



Research article

Remote magnetic navigation compared to contemporary manual techniques for the catheter ablation of ventricular arrhythmias in structural heart disease



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ABSTRACT

Background: There are limited data comparing remote magnetic navigation (RMN) to contemporary techniques of manual-guided ventricular arrhythmia (VA) catheter ablation.

Objectives: We compared acute and long-term outcomes of VA ablation guided by either RMN or contemporary manual techniques in patients with structural heart disease.

Methods: From 2010–2019, 192 consecutive patients, with ischemic cardiomyopathy (ICM) or non-ischemic cardiomyopathy (NICM) underwent catheter ablation for sustained ventricular tachycardia (VT) or premature ventricular complexes (PVCs), using either RMN (n = 60) or manual (n = 132) guided techniques. Acute success and VA-free survival were compared.

Results: In ICM, acute procedural success was comparable between the 2 techniques (manual 43.5% vs. RMN 29%, $P = 0.11$), as was VA-free survival (manual 83% vs. RMN 74%, $P = 0.88$), and survival free from cardiac transplantation and all-cause mortality (manual 88% vs. RMN 87%, $P = 0.47$), both at 12-months after final ablation. In NICM, manual compared to RMN guided, had superior acute procedural success (manual 46% vs. RMN 19%, $P = 0.003$) and VA-free survival 12-months after final ablation (manual 79% vs. RMN 41%, $P = 0.004$), but comparable survival free from cardiac transplantation and all-cause mortality 12-months after final ablation (manual 95% vs. RMN 90%, $P = 0.52$). Procedural duration was shorter in both subgroups undergoing manual guided ablation, whereas fluoroscopy dose and complication rates were comparable.

Conclusion: RMN provides similar outcomes to manual ablation in patients with ICM. In NICM however, acute success, and long-term VA-free survival was better with manual ablation. Prospective, multi-centre randomised trials comparing contemporary manual and RMN systems for VA catheter ablation are needed.

1. Introduction

Catheter ablation is recommended for the treatment of drug refractory ventricular arrhythmias (VA; ventricular tachycardia [VT], premature ventricular complexes [PVCs]) with underlying structural heart disease (SHD) [1]. Comparative retrospective, case-control and small randomised controlled trials have shown remote magnetic navigation (RMN) to be safe and comparable in outcomes compared to

manual ablation [2, 3, 4, 5, 6, 7, 8], with potential for reduced fluoroscopy duration and fewer complications [8]. RMN may also allow for greater catheter stability, possibility for greater lesion volume, and possibly negates the influence of variation in manual dexterity between operators on subsequent outcomes [9]. In recent years, advances in high-density multi-electrode mapping, intracardiac echocardiography (ICE), live anatomical image integration and contact force (CF)-sensing ablation catheters, may have resulted in incremental improvement in

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outcomes of manual catheter ablation of VA [10, 11, 12, 13]. It is unclear if these novel technologies provide better outcomes in catheter ablation of VA, compared to RMN systems. Studies comparing manual vs. RMN guided ablation in the contemporary era, where these new technologies were used during manual ablation, are lacking. In this retrospective study, we compare the acute and long-term outcomes in patients with SHD undergoing catheter ablation for sustained VT or PVCs, by either manual or RMN guided approach. Importantly, we examined the influence of SHD aetiology, ischemic or non-ischemic cardiomyopathy (ICM, NICM), on ablation outcomes.

2. Methods

This was a retrospective series of 192 consecutive patients who presented for catheter ablation of either sustained monomorphic VT, symptomatic PVC or presumed PVC induced ventricular fibrillation, secondary to SHD, between June 2010–July 2019 at a single tertiary referral centre (Westmead Hospital, Sydney, Australia). Study analysis was performed according to protocols approved by the Western Sydney Local Health District Human Research Ethics Committee and all patients provided written, informed consent.

Transthoracic echocardiography \pm cardiac magnetic resonance imaging was performed on all patients prior to procedure, to assess for SHD and define ventricular function. Distinction between ICM and NICM was made by the presence or absence of relevant coronary artery disease, diagnosed by coronary angiography. NICM was identified based on the absence of relevant coronary artery disease and defined as per the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases [14].

Patients were allocated to RMN, or manual ablation based on lab availability and operator preference. Our approach to mapping and ablation of VA has been described previously [15, 16]. Procedures were performed under either conscious sedation or general anaesthesia. A decapolar catheter was inserted into the coronary sinus via an SL3 sheath (Abbott Medical, Abbott Park, IL, USA) and a quadripolar catheter was deployed to the RV apex. Anti-arrhythmic drug (AAD) therapy was withheld for 5 half-lives pre-ablation (except in the case of an emergent procedure, or with amiodarone where its half-life is significantly longer than 5 days). Systemic anticoagulation was administered immediately after sheath insertion using intravenous unfractionated heparin to maintain an activated clotting time of ≥ 400 s prior to LV access or ≥ 250 s for RV access, unless epicardial approach was planned. If an epicardial approach was planned, anticoagulation was commenced after safe epicardial access was established. Implantable cardioverter defibrillators (ICDs) were re-programmed to disable therapies prior to ablation and re-enabled at the end of the procedure. The endocardial LV was accessed either transeptally (Large curve Agilis™, Abbott Medical), or retrogradely (SL1 8.5Fr, Abbott Medical), or both. Epicardial access was obtained via a percutaneous approach in patients where pre-procedural imaging strongly suggested intramural/epicardial substrate or in patients with a previously failed endocardial catheter ablation. Prior to epicardial ablation, coronary angiography was performed to avoid ablation related coronary artery injury. High output pacing from the ablation catheter (10 milli Amps [mA] and 9 milliseconds [ms] output) was performed to exclude phrenic nerve stimulation.

