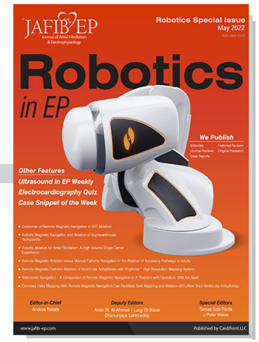
JAFIB EP
Robotics Special Issue
May 2022
Journal of Atrial Fibrillation & Electrophysiology



www.jafib-ep.com

Robotic Magnetic Navigation in Premature Ventricular Complex Ablation

Fengwei Zou[1], John D. Burkhardt[2], Xiaodong Zhang[1], Aung Naing Lin[1], Domenico Giovanni Della Rocca[2], Sanghamitra Mohanty[2], Amin Al-Ahmad[2], Dhanunjaya Lakkireddy[3], Andrea Natale[2], Luigi Di Biase[1,2]

[1]Montefiore-Einstein Center for Heart & Vascular Care, Montefiore Medical Center, Bronx, NY, USA
[2]Texas Cardiac Arrhythmia Institute, St. David's Medical Center, Austin, Texas, USA
[3]Kansas City Heart Rhythm Institute at HCA Midwest in Overland Park, Kansas

Abstract

Premature ventricular complexes (PVCs) are widely common in the general population. In patients with recurrent symptoms and structural heart diseases, catheter ablation is highly effective in treating PVCs. Robotic magnetic navigation (RMN) was developed and applied in PVC ablation in the past two decades. RMN has exhibited inherent advantages over manual ablation since its creation, namely drastically decreased fluoroscopy time, improved catheter maneuverability and stability, and better safety profile. Despite earlier reports of lower efficacy and longer procedure times, technological advances and accumulated user experience have significantly decreased procedure time and improved ablation efficacy while retaining its merits. This review provides a summary of the current evidence in the applications, procedural characteristics, efficacy and safety of RMN in PVC ablations.

Introduction

Premature ventricular complexes (PVCs) are some of the most common cardiac arrhythmias in the general population. Based on the duration of monitoring, the prevalence of PVC can range from 1% in 12-lead electrocardiogram (ECG) to 70% on 24-hour telemetry[1-3]. Despite its wide prevalence, most patients with PVCs only require reassurance and clinical monitoring especially when PVCs were discovered incidentally without symptoms. In cases of underlying structural heart disease, high PVC burdens, or recurrent symptoms (palpitations, shortness of breath, syncope and etc.), further interventions are needed. For years, manual percutaneous catheter ablation is has been shown to be an effective and safe approach to eliminate or reduce the burden of PVCs with ablation success rates ranging from 80-95% and low complication rates[4]. However, manual catheter ablation of PVCs originating from anatomical locations difficult to reach such as the left ventricular (LV) summit region still remains a challenge. Ablation success of these PVC origins is limited by restricted catheter maneuverability, close proximity to core vasculature including the left anterior descending (LAD) coronary artery, the need for epicardial access, long procedure times and operator fatigue[5]. To overcome these obstacles, better control of catheter movement, more accurate mapping, and an improved safety profile are needed.

Key Words

Premature Ventricular Complex; Catheter Ablation; Robotic Magnetic Navigation, Manual Ablation

Corresponding Author
Luigi Di Biase MD, PhD
Section Head of Electrophysiology and Director of Arrhythmias Services
Montefiore-Einstein Center for Heart & Vascular Care
111 East 210th Street, Bronx, NY 10467.

Robotic Magnetic Navigation (RMN)

The past two decades have witnessed the development of RMN. Among the several RMN systems developed over time, the Stereotaxis Niobe (Stereotaxis, St. Louis, MO) is the most widely used and reported in clinical studies. The RMN system is composed of two large magnets that generate a magnetic field within the patient's chest. Specially designed magnetically compatible catheters are navigated by tilting, rotating, and moving the magnets to allow for directional movement in three dimensions (3D). Cardiac computed tomography, fluoroscopic images and 3D mapping are fully integrated into the system and operators can control the mapping and ablation process remotely. The delicate magnetic vector steering of ablation and mapping catheters is better suited for the ventricle compared to manual catheters. Manual catheters are often limited by fixed curvatures and pivot points from surrounding cardiac structures, resulting in inconsistent contact. Stable catheter movements during RMN mapping tend to reduce catheter-induced ectopy. Stable tissue-tip contact also creates more durable lesions. These factors can influence the quality of both mapping and ablation of PVCs[6,7]. Continued development of RMN compatible catheters also brought open-irrigated ablation catheters and contact sensing to RMN, expanding its armada to become more popular in

