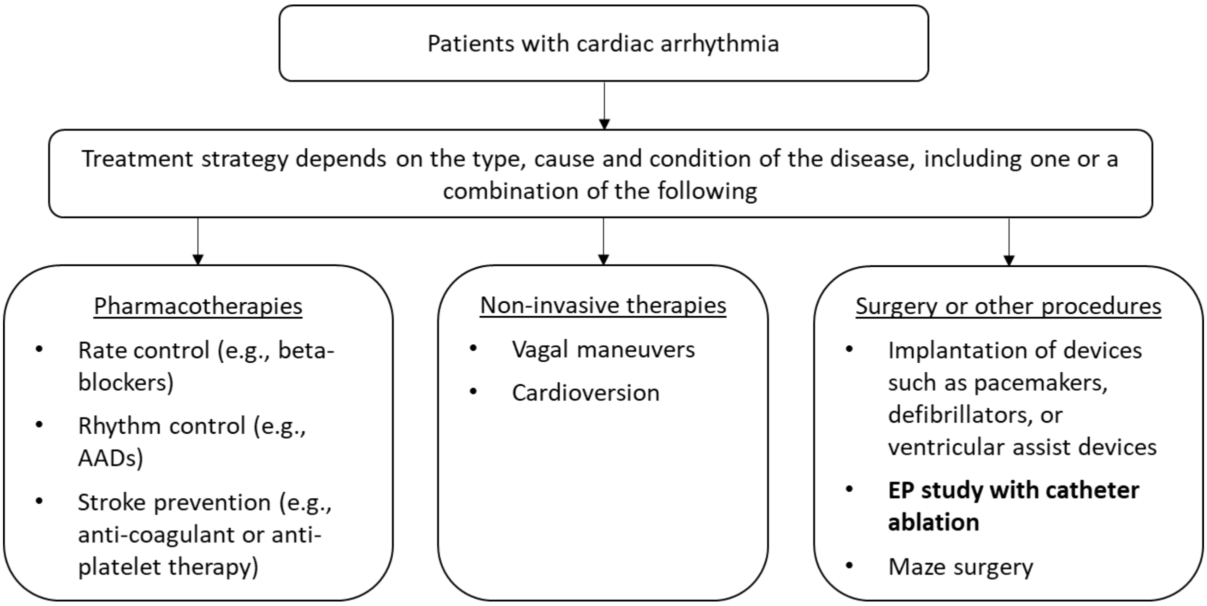

Figure A1: Clinical pathway for the treatment of cardiac arrhythmia. Treatment strategy for patients with cardiac arrhythmia includes EP study with catheter ablation, which allows ablation of arrythmia triggers. Abbreviations: AAD, anti-arrhythmic drug; EP, electrophysiology.

Appendix B: Studies included and study design

Table B1: List of included studies

Type of study	Key evidence base
Health technology assessment report	1
Comparative study	5
Single-arm study	2
Note: 1. Inclusion criteria a. Studies that fulfil the PICO criteria listed in Table 1. 2. Exclusion criteria a. Studies only available in the abstract form.	

Table B2: Characteristic of included studies

Study	Study design	Population (N)[a]	Intervention	Comparator
NICE MIB246 (2021)[11]	HTA	Patients with cardiac arrhythmia (5 studies)	AcQMap	—
Shi et al. (2021)[23]	Prospective observational study	Patients undergoing de novo radiofrequency catheter ablation of persistent AF (n=120)	PVI + AcQMap (n=40)	Propensity score-matched control: PVI + PWI (n=80)
Gagyi et al. (2022)[20]	Prospective registry	Consecutive patients undergoing mapping and catheter ablation using the AcQMap system (n=238)	AcQMap-RMN (n=147)	Age and sex matched control: CARTO-RMN (n=91)
Liebregts et al. (2022)[25]	Prospective study	Patients treated for persistent AF or atypical atrial flutter with the AcQMap system (n=21)	AcQMap	—
Pope et al. (2022)[22]	Prospective observational study (n=31)	Consecutive patients undergoing SuperMap non-contact mapping of organised Ats and during pacing for assessment of block in subsequent linear ablation lesions (n=31)	SuperMap non-contact mapping (n=31)	High-density contact mapping (n=19)[b]
Betts et al. (2023)[24]; RECOVER-AF	Prospective study	Patients aged 18 or older, scheduled for repeat endocardial ablation for recurrent AF (n=103)	AcQMap	—
Gagyi et al. (2023)[21]	Retrospective study	Patients aged 18 to 80 years with AT undergoing de novo or redo catheter ablation procedure (n=125)	AcQMap (n=67)	Historical control: Patients with AT mapped and ablated using sequential 3D mapping integrated with RMN (CARTO; n=58)
Gagyi et al. (2023)[19]	Retrospective study	Patients presenting with highly symptomatic short runs of ATs or PACs (n=31)	AcQMap (n=31)	Historical control: Historical data from the German ablation registry used for comparison of procedural outcomes (n not reported)