In the RMN cases, the Niobe® II (Stereotaxis, St Louis, Missouri, USA) system was used from 1st June 2010 to 24th October 2013, followed by the Niobe® ES system thereafter. These systems are both integrated into the Carto® RMT (Biosense Webster, Irvine, California, USA) platform, allowing for point-by-point electroanatomic mapping (EAM) of the right ventricle (RV), left ventricle (LV), or both to be obtained. No multi-electrode mapping catheters were used in the RMN cases. In the manual cases, three-dimensional EAM of the RV, LV (or both) was performed using either the Carto® EAM system (Biosense Webster), EnSite Precision™ (Abbott Medical) or Rhythmia HDx™ (Boston Scientific, Natick, MA, USA: only in 2 cases). High-resolution multi-electrode

mapping catheters were predominantly used; Advisor HD Grid™ or Livewire Duodeca™ (Abbott Medical), alternatively PentaRay® or DecaNav® (Biosense Webster) with Cartow® and the Intellimap Orion™ (Boston Scientific) with Rhythmia HDx™. When multi-electrode mapping catheters were not used, point-by-point mapping using the ablation catheter was performed. In the EAM system and Cardiolab EP recording system, band pass filtering was performed 30–500 Hertz (Hz). An endocardial and/or epicardial three-dimensional shell of chamber geometry was constructed for each ventricle with electrogram recordings during the patient's native rhythm (sinus or paced rhythm) or paced rhythm (RV or biventricular pacing). Activation maps of each VT were obtained if the rhythm was sustained and hemodynamically tolerated; additional substrate-based mapping was followed in all patients. Conventional ventricular bipolar substrate voltage parameters were used (dense scar: < 0.5 millivolts [mV], low voltage: 0.5 mV–1.5 mV, normal > 1.5 mV) [17]. Unipolar low voltage was defined as electrogram amplitude < 8.3 mV (LV) [18], and < 5.5 mV (RV) [19]. The chamber mapped was based on the characteristics of the induced or spontaneously occurring VT.

RMN guided ablation was performed using the 3.5 mm Navistar Thermocool® RMT catheter (Biosense Webster). When CF was used, manual ablation was routinely delivered with a CF of ≥ 10 g via a 3.5 mm-tip open-irrigation catheter ThermoCool® STSF (Biosense Webster) or the TactiCath™ SE catheter (Abbott Medical). Radiofrequency energy of up to 50 Watts was delivered, aiming for an impedance drop of between 10–20 Ω . When available, real-time visualisation of the catheter tip using ICE, guided ablation in the manual procedures, ensuring adequate tissue contact and catheter stability along with lesion formation. Where possible, ablation lesions were repeated until the site was electrically inexcitable with pacing at 10 mA at 9 ms pulse width [20, 21].

Ablation was guided by substrate, and/or activation mapping. Ablation targeted presumptive isthmi and exits, based on activation and entrainment mapping, if the VT was hemodynamically tolerated. If the VT was not tolerated or short in duration, a substrate-based ablation was performed for scar-related VTs. The specific approach targeted presumptive channels and exits as determined by paced QRS morphology matched against the VT QRS morphology with a stimulus-to-QRS interval > 40 ms, abnormal fractionated potentials, double potentials, late potentials during sinus and paced rhythm, and local abnormal ventricular activities. Each induced VT was targeted with catheter ablation until it was no longer inducible [22].

Our VT induction protocol is outlined in Supplemental Methods.

Acute procedural outcomes were reported as follows:

1. Complete success was defined as non-inducibility of any PVC or VT at the end of the procedure.
2. Partial success was defined as non-inducibility of at least one spontaneous PVC or VT morphology but other spontaneous or undocumented PVC/VTs remain.
3. Failure was defined as the inducibility of the spontaneous PVC or VT at the end of the procedure (Supplemental Methods).

In follow-up, outcomes reported were as follows:

1. VA free survival (defined as the absence of sustained VT/VF ≥ 30 s, VA requiring any ICD therapy or external cardioversion, and/or VA resulting in hospitalisation).
2. PVC free survival (defined as failure to reduce PVC burden by $> 50\%$ Holter monitoring, electrocardiogram (ECG) or symptomatic recurrence of PVCs captured on ECG).
3. Survival free from cardiac transplantation
4. Survival free from all-cause mortality

ICD programming is outlined in Supplemental Methods. Long-term outcomes were reported after the final procedure.

Table 1. Baseline patient characteristics.