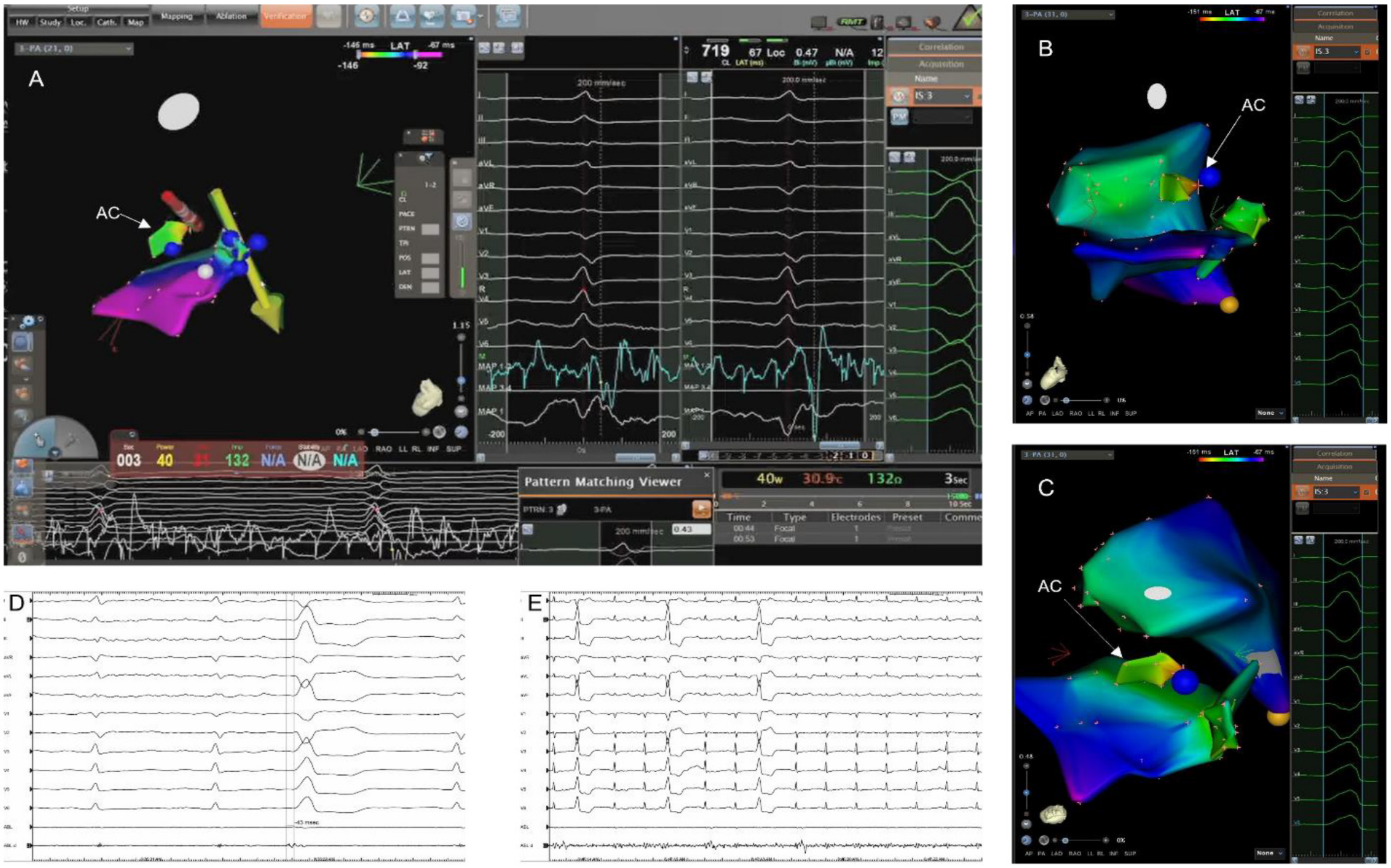


Figure 1: **RMN ablation of PVC originating from the anterior cusp (AC) of the pulmonary valve.**