[a] Refer to the number of included studies, or total number of patients including matched controls where relevant.

[b] Subset of patients where concurrent contact mapping was conducted.

Abbreviations: AF, atrial fibrillation; AT, atrial tachycardia; HTA, health technology assessment; PVI, pulmonary vein isolation; PWI, pulmonary wall isolation; RMN, robotic magnetic navigation.

Appendix C: List of supplementary figures

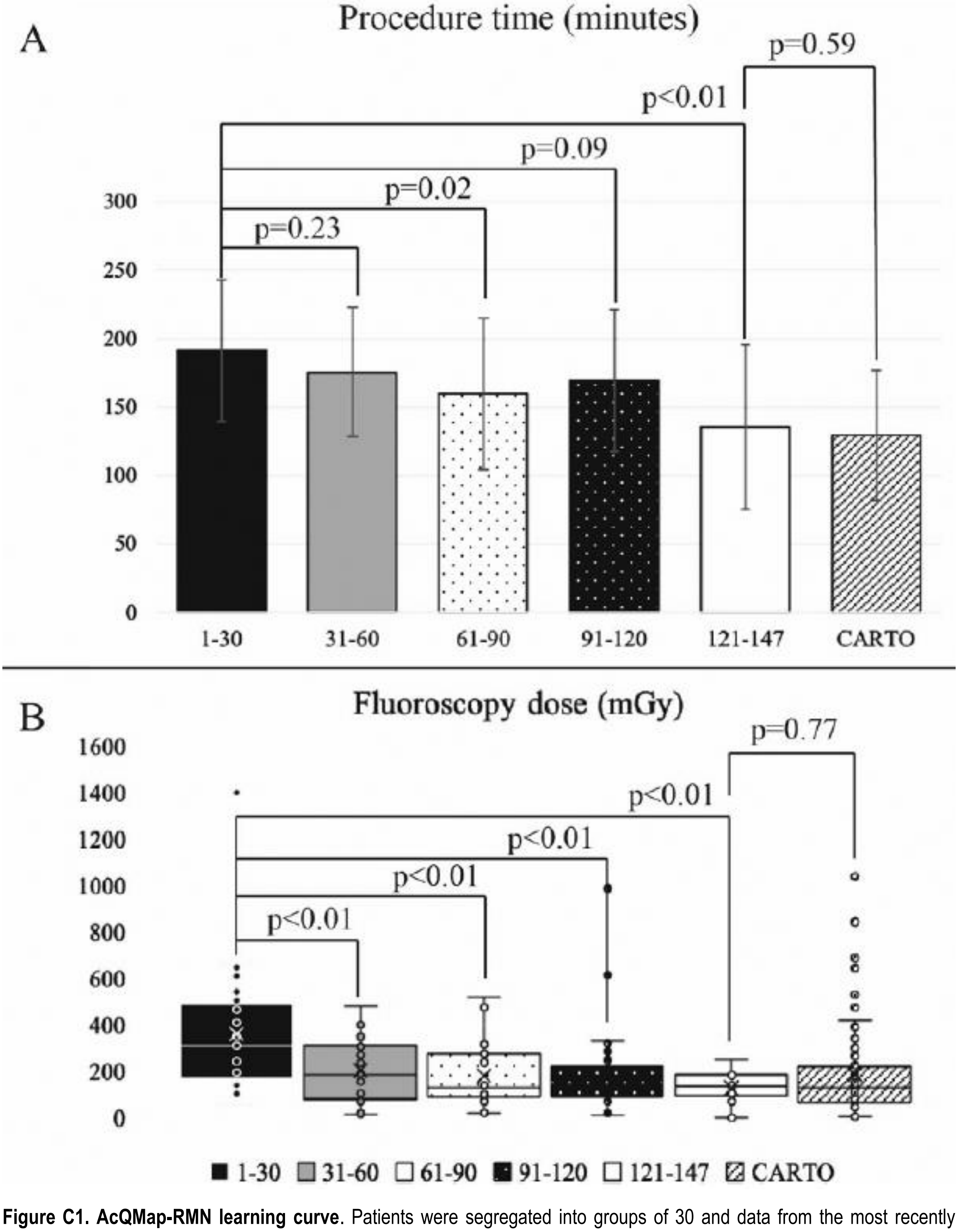

Figure C1. AcQMap-RMN learning curve. Patients were segregated into groups of 30 and data from