	RMN (n = 60)	Manual (n = 132)	P-value
	ICM (n = 31)	ICM (n = 57)	
Age, mean ± SD (years)	66.4 ± 10.5	69.9 ± 8.0	0.08
Sex: Male gender, n (%)	28 (90)	55 (97)	0.17
LVEF, mean ± SD (%)	42 ± 12	37 ± 15	0.11
LVEF ≤35%, n (%)	10 (32)	26 (46)	0.21
ICD before ablation, n (%)	27 (87)	48 (84)	0.71
CRT before ablation, n (%)	6 (19)	9 (16)	0.72
Number of failed AADs before index ablation, median (IQR)	1 (1–2)	1 (1–2)	0.65
Failed amiodarone before index ablation, n (%)	11 (36)	23 (40)	0.71
Failed mexiletine before index ablation, n (%)	8 (26)	6 (11)	0.07
Failed sotalol before index ablation, n (%)	0 (0)	10 (18)	0.01
LVAD in situ, n (%)	0 (0)	0 (0)	-
Comorbidities, n (%):			
<i>Hypertension</i>	19 (61)	35 (61)	1
<i>Atrial fibrillation/flutter</i>	6 (19)	12 (21)	0.83
<i>Diabetes</i>	11 (36)	16 (28)	0.44
<i>Prior CABG</i>	9 (29)	21 (37)	0.45
<i>Peripheral vascular disease</i>	7 (23)	5 (9)	0.07
<i>Chronic kidney disease</i>	8 (26)	7 (13)	0.13
<i>Chronic lung disease</i>	6 (19)	8 (14)	0.54
<i>Thyroid dysfunction</i>	0 (0)	2 (4)	0.26
<i>Obstructive sleep apnea</i>	2 (7)	5 (9)	0.75
<i>Previous stroke</i>	5 (16)	4 (7)	0.19
<i>Previous valvular intervention*</i>	1 (3)	5 (9)	0.29
	NICM (n = 29)	NICM (n = 75)	
Age, mean ± SD (years)	55.8 ± 13.5	58.6 ± 14.8	0.38
Sex: Male gender, n (%)	22 (76)	58 (73)	0.76
LVEF, mean ± SD (%)	39 ± 12	44 ± 15	0.11
LVEF ≤35%, n (%)	12 (41)	23 (29)	0.24
ICD before index procedure, n (%)	17 (59)	67 (85)	0.004
CRT before index procedure, n (%)	4 (14)	15 (19)	0.55
Number of failed AADs before index procedure, median (IQR)	1 (1–1)	1 (1–1)	0.33
Failed amiodarone before index procedure, n (%)	6 (21)	25 (32)	0.27
Failed mexiletine before index procedure, n (%)	2 (7)	6 (8)	0.87
Failed sotalol before index procedure, n (%)	1 (3)	14 (18)	0.048
LVAD in situ, n (%)	0 (0)	1 (1)	0.59
Comorbidities, n (%):			
<i>Hypertension</i>	6 (21)	15 (19)	0.82
<i>Atrial fibrillation/flutter</i>	9 (31)	14 (18)	0.15
<i>Diabetes</i>	2 (7)	8 (10)	0.64
<i>Peripheral vascular disease</i>	1 (3)	1 (1)	0.46
<i>Chronic kidney disease</i>	3 (10)	9 (10)	1
<i>Chronic lung disease</i>	2 (7)	10 (13)	0.39
<i>Thyroid dysfunction</i>	1 (3)	5 (5)	0.66
<i>Obstructive sleep apnea</i>	5 (17)	5 (6)	0.08
<i>Previous stroke</i>	1 (3)	1 (1)	0.46
<i>Previous valvular intervention*</i>	2 (7)	0 (0)	0.02
Subtype of NICM, n (%):			
<i>Idiopathic DCM</i>	16 (55)	46 (61)	0.58
<i>Lamin A/C cardiomyopathy</i>	1 (3)	2 (3)	1
<i>ARVC</i>	2 (7)	7 (9)	0.74
<i>Infiltrative (sarcoid/amyloid)</i>	2 (7)	4 (5)	0.69
<i>HCM</i>	0 (0)	5 (7)	0.15
<i>Valvular</i>	1 (3)	3 (4)	0.81
<i>Congenital</i>	1 (3)	5 (7)	0.44
<i>Other (chemotherapy/PVC-induced/non-compaction/inflammatory)</i>	6 (21)	3 (4)	0.006

* Previous valvular intervention includes mitral valve replacement, mitral valvuloplasty, aortic valve replacement and transcatheter aortic valve implantation.

Abbreviations: AADs, anti-arrhythmic drugs; ARVC, arrhythmogenic right ventricular cardiomyopathy; CABG, coronary artery bypass graft surgery; CRT, cardiac resynchronisation therapy; DCM, dilated cardiomyopathy; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter defibrillator; ICM, ischemic cardiomyopathy; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; NICM, non-ischemic cardiomyopathy; PVC, premature ventricular complex; RMN, remote magnetic navigation; SHD, structural heart disease.

Table 2. Procedural characteristics.