The anterior cusp of the pulmonary valve is an anatomical structure difficult to reach by conventional manual ablation catheters but is readily accessible by RMN. This is a case of successful ablation of PVC originating from the AC of pulmonary valve using RMN (A). Activation mapping in the RV and RVOT identified the earliest activation site of PVC is being located in the AC of the pulmonary valve (B), and this site is also confirmed by pattern matching in intracardiac electrogram showing 43ms early activation. Panel B and C show the anatomical location of the AC in Carto reconstruction. Radiofrequency energy is delivered using the magnetic ablation catheter (red catheter in panel A) at 40W resulting in the successful termination of PVC (E).

everyday use. Last but not least, operators experience significantly less fatigue and radiation exposure in more ergonomic seated positions during long cases of PVC ablation especially when intramural origins are suspected or when multi-site ablation is required[8]. This review will explore the pros and cons of using RMN in PVC ablation. Table 1 lists the studies that have reported the use of RMN in PVC ablation.

PVC Origin and Catheter Access

Catheter ablation of various origins of PVCs using RMN has been reported. The initial studies utilizing RMN in PVC ablation included PVCs originating from both ventricular outflow tracts (RVOT and LVOT)[9-12]. For ablations in the RVOT, the ability to move floppy RMN catheters in small increments within the ventricular space overcomes the inherent difficulty of moving manual catheters limited by curvatures at the right atrium (RA)/ right ventricle (RV) and RV/ RVOT junctions. Anatomical structures such as the anterior cusp of the pulmonary valve which can be difficult to reach by manual catheters are easily accessible with the 3D directional movements enabled by RMN (Figure 1). The soft tip of RMN catheters generally produces less contact force (10-20 grams) compared to conventional hard-tipped manual catheters (as much as 100 grams), reducing the likelihood of steam pops and perforations in thin-walled structures like the RV. Many studies have demonstrated the ability to ablate PVCs in the RV and RVOT with RMN[13-16]. Di Biase et al also demonstrated RMN's maneuverability and capability to perform epicardial mapping/ablation in PVCs and other ventricular arrhythmias (VA) originating from the left ventricle (LV)[10]. In this study, VA ablation (74% PVC) were was performed at the left coronary cusp (LCC), aortomitral continuity (AMC), LV septum, LV anterior wall, LV inferior wall, LV apex, coronary sinus, and mitral valve annulus with both anterograde and retrograde approaches[10]. In cases where epicardial access is required, RMN holds a few advantages compared to conventional manual catheters. Unlike manual endocardial catheters requiring torque points for manipulation, magnetic catheters are controlled by the tip and can move more freely within the pericardial space where no torque points are readily available[17]. These This evidence demonstrate that RMN might be more suitable for PVC ablations compared to the conventional manual approach.

Fluoroscopy, Ablation and Procedure Time

One of the most important advantages of RMN over manual ablation is the reduction in fluoroscopy time in ablation of all types of arrhythmias. Specifically for PVC ablations, most studies reported