the most recently included '121-147' patient group was compared to the overall CARTO-RMN group. (A) Learning curve for the AcQMap-RMN procedure duration. (B) Fluoroscopy use of AcQMap-RMN compared to CARTO-RMN. Figure adapted from Gagyi et al. (2022).[20]

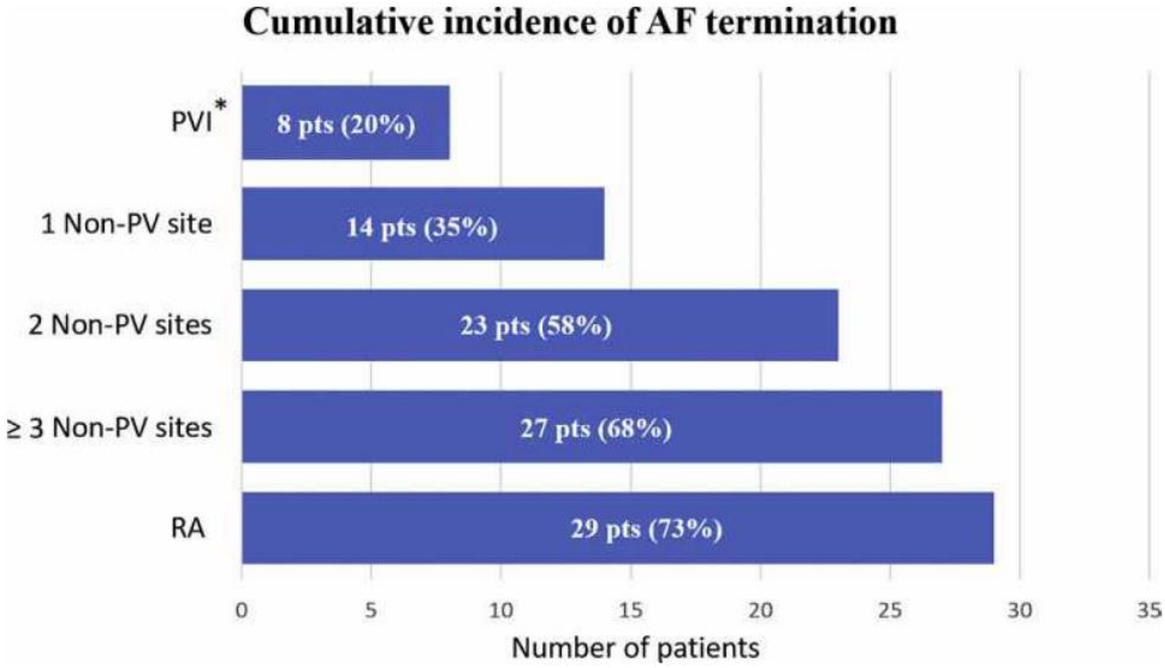

Figure C2. Acute outcome from the individualised ablation strategy with AcQMap (PVI + Core to Boundary strategy). Figure adapted from Shi et al. (2021).[23]

Abbreviations: AF, atrial fibrillation; PV, pulmonary vein; PVI, pulmonary vein isolation; RA, right atrium.