	RMN (n = 60)	Manual (n = 132)	P-value
	ICM (n = 31)	ICM (n = 57)	
Number of ablation procedures performed; n/total no. of procedures (%)	31/51 (61)	57/69 (83)	0.007
Number of patients undergoing:			
1 procedure, n (%)	16 (51.6)	46 (81)	0.004
2 procedures, n (%)	12 (38.7)	8 (14)	0.009
3 or more procedures, n (%)	3 (9.7)	3 (5)	0.40
Sustained VT* as indication for procedure, n/total no. of procedures (%)	46/51 (90)	61/69 (88)	0.73
PVCs/PVC induced VF as indication for procedure, n/total no. of procedures (%)	5/51 (10)	8/69 (12)	0.73
VT storm as indication for procedure, n/total no. of procedures (%)	18/51 (35)	25/69 (36)	0.91
VT cycle length, mean ± SD (ms)	370.8 ± 92.2	358.2 ± 94.9	0.28
Number of VT/PVCs induced or spontaneously occurring per procedure, median (IQR)	2 (1–3.5)	2 (1–3)	0.17
Procedure duration, mean ± SD (mins)	364.2 ± 121.3	286.1 ± 88.4	<0.001
Fluoroscopy dose, median (IQR) (Gy cm ²)	23.1 (14.4–34.5)	18.3 (10.0–30.4)	0.41
RF ablation duration, median (IQR)	29.9 (20.6–46.4)	31 (17.1–47.5)	0.73
Number of AADs after final procedure, median (IQR)	1 (1–2)	1 (1–2)	0.96
Number on amiodarone after final procedure, n (%)	10 (32)	15 (26)	0.55
Number on mexiletine after final procedure, n (%)	3 (10)	4 (7)	0.62
Number on sotalol after final procedure, n (%)	6 (19)	9 (16)	0.72
ICE with Cartosound®** used in any procedure, n/no. of procedures (%)	0/51 (0)	26/69 (38)	<0.001
CF-sensing catheter used during procedure, n/no. of procedures (%)	-	40/69 (58)	-
Number of procedures when epicardial ablation performed, n/no. of procedures (%)	3/51 (6)	1/69 (2)	0.25
VA-ECMO required during procedure, n/no. of procedures (%)	0/51 (0)	1/69 (2)	0.25
Acute procedural outcomes, n/no. of procedures (%):			
Complete success	15/51 (29)	30/69 (43.5)	0.11
Partial success	19/51 (37)	28/69 (40.5)	0.70
Failure	10/51 (20)	4/69 (6)	0.02
Unknown	7/51 (14)	7/69 (10)	0.50
Major complications, n/no. of procedures (%):	3/51 (6)	2/69 (3)	0.42
	NICM (n = 29)	NICM (n = 75)	
Number of ablation procedures performed, n/total no. of procedures (%)	29/43 (67)	75/95 (79)	0.13
Number of patients undergoing:			
1 procedure, n (%)	18 (62)	59 (79)	0.08
2 procedures, n (%)	8 (28)	13 (17)	0.21
3 or more procedures, n (%)	3 (10)	3 (4)	0.24
Sustained VT* as indication for procedure, n/total no. of procedures (%)	36/43 (84)	75/95 (79)	0.49
PVCs/PVC induced VF as indication for procedure, n/total no. of procedures (%)	7/43 (16)	20/95 (21)	0.49
VT storm as indication for procedure, n/total no. of procedures (%)	12/43 (28)	27/95 (28)	1
VT cycle length, mean ± SD (ms)	327.8 ± 95.9	338.0 ± 100.5	0.44
Number of VT/PVCs induced or spontaneously occurring per procedure, median (IQR)	2 (1–3)	2 (1–4)	0.15
Procedure duration, mean ± SD (mins)	399.0 ± 158.9	315.8 ± 112.8	<0.001
Fluoroscopy dose, median (IQR) (Gy cm ²)	22.3 (10.5–35.6)	16.7 (7.8–28.9)	0.34
RF ablation duration, mean ± SD (mins)	26.0 (16.7–51.7)	34.7 (17.8–58.6)	0.40
Number of AADs after final procedure, median (IQR)	1 (1–2)	1 (1–1)	0.34
Number on amiodarone after final procedure, n (%)	6 (21)	14 (19)	0.82
Number on mexiletine after final procedure, n (%)	3 (10)	4 (5)	0.35
Number on sotalol after final procedure, n (%)	3 (10)	18 (24)	0.11
ICE with Cartosound®** used during procedure, n/no. of procedures (%)	1/43 (2)	41/95 (43)	<0.001
CF-sensing catheter used during procedure, n/no. of procedures (%)	-	57/95 (60)	-
Number of procedures when epicardial mapping/ablation performed, n/no. of procedures (%)	4/43 (9)	13/95 (14)	0.41
VA-ECMO required during procedure, n/no. of procedures (%)	0/43 (0)	1/95 (1)	0.51
Acute procedural outcomes, n/no. of procedures (%):			
Complete success	8/43 (19)	44/95 (46)	0.003
Partial success	15/43 (35)	29/95 (30.5)	0.60
Failure	13/43 (30)	11/95 (11.5)	0.008
Unknown	7/43 (16)	11/95 (11.5)	0.47
Major complications, n/no. of procedures (%):	5/43 (12)	8/95 (8)	0.45

*Includes VT storm.

**Cartosound® only includes procedures where ICE was used for image integration into the CARTO® EAM system.

Abbreviations: AAD, anti-arrhythmic drug; VA-ECMO, venous arterial-extracorporeal membrane oxygenation; ICE, intracardiac echocardiography; ICM, ischemic cardiomyopathy; IQR, interquartile range; LV, left ventricular; ms, milliseconds; NICM, non-ischemic cardiomyopathy; PVC, premature ventricular complex; RF, radiofrequency; RMN, remote magnetic navigation; RV, right ventricular; RVOT, right ventricular outflow tract; SD, standard deviation; VF, ventricular fibrillation; VT, ventricular tachycardia.

SPSS version 25 (IBM Corp., Armonk, NY) was used for analysis. Continuous variables were expressed as mean ± standard deviation (SD) if normally distributed; median and 25%–75% interquartile range (IQR) were used if the data were clearly skewed. Continuous variables were compared using a student t-test when normally distributed, or a Mann-Whitney U test when they were not normally distributed. Chi-squared or Fisher's exact test were used when comparing categorical variables. Survival free of VA was estimated using the Kaplan-Meier method and the log rank chi-squared method. Cox proportional hazard models were created to determine predictors of VA recurrence. Hazard ratios (HRs) and 95% confidence intervals (CIs) were used to express risk of VA recurrence. A 2-tailed P-value of <0.05 was considered statistically significant.

3. Results

In the manual group, 132 patients (ICM n = 57, NICM n = 75) underwent a total of 164 procedures. In the RMN group, 60 patients (ICM n = 31, NICM n = 29) underwent a total of 94 procedures. There were 9 patients who initially received RMN guided ablation and then received a redo procedure using manual techniques, alternatively there was 1 patient who initially received manual guided ablation and then received a redo procedure using RMN techniques. For study analysis, these patients remained in the group of their index procedure, based on the intention to treat principle.