Table 1: Studies of RMN in PVC ablation

Study	Number of PVC patients	PVC origins	Procedure time (min)	Ablation time (min)	Fluoroscopy time (min)	RMN Ablation Catheter	Complications/Safety	Outcomes
Guckel 2021	176 (PVC+VT, 132 PVC)	LVOT, RVOT, LV, RV, multiple origins	206±88	19±24	5±6	3.5mm open-irrigated	9% combined (2%VF, <1% shock, 3% pericardial effusion, 2% tamponade, <1% steampop, <1%RBBB/3AVB, no death)	RMN: 82% combined acute success, 33% PVC recurrence at 5.48y
Li 2020	290 (PVC+VT)	n/a	103.5±64.4	9.4±7.7	3.7±4	3.5mm open-irrigated	0.3% (1 minor unspecified complication)	RMN: 90.3% combined acute success
Li 2021	30 (PVC+VT)	LV, RV	89±38.6	8.8±6.4	4.2±2.4	3.5mm open-irrigated	None	RMN: 93% combined acute success, 4% recurrence at 22.1mo
Xie 2020	65 (PVC+VT)	RVOT	n/a	n/a	n/a	3.5mm open-irrigated	None	RMN: 93.8% combined acute success, 3.3% recurrence at 14.4mo
Xie 2019	15	Parahisian PVCs	n/a	n/a	n/a	3.5mm open-irrigated	None	RMN: 80% acute success, 8% recurrence at 12mo
Dang 2018	43	RVOT, LVOT, RV, LV	96±28	6.7±5.2	3.9±1.9	3.5mm open-irrigated	2% (1 groin hematoma)	RMN:91% acute success 91%, 7% recurrence at 16.2mo
Qiu 2018	64	Outflow tracts, valve annuli	RMN: 129±55 Manual: 130±52	RMN: 12.7±9.4 Manual: 14.2±9.2	RMN: 3.7±3.1 Manual: 12±12.8	3.5mm open-irrigated	None	RMN: 87.5% acute success, 4% recurrence at 16.9mo Manual: 84% acute success, 4% recurrence at 15.8mo
Shauer 2018	42 (PVC+VT)	RVOT	RMN: 113±53 Manual: 116±69	RMN: 7±4.7 Manual: 11.9±16	RMN: 10.9±5.8 Manual: 20.5±13.8	n/a	5% (1 RBBB, 1 hematoma)	RMN: 80% combined acute success, 45% recurrence at 25mo Manual: 74% combined acute success, 47% recurrence at 25mo
Kawamura 2017	22 (PVC+VT, 14 PVC)	RVOT, LVOT, RV, LV	RMN: 152±71 Manual: 158±71	n/a	RMN: 19±14 Manual: 34±22	3.5mm open-irrigated (68% in RMN vs 69% in manual), 4mm non-irrigated	5% (1 hematoma)	RMN: 91% combined acute success, 9% recurrence at 24mo Manual: 69% combined acute success, 10% recurrence at 26mo
Zhang 2013	15 (PVC+VT)	RVOT	RMN: 131.8±19.4 Manual: 115.1±27.4	RMN: 1.1±0.5 Manual: 1.2±0.6	RMN: 5.2±2.6 Manual: 10.5±5.0	4mm non-irrigated	7% (1 RBBB)	RMN: 67% combined acute success, 13% recurrence at 22.1mo Manual: 93% combined acute success
Di Biase 2010	110 (PVC+VT, 84 PVC)	LV only	RMN: 198±66 Manual: 174±72	RMN: 33±18 Manual: 24±12	RMN: 26±14 Manual: 35±33	3.5mm open-irrigated	6% combined (4% VF, 1% CHB, 1% catheter charring, 1% death due to HF)	RMN: 100% combined acute success, 15% recurrence at 11.8mo Manual: 100% combined acute success, 14% recurrence at 18.7mo
Di Biase 2009	65 (PVC+VT)	n/a	276+/-120	n/a	56.8+/-32	4mm, 8mm non-irrigated	3% (2 groin hematoma)	RMN: 52% combined acute success, 85-87% acute success normal heart with RVOT VA 8mm higher success in structural heart disease 59% vs 22% (4mm), 40% recurrence at 12mo
Thornton 2006	3	RVOT only	95-148	2.9-7.3	8.4-13.8	4mm non-irrigated	None	RMN: 100% acute success for PVC, 100% asymptomatic at 1 year follow up

significantly shorter fluoroscopy time[10,12,16,18,19]. The reduction in mean fluoroscopy time was reported from 25% in early studies to close to 70% in later ones[10,19]. This drastic reduction might be related to increased operator confidence that the soft-tip catheters in RMN are less likely to cause myocardial trauma compared to manual catheters. Better catheter stability from robotic arms also reduces the need to reconfirm catheter location with fluoroscopy[20]. Moreover, the RMN platform stores previously utilized vectors and enables catheter navigation along the same vectors without repeat fluoroscopy[21]. Reduced fluoroscopy time not only benefits patients but also operators who are constantly exposed to hazardous radiation.