Within the manual group, there were 97/164 (59%) procedures performed with CF-sensing ablation catheters, predominantly from 2015 onwards. ICE was used in 85/164 (52%) manual procedures, and full image integration using ICE with the Cartosound® (Biosense Webster) system was performed in 67/164 (41%) manual procedures.

Table 1 describes the patient baseline characteristics. Within the subgroup of ICM, patients who received manual ablation were more likely to have failed sotalol (manual 18% vs. RMN 0%, P = 0.01). There were non-significant trends towards patients in the manual group being older (manual 69.9 ± 8 years vs. RMN 66.4 ± 10.5 years, P = 0.08), having less peripheral vascular disease (manual 9% vs. RMN 23%, P = 0.07) and failing less mexiletine (manual 11% vs. RMN 26%, P = 0.07). In the subgroup with NICM, patients who received manual ablation were more likely to have an ICD before the procedure (manual 85% vs. RMN 59%, P = 0.004), less likely to have undergone prior valvular intervention (manual 0% vs. RMN 7%, P = 0.02), were more likely to have failed sotalol (manual 18% vs. RMN 3%, P = 0.048) and were less likely to have

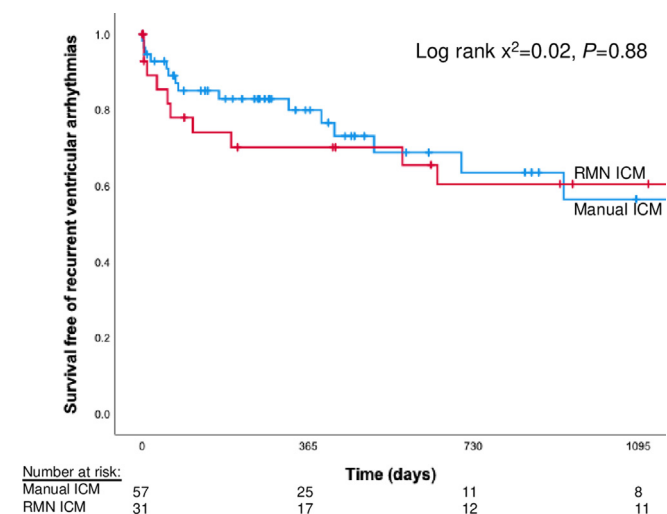


Figure 1. Survival free from recurrent ventricular arrhythmias in the ICM subgroups after final catheter ablation. Survival free from ventricular arrhythmias was comparable in the manual (blue) and RMN (red) groups. Abbreviations: ICM, ischemic cardiomyopathy; RMN, remote magnetic navigation.

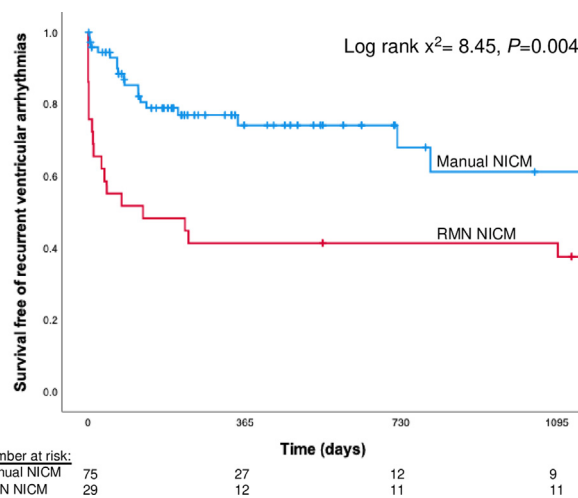


Figure 2. Survival free from recurrent ventricular arrhythmias in the NICM subgroups after final catheter ablation. Survival free from ventricular arrhythmias was higher in the manual (blue) vs. RMN (red) group. Abbreviations: NICM, non-ischemic cardiomyopathy; RMN, remote magnetic navigation.

Table 3. Factors associated with VA recurrence in ICM. Included are univariate variables with a P-value < 0.2 and multivariate variables with a P-value < 0.1.

Variable	Univariate HR for VA recurrence (95% CI)	P-value	Multivariate HR for VA recurrence (95% CI)	P-value
LVEF ≤35%	2.12 (0.98–4.60)	0.06	2.12 (0.98–4.60)	0.06
Obstructive sleep apnea	2.39 (0.95–5.99)	0.06		
Chronic lung disease	1.83 (0.80–4.21)	0.15		

Abbreviations: CI, confidence interval; HR, hazard ratio; LVEF, left ventricular ejection fraction; VA, ventricular arrhythmia.

Table 4. Factors associated with VA recurrence in NICM. Included are univariate variables with a P-value < 0.2 and multivariate variables with a P-value < 0.1.

Variable	Univariate HR for VA recurrence (95% CI)	P-value	Multivariate HR for VA recurrence (95% CI)	P-value
RMN guided ablation	2.53 (1.33–4.82)	0.005	3.31 (1.62–6.75)	0.001
Age ≥65 years	1.65 (0.88–3.11)	0.12		
Failed ≥2 AADs	3.20 (1.68–6.10)	<0.001	3.27 (1.57–6.80)	0.001
>1 procedure	2.54 (1.36–4.77)	0.004	1.82 (0.95–3.47)	0.07
>2 VTs inducible/spontaneous in procedure	1.75 (0.94–3.25)	0.08		
Acute success	0.34 (0.16–0.73)	0.006		
Procedural complication	2.05 (0.80–5.26)	0.14		
CF-sensing catheter used	0.41 (0.19–0.89)	0.02		
Operator 1	0.58 (0.28–1.21)	0.15		

Abbreviations: AAD, anti-arrhythmic drug; CF, contact force; CI, confidence interval; HR, hazard ratio; RMN, remote magnetic navigation; VA, ventricular arrhythmia; VT, ventricular tachycardia.

a chemotherapy/PVC/non-compaction or inflammatory mediated NICM (manual 4% vs. RMN 21%, P = 0.006).

Table 2 describes the procedural characteristics. Patients receiving manual ablation had shorter procedure times, regardless of substrate aetiology (ICM: manual 286.1 ± 88.4 min vs. RMN 364.2 ± 121.3 min, P < 0.001; NICM: manual 315.8 ± 112.8 min vs. RMN 399.0 ± 158.9 min,

Table 5. Previous studies comparing manual vs. RMN guided ablation for the treatment of ventricular arrhythmias.

Study	Substrate aetiology (idiopathic/ICM/NICM)	Number of patients (Manual/RMN)	% patients with LVEF <35% (Manual/RMN)	RFA time (mins) (Manual/RMN)	Procedure time (mins) (Manual/RMN)	Fluoroscopy time (mins) (Manual/RMN)	Acute success (Manual/RMN)	Definition of acute success	Major Complication (Manual/RMN)	VA recurrence rate (Manual/RMN)	Definition of VA recurrence
Qian et al. 2018 [1] Single centre Retrospective	Idiopathic, ICM and NICM	58/55	30%/26%	Mean: 48.7 ± 30.8/67.2 ± 35.7 (P = 0.1)	Mean: 291 ± 101/429 ± 121 (P < 0.001)	Mean: 38.8 ± 24.08/32.45 ± 24.24 (P = 0.059)	60%/80% (P = 0.011)	Clinical VT non-inducible	11%/13% (P = 0.8)	Median VT free survival in months: 15.0 (95% CI 8.6–21.3)/46 (95% CI 41.6–50.4) months (P = 0.018)	VT causing ICD shock/hospitalisation, redo ablation, all-cause mortality
Hendricks et al. 2015 [2] Single centre Prospective	Idiopathic, ICM and NICM	112/(41 CF)/86	12%/(19% CF)/5.8%	Median: 7.9 (IQR 5–32)/[CF 8 (IQR 3.6–16)]/6.7 (IQR 3.2–17.8) (P = 0.1)	Median: 190 (IQR 135–220)/[CF 120 (IQR 90–180)]/150 (IQR 120–220) (P = 0.39)	Not available	71%/(CF 71%)/86% (P = 0.03)	Non-inducibility of VT (unclear if only clinical or all VT targeted)	2.7%/(CF 10%)/1.2% (P = 0.04)	57%/(CF 59%)/42% (P = 0.07)	Recurrence of any VT. If PVCs; <95% reduction on Holter compared to before ablation
Di Biase et al. 2010 [24] Single centre Retrospective	ICM, NICM, idiopathic	92/110	Not available	Mean: 24 ± 12/33 ± 18 (P = 0.005)	174 ± 72/198 ± 66 (P = 0.04)	35 ± 22/26 ± 14 (P = 0.033)	No direct comparison	Non-inducibility of clinical VA	No direct comparison	14%/15% (P = 0.817)	Recurrence of a clinical VA
Dinov et al. 2012 [3] Single centre Retrospective	ICM	52/50	Not available	Mean: 39 ± 20.8/26.5 ± 17.5 (P = 0.049)	Mean: 148 ± 50/157 ± 40 (P = 0.42)	Mean: 32 ± 17/13 ± 12 (P < 0.001)	71%/82% (P = 0.246)	Non-inducibility of all VTs	Overall rate: 2.94%	47%/37% (P = 0.206)	Any sustained VA, VA related death
Zhang et al. 2013 [4] Single centre RCT	Idiopathic	15/15	0%/0%	Mean: 72.8 ± 35.6/63.3 ± 27.3 (P = 0.15)	Mean: 115.1 ± 27.4/131.8 ± 19.4 (P = 0.13)	Mean: 10.5 ± 5.0/5.2 ± 2.6 (P < 0.05)	93%/66.6% (P = 0.07)	Non-inducibility of VT or PVC with PES (unclear if only clinical or all VT/PVCs targeted)	0%/0%	0%/13%	Symptomatic recurrence with ECG evidence of VA or PVCs >5000/day
Akca et al. 2013 [5] Single centre Prospective	Not available	10/18	Not available	Median: 4.5 (IQR 0.9–20)/8 (IQR 3.6–16.5) (P = 0.495)	Mean: 190 ± 62/181 ± 100 (P = 0.891)	Mean: 41.2 ± 10.8/22.8 ± 14.7 (P = 0.011)	87.5%/66.7% (P = 0.23)	Clinical VT non-inducible. If PVCs; complete cure of PVCs over 24 hours on telemetry	Not available	40%/16.7% (P = 0.33)	Not available
Szili-Torok et al. 2012 [6] Single centre Retrospective	Idiopathic, ICM and NICM	41/72	Not available	Mean: 22.2 ± 21.5/13.6 ± 15 (P = 0.024)	Mean: 232 ± 99/177 ± 79 (P = 0.011)	Mean: 56 ± 32/27 ± 19 (P < 0.001)	66%/82% (P = 0.046)	Non-inducibility of VT. If PVCs; complete cure of PVCs over 24 h on telemetry	4.9%/0% Non-significant	44.4%/23.7% (P = 0.047)	Not available
Bauernfeind et al. 2011 [7] Single centre Prospective	Idiopathic/SHD (no subgroup data on aetiology of SHD)	29/54	Not available	Not available	Mean: 222 ± 97/166 ± 54 (P = 0.009)	Mean: 56 ± 31/27 ± 21 (P = 0.001)	72%/93% (P = 0.013)	Non-inducibility of VT. If PVCs; complete cure of PVCs over 24 h on telemetry	Not available	14%/14% (Non-significant)	Not available

Abbreviations: CF, contact force; ICD, implantable cardioverter defibrillator; ICM, ischemic cardiomyopathy; IQR, interquartile range; NICM, non-ischemic cardiomyopathy; PVC, premature ventricular complex; RCT, randomised controlled trial; RMN, remote magnetic navigation; SHD, structural heart disease; VA, ventricular arrhythmia; VT, ventricular tachycardia.