Early data from Di Biase et al reported longer total procedure time in VA ablation using RMN compared to manual approaches[10]. This study, performed in 2010, included 84 patients (out of 110 patients) in the RMN group undergoing PVC ablation. However, with advancement of the RMN platforms, procedure time in PVC/VT ablations also declined. The introduction of the Vdrive system and the V-SONO module (Stereotaxis, St. Louis, MO) integrated intracardiac echocardiogram (ICE) catheters into the remote process, reducing the need to re-scrub for ICE positioning. More recent studies comparing RMN vs manual ablation in PVC/VT reported comparable total procedure time[16,18,19]. There is also an overall trend of decreasing total procedure time with more experience with the RMN platform. Li et al performed a learning curve analysis of procedure time in patients undergoing atrial fibrillation ablation with RMN. The procedure time decreased along the learning curvse and flattened after 300 procedures[22]. The authors can only expect a similar trend in PVC ablations using RMN. This should serve as a confidence booster for operators planning to incorporate RMN in their practice. Only selected studies reported ablation time in PVC ablation using RMN vs manual approach. Similar to total procedure time, a trend of decreased and more comparable ablation time compared to manual ablations were observed with the introduction of an open irrigated catheter to the RMN platform[10,12,16,19].

Efficacy of RMN in PVC Ablation

Most studies to date reported combined efficacy of PVC and VT ablations and has showed promising results. RMN in PVC ablations overall showed comparable if not better acute success and long-term arrythmia-free rate compared to manual ablations. The first case series by Thornton et al reported successful ablation of all 3 patients with RVOT PVCs using the 4mm RMN ablation catheter. All three patients remained asymptomatic with a mean clinical follow up time of 1 year[9]. However, success rate varied with catheter size and in patients with or without structure heart disease. Di Biase et al reported 85-87% success rate in RMN ablation of RVOT PVC/VT in patients with structurally normal hearts. Acute success decreased significantly in patients with structural heart disease and the 8mm catheters yielded higher efficacy compared to 4mm ones (59% vs 22%)[11]. However, this early study was performed before open irrigated RMN catheters were introduced, which improved lesion formation. Lower maximum contact forces produced by RMN catheter tips can negate the stable catheter-tissue contact and potentially limit lesion formation. The lack of irrigation decreases efficiency of energy delivery due to char formation[20]. This was supported by 10-30% charring observed in this cohort[11]. With the introduction of open-irrigated-tip catheters (OIC) in VA ablation using RMN, the success rate has drastically improved. OIC delivers energy more effectively and produces larger lesions often needed in VA ablation. The same group reported an improved success rate when 3.5mm OIC were introduced the following year[10]. In the 2010 study comparing 110 patients undergoing left sided VA ablation using RMN with 92 patients using manual approach, eighty-four patients presented with PVCs in the RMN group. Overall acute success for RMN was 100% with 15% of patients in the RMN group crossing over to manual ablation. Long term follow-up at 11.8 months in the RMN group showed 85% VA-free rate, comparable to 86% in the manual group at 18.7-month follow up. Unfortunately, the only small randomized controlled trial comparing RMN and manual ablation in VA were performed using traditional 4mm non-irrigated catheters[12]. Combined acute success of PVC/VT ablation was achieved in 67% in the RMN group compared to 93% in the manual group[12].

Since then, almost all studies using RMN in PVC/VT ablation utilized OICs and acute success rates have improved to 80-94%[14,15,18,19,22-24]. Qiu et al reported a prospective comparison of RMN vs manual ablation in patients only with PVCs[19]. Acute success was achieved in 87.5% in the RMN group compared to 84% in the manual group. At follow up, recurrence rate was similar across the two groups (4% vs 4%). RMN not only achieved a comparable success rate compared to the manual approach at index procedures, it was also shown to be effective in patients with previously failed PVC ablations. The retrospective comparison of RMN vs manual in redo idiopathic VA ablations included 14 patients with PVC (out of 22 PVC and VT patients) in the RMN group[18]. Redo success rate was significantly higher in the RMN group (91%) compared to the manual group (69%). The stark difference was likely driven by the higher success rate in ablating PVC/VT arising from the posterior RVOT and posterior-basal RV/tricuspid annulus (92% vs 50% success rate). This finding again emphasizes the superior maneuverability and stability in mapping and ablation of difficult anatomical locations as sharp catheter curves are often needed to reach these landmarks[18] (Figure 1). Not unexpectedly, in the prospective cohort by Qiu et al, a trend of higher index ablation success rate of RMN vs manual in PVCs originating from the valve annuli were also observed (91% vs 70%, p = 0.162)[19].