$P < 0.001$). There was no significant difference in fluoroscopy dose received by patients in the manual vs. RMN groups (ICM: manual 18.3 [IQR 10–30.4] Gy cm² vs. RMN 23.1 [IQR 14.4–34.5] Gy cm², $P = 0.41$; NICM: manual 16.7 [IQR 7.8–28.9] Gy cm² vs. RMN 22.3 [IQR 10.5–35.6] Gy cm², $P = 0.34$), and radiofrequency ablation times were also comparable. There were fewer patients in the manual group requiring a repeat procedure, this reached statistical significance in the ICM subgroup (manual 19% vs. RMN 48%, $P = 0.005$), but was not statistically significant in the NICM subgroup (manual 21% vs. RMN 38%, $P = 0.08$).

Acute outcomes are described in Table 2. In patients with ICM, acute procedural success was not significantly different between the two groups (manual 30/69 [43.5%] vs. RMN 15/51 [29%] $P = 0.11$; Table 2), however acute procedural failure occurred less commonly in the manual group (manual 4/69 [6%] vs. RMN 10/51 [20%], $P = 0.02$). In patients with NICM, acute procedural success was higher in the manual group (manual 44/95 [46%] vs. RMN 8/43 [19%], $P = 0.003$) and acute procedural failure occurred less commonly in the manual group (manual 11/95 [11.5%] vs. RMN 13/43 [30%], $P = 0.008$).

Overall, and in both subgroups of ICM and NICM, there were no differences in major complications (Supplemental Methods). Specific complications can be found in Supplemental Table 1.

Overall median follow-up was 16.1 (IQR 5.7–39.2) months. There were 4/192 (2%) patients lost to follow-up. Patients with ICM had comparable VA free survival with both techniques at 12-months after final procedure (manual 83% vs. RMN 74%, $P = 0.88$; Figure 1). In the NICM subgroup, patients undergoing manual ablation had better VA free survival compared to RMN ablation at 12-months after final procedure (manual 79% vs. RMN 41%, $P = 0.004$; Figure 2). In the ICM subgroup, LVEF $\leq 35\%$ at baseline was an independent predictor of VA recurrence (HR 2.12 [95% CI 0.98–4.60], $P = 0.06$; Table 3). In the NICM subgroup, independent predictors of VA recurrence included the use of RMN (HR 3.31 [95% CI 1.62–6.75], $P = 0.001$; Table 4) and failing ≥ 2 AADs prior to index ablation (HR 3.27 [95% CI 1.57–6.80], $P = 0.002$; Table 4).

During overall median follow-up 30 patients died (ICM $n = 18$, NICM $n = 12$), and 3 patients received a cardiac transplant (ICM $n = 1$, NICM $n = 2$). There was comparable survival free from the composite endpoint of cardiac transplantation and all-cause mortality at 12-months after the final ablation between manual and RMN techniques, both in the ICM (manual 88% vs. RMN 87%, $P = 0.47$) and NICM (manual 95% vs. RMN 90%, $P = 0.52$) groups.

Whereas manual ablation procedures increased significantly since 2017 in our centre, RMN procedures stayed at a low rate < 30 per year. We examined the potential effect of this on long-term outcomes, by dividing the study period into Tertiles of time (Tertile 1 [T1]: July 2016–July 2019; Tertile 2 [T2]: July 2013–June 2016; Tertile 3 [T3]: June 2010–June 2013). There was comparable VA-free survival at 12-months after final ablation in each Tertile of time, in both the ICM (T1: 82% vs. T2: 78%, $P = 0.48$; T1: 82% vs. T3: 73%, $P = 0.64$; T2: 78% vs. T3: 73%, $P = 0.70$), and NICM (T1: 68% vs. T2: 64%, $P = 0.96$; T1: 68% vs. T3: 74%, $P = 0.50$; T2: 64% vs. T3: 74%, $P = 0.87$) groups. Following Cox regression analysis, no Tertile of time was identified as an independent predictor of VA recurrence, in either the ICM or NICM subgroups.

Eight operators performed catheter ablation during the study. All operators performed manual guided ablation and 5 performed both RMN and manual procedures. There were 3 operators who performed most of the procedures (operator 1: $n = 102$, operator 2: $n = 76$ and operator 3: $n = 55$). Following Cox regression analysis, none of these 3 main operators were identified as independent predictors of VA recurrence, in either the ICM or NICM subgroups (Tables 3 and 4).

4. Discussion

Our study describes the acute and long-term outcomes in patients with SHD, who underwent catheter ablation for VA using either RMN or

contemporary manual techniques. We convey the following important findings:

1. Acute procedural success and VA-free survival were comparable between manual and RMN guided ablation in patients with ICM related VA.
2. Acute procedural success and VA-free survival were superior with manual compared to RMN guided ablation in patients with NICM related VA.
3. Procedural duration was longer in patients undergoing RMN guided ablation, regardless of underlying VA aetiology.
4. Fluoroscopy dose and procedural complications were comparable between manual and RMN guided ablation.
5. RMN was an independent predictor of VA recurrence in the NICM population, after adjusting for important clinical and procedural characteristics.