Safety of RMN in PVC Ablation

Very few safety events have been reported with PVC ablations using RMN since its initial utilization. Most studies reported either no complications in patients undergoing PVC ablations using RMN or minor complications such as groin hematoma, transient conduction blocks at low rates from 0.3% to 9%[10,12,13,15,16,18,19,22]. Major complications including ventricular fibrillation, cardiac tamponade, pericardial effusion, shock and patient death were rarely reported in studies when PVC and VT ablation outcomes were combinedly presented in combination[10,13]. In a direct comparison of RMN vs manual ablation in patients with PVC only, no complications were reported in the RMN group while 3 patients suffered from cardiac tamponade in the manual group[19]. Although no meta-analyses of the safety profile of PVC ablations using RMN has been reported, extrapolation of its superior safety compared to manual ablation can be derived from significantly lower rates of complications in VT ablation using RMN (OR 0.35, p = 0.0006)[21]. The safety of performing PVC ablations with RMN is likely driven by several factors. The soft tip design of RMN ablation catheters delivers lower maximal contact forces, reducing the risk of perforation, steam pops and catheter induced arrhythmias. Better maneuverability and stability also improve mapping accuracy and decrease unexpected catheter movement. In patients with cardiac implanted electronic devices (CIED), a theoretical risk of asynchronous pacing and device dysfunction exists because catheters are maneuvered by 2 large magnets. However, no clinical adverse events resulting from this theoretical risk has been reported[25].

Summary

Despite its existence for the past 2 decades, the application of RMN is still limited by cost, perceived steep learning curve and initial technology lag. However, RMN underwent tremendous improvement in technology since its initial use. Through years of application, evidence is pointing towards comparable high success rates at index procedures and superior efficacy at select redo cases involving complex anatomies. Its inherent advantage over conventional manual approaches in treating PVCs such as safer ablation profile and significantly lower fluoroscopy time also cannot be ignored. More centers should consider incorporating RMN in their routine practice of PVC ablation.

References

1. Nguyen KT, Vittinghoff E, Dewland TA, et al. Ectopy on a Single 12-Lead ECG, Incident Cardiac Myopathy, and Death in the Community. J Am Heart Assoc. 2017;6(8).
2. Agarwal SK, Simpson RJ, Jr., Rautaharju P, et al. Relation of ventricular premature complexes to heart failure (from the Atherosclerosis Risk In Communities [ARIC] Study). Am J Cardiol. 2012;109(1):105-109.