Previous studies comparing RMN vs. manual catheter ablation of VA, include several case-control studies and a single, small randomised controlled trial (Table 5). In a meta-analysis by Turagam et al. [23], RMN was associated with a better long-term VA-free survival compared to manual ablation in patients with idiopathic VT. In patients with SHD, outcomes were comparable between the two techniques.

Dinov et al. [4] focused on outcomes of RMN vs. manual ablation of VT in patients with ICM. Whilst they demonstrated reduced fluoroscopy and ablation times with RMN, there were no significant differences in acute or long-term outcomes between the respective groups. These similarities with our study may in part be explained by the fact that Dinov et al. [4] were the only investigators to clearly define acute success as non-inducibility of all VT, and their long-term end point of freedom from all sustained VT was also in keeping with our own. In contrast, Qian et al. [8] demonstrated better long-term VT free survival in patients with ICM undergoing ablation with RMN compared to manual. Potential reasons for the differing results may be explained by smaller patient numbers (37 vs. 88 in our study) and differing definitions of acute and long-term success. Qian et al. [8] defined acute success as non-inducibility of only the clinical VT and used a primary endpoint of VA recurrence resulting in ICD shock, hospitalisation, repeat procedure or all-cause mortality, potentially detecting less VA recurrences than our stricter primary endpoint. Furthermore, loss of follow-up in that study was much larger, with only 79/113 (70%) patients followed up after ablation.

There have been no studies comparing RMN vs. manual ablation in solely NICM patients, but several studies have included relatively small numbers of NICM patients, ranging from 14–38 patients [5, 6, 8, 24]. In contrast, our study numbers of patients with NICM were much larger ($n = 104$ patients). None of these studies have shown significant differences in outcomes between the two techniques, within this subgroup of patients. In our study, patients undergoing manual ablation for NICM-related VT had greater acute procedural success and better long-term VA-free survival. NICM patients commonly have intramural substrate, often located in the thick-walled perivalvular and basal septal regions. Specific catheter manipulation techniques, along with higher powers and prolonged delivery of radiofrequency ablation may be required to allow sufficient delivery of ablation to the intended target. It may be that the soft tipped RMN ablation catheter is less effective at delivering sufficient CF, which importantly influences the depth of radiofrequency lesion required to successfully treat VT in some NICM patients. A further consideration is the multiple irrigation holes in contemporary ablation catheters (e.g., Smart Touch Surround Flow, Biosense Webster; Flexibility, Abbott Medical), which may allow for larger lesion delivery, compared to the 6 holes in the Navistar Thermocool® RMT catheter (Biosense Webster). It is feasible that newer technologies in RMN such as force-sensing (not available at our centre), ICE-integration, and improvement in catheter irrigation dynamics may allow for increments in procedural outcomes with RMN, compared to manual ablation.

One prior randomised trial has compared RMN vs. manual ablation [7], but it only included patients with idiopathic outflow tract VA, the numbers were small ($n = 30$ patients), and the non-contact mapping system was used. The study aimed to compare fluoroscopy exposure between the 2 techniques, with RMN found to be associated with lower patient and physician fluoroscopy exposure. Possible reasons for this difference compared to our study, include not only the differing aetiologies of VA, but also the relatively high use of ICE with image integration in our manual group. This may have reduced operator reliance on fluoroscopy, and potentially aided catheter manipulation and lesion delivery in challenging locations such as the perivalvular LV, aortic cusps, RV moderator band and papillary muscles. Indeed, ICE has been shown to be associated with better outcomes with VA-ablation in several recent studies [13, 25].

The non-randomised nature of this study, and all but one of the previously mentioned studies means that there is a need for a randomised trial. The MAGNETIC VT study by Di Biase et al. [26] is an important ongoing multi-centre randomised controlled trial aiming to compare manual vs. magnetic VT substrate guided catheter ablation in patients with ICM and reduced LVEF ($\leq 35\%$). It is hoped that this study will clarify outcome differences in ICM between the two ablation techniques.

5. Study limitations

This is a retrospective report from a centre performing both manual and RMN-guided ablation procedures. There is the possibility of operator and selection bias that is unavoidable. Our centre does not have recent improvements in RMN such as the V-drive[®] system for Niobe[®] or the latest Genesis RMN[®] system (Stereotaxis, St Louis, Missouri, USA). If these were available, an improvement in outcomes following RMN guided ablation could have been seen, compared to manual guided ablation.

6. Conclusion

In our single centre observational study comparing outcomes between manual and RMN guided ablation, patients with ICM related VA experienced comparable acute success and VA-free survival with either technique, whereas patients with NICM related VA experienced improved acute success and VA-free survival with manual compared to RMN guided ablation. Fluoroscopy dose, procedural complications, and survival free from the composite of cardiac transplantation and all-cause mortality were all comparable between the two techniques. Prospective randomised trials are needed comparing contemporary RMN versus manual techniques for the catheter ablation of VA.

Declarations

Author contribution statement

Saurabh Kumar: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

Richard G Bennett: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Stuart P. Thomas, Lloyd Davis and Mark J Cooper: Performed the experiments; Analyzed and interpreted the data.

Eddy Kizana: Performed the experiments.

Timothy Campbell, Ashish Sood and Kasun De Silva: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Clara K. Chow, Aravinda Thiagalingam, Gopal Sivagangabalan, A. Robert Denniss, Pierre Qian, Ashwin Bhaskaran: Analyzed and interpreted the data.

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Data availability statement

Data will be made available on request.

Declaration of interests statement

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Additional information

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