3. von Rotz M, Aeschbacher S, Bossard M, et al. Risk factors for premature ventricular contractions in young and healthy adults. Heart. 2017;103(9):702-707.
4. Cronin EM, Bogun FM, Maury P, et al. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias. Heart Rhythm. 2020;17(1):e2-e154.
5. Romero J, Shivkumar K, Valderrabano M, et al. Modern mapping and ablation techniques to treat ventricular arrhythmias from the left ventricular summit and interventricular septum. Heart Rhythm. 2020;17(9):1609-1620.
6. Burkhardt JD. Remote magnetic navigation for ventricular ablation: did the machine win this round? J Interv Card Electrophysiol. 2017;48(1):5-7.
7. Tahir SM, Chaudhry GM, Syed MA, et al. Remote magnetic navigation system provides a superior catheter stability in acquisition of His bundle electrogram. J Interv Card Electrophysiol. 2008;21(3):209-213.
8. Aagaard P NA, Di Biase L. . Robotic navigation for catheter ablation: benefits and challenges. . Expert Rev Med Devices 2015;12(4):457-469. .
9. Thornton AS, Jordaens LJ. Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia. Heart Rhythm. 2006;3(6):691-696.
10. Di Biase L, Santangeli P, Astudillo V, et al. Endo-epicardial ablation of ventricular arrhythmias in the left ventricle with the Remote Magnetic Navigation System and the 3.5-mm open irrigated magnetic catheter: results from a large single-center case-control series. Heart Rhythm. 2010;7(8):1029-1035.
11. Di Biase L, Burkhardt JD, Lakkireddy D, et al. Mapping and ablation of ventricular arrhythmias with magnetic navigation: comparison between 4- and 8-mm catheter tips. J Interv Card Electrophysiol. 2009;26(2):133-137.
12. Zhang F, Yang B, Chen H, et al. Magnetic versus manual catheter navigation for mapping and ablation of right ventricular outflow tract ventricular arrhythmias: a randomized controlled study. Heart Rhythm. 2013;10(8):1178-1183.
13. Guckel D, Niemann S, Ditzhaus M, et al. Long-Term Efficacy and Impact on Mortality of Remote Magnetic Navigation Guided Catheter Ablation of Ventricular Arrhythmias. J Clin Med. 2021;10(20).
14. Xie Y, Liu A, Jin Q, et al. Novel strategy of remote magnetic navigation-guided ablation for ventricular arrhythmias from right ventricle outflow tract. Sci Rep. 2020;10(1):17839.
15. Dang S, Jons C, Jacobsen PK, Pehrson S, Chen X. Feasibility of a novel mapping system combined with remote magnetic navigation for catheter ablation of premature ventricular contractions. J Arrhythm. 2019;35(2):244-251.
16. Shauer A, De Vries LJ, Akca F, et al. Clinical research: remote magnetic navigation vs. manually controlled catheter ablation of right ventricular outflow tract arrhythmias: a retrospective study. Europace. 2018;20(suppl_2):ii28-ii32.
17. Burkhardt JD, Di Biase L, Horton R, Schweikert RA, Natale A. Remote Navigation and Electroanatomic Mapping in the Pericardial Space. Card Electrophysiol Clin. 2010;2(1):121-125.
18. Kawamura M, Scheinman MM, Tseng ZH, Lee BK, Marcus GM, Badhwar N. Comparison of remote magnetic navigation ablation and manual ablation of idiopathic ventricular arrhythmia after failed manual ablation. J Interv Card Electrophysiol. 2017;48(1):35-42.
19. Qiu X, Zhang N, Luo Q, et al. Remote magnetic navigation facilitates the ablations of frequent ventricular premature complexes originating from the outflow tract and the valve annulus as compared to manual control navigation. Int J Cardiol. 2018;267:94-99.
20. Aagaard P, Natale A, Briceno D, et al. Remote Magnetic Navigation: A Focus on Catheter Ablation of Ventricular Arrhythmias. J Cardiovasc Electrophysiol. 2016;27 Suppl 1:S38-44.
21. Turagam MK, Atkins D, Tung R, et al. A meta-analysis of manual versus remote magnetic navigation for ventricular tachycardia ablation. J Interv Card Electrophysiol. 2017;49(3):227-235.
22. Li X, Jin Q, Zhang N, et al. Procedural outcomes and learning curve of cardiac arrhythmias catheter ablation using remote magnetic navigation: Experience from a large-scale single-center study. Clin Cardiol. 2020;43(9):968-975.
23. Li X, Shang W, Zhang N, et al. Remote magnetic-guided ablation for three origins of idiopathic ventricular arrhythmias with right bundle branch block and superior axis. Clin Cardiol. 2021;44(3):379-385.
24. Xie Y, Jin Q, Zhang N, et al. Strategy of catheter ablation for para-Hisian premature ventricular contractions with the assistance of remote magnetic navigation. J Cardiovasc Electrophysiol. 2019;30(12):2929-2935.
25. Luthje L, Vollmann D, Seegers J, Sohns C, Hasenfuss G, Zabel M. Interference of remote magnetic catheter navigation and ablation with implanted devices for pacing and defibrillation. Europace. 2010;12(11):1574-1580.