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REVIEWS

Safety and efficacy of the remote magnetic navigation for ablation of ventricular tachycardias—a systematic review

Ferdi Akca · Ibrahim Önsesveren · Luc Jordaens · Tamas Szili-Torok

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Abstract
Objective Remote magnetic navigation (RMN) is considered to be a solution for mapping and ablation of several arrhythmias. In this systematic review we aimed to assess the safety and efficacy of RMN in ablation of ventricular tachycardia (VT).
Methods The National Library of Medicine's PubMed database was searched for articles containing any of a predetermined set of search terms that were published prior to November 1, 2011. Quality of evidence was rated using the GRADE system.
Results The database search resulted in 11 relevant articles evaluating the usefulness of RMN. Three groups of VTs were studied: VT in patients with ischemic cardiomyopathy (ICMP), non-ischemic cardiomyopathy (NICMP) and structurally normal hearts (SNH). The use of RMN in patients with ICMP has been associated with success rates ranging from 71 to 80%. RMN has been shown to be a feasible and effective method for ablation of VT in NICMP and SNH patients. Success rates between 50% and 100% have been reported in NICMP populations. Rates ranging from 86% to 100% have been reported for SNH patients. The lowest rates of arrhythmia recurrence are reported for SNH patients (0–17%). In ICMP and NICMP, recurrence rates of 0–30% and 14–50%, respectively, have been reported. One patient experienced total heart block, and one patient experienced a thromboembolic event after RMN catheter ablation procedures.
Conclusions RMN has been shown to be an effective and safe method for ablation of VT in various patient populations with low recurrence and complication rates. However, more comparative and randomized studies are necessary, and therefore the true value of RMN for VT ablation remains still unknown.

Keywords Ventricular tachycardia · Magnetic navigation · Catheter ablation · Electrophysiology · Systematic review

F. Akca · I. Önsesveren · L. Jordaens · T. Szili-Torok (✉)
Clinical Electrophysiology, Department of Cardiology, Erasmus MC,
Rotterdam, The Netherlands
e-mail: t.szilitorok@erasmusmc.nl

1 Introduction

Treatment of ventricular tachycardia (VT) has gone through great improvements in recent years [1–3]. When drug therapy is not effective, catheter ablation of VT can be an effective alternative that has been shown to eliminate ventricular tachycardias with high efficacy [4, 5]. Different approaches can be used depending on the arrhythmia's origin: left endocardial, right endocardial and epicardial approach [6]. Accurate mapping of the area of interest can be difficult to achieve due to complex anatomical structures or structural heart diseases. Remote magnetic navigation (RMN) is considered to be an effective tool for mapping and ablation of arrhythmias that has the potential to overcome some of these challenges [6, 7]. It is a navigation system, which provides good catheter stability during mapping and ablation procedures [8–10]. While the capabilities of manual navigation are limited by the fixed curves of manual catheters, the magnetic catheters have a flexible catheter design enabling them to access otherwise difficult anatomy [11]. The RMN-guided ablation catheter is manipulated by two external magnetic fields situated on either side of the patient. The catheter tip aligns with the magnetic vector produced by the system, allowing the operator to navigate the catheter from its distal tip. Additionally, the RMN system allows the operator to store and reapply specific magnetic vectors in order to facilitate repeated access to difficult anatomy [12]. Some data suggest that utilizing an atraumatic catheter design results in less cardiac perforations [13, 14]. Previous research has shown that RMN may allow the operator to reduce fluoroscopy time [14–16]. RMN has been reported as a feasible tool for ablation of several types of arrhythmias, including AV nodal and AV reentrant tachycardias and atrial fibrillation [17–21]. VT can occur in patients with or without structural heart disease (SHD). SHD can be a result of either ischemic cardiomyopathy (ICMP) or non-ischemic cardiomyopathy (NICMP) [22]. Scar-related VT (SRVT) could have several causes such as myocardial infarction (MI), dilated cardiomyopathy (DCMP), arrhythmogenic RV cardiomyopathy (ARVC) and hypertrophic cardiomyopathy (HCMP) [6]. Idiopathic VT originated in most cases from the outflow tract regions or the fascicles of the left ventricle in patients with structurally normal hearts (SNH) [23]. VTs originating from the left ventricular outflow tract (LVOT) and VT originating from above the pulmonary and aortic valve are recognized more often than before [24–26].

This systematic review aims to provide an overview of the safety and efficacy of RMN in VT ablation.

2 Methods

Our aim was to identify all articles that discuss the use of RMN for VT ablation procedures. The National Library of Medicine's PubMed database was searched until November 1, 2011. The following predetermined set of search terms was applied:

> "Tachycardia, Ventricular"[Mesh] AND "Magnetics"[Mesh] AND Catheter Ablation"[Mesh] OR "Ventricular"[All Fields] AND "Magnetic"[All Fields] AND "Remote"[All Fields] AND "Ablation"[All Fields].

The reference list of each returned article was examined for additional studies that may have been missed in the PubMed database search. All studies discussing use of RMN for VT ablation in human were included.

2.1 GRADE system

All data from the included articles were analysed according to the internationally developed GRADE system in order to define the quality of the evidence [27]. The overall quality of the evidence was rated into four categories (high, moderate, low, very low) using the criteria of GRADE. From the studies that met the inclusion criteria, four factors were considered in appraising the overall strength of the evidence according the GRADE system: study design, study quality, consistency of evidence and directness of evidence.

2.2 Data extracting process

Two authors independently reviewed the eligible articles and extracted the following data: VT type, RMN catheter type, acute success rate, manual crossover rate, follow-up time, follow-up recurrence rate and procedural complications. The authors then cross-checked their results to ensure accuracy. If the authors did not reach complete agreement, the results were discussed and a consensus opinion was reached.

2.3 Outcome measurement

The studies on RMN-guided VT ablation were compared with respect to all extracted data.

3 Results

Our PubMed search returned in 22 results based on the predefined search method. Eleven of the returned articles did not evaluate the use of RMN in VT and were consequently excluded [21, 28–37]. In all, data from 11 articles—seven clinical trials, three case reports and one case series—were assessed [6, 7, 11, 20, 22, 38–43]. After quality assessment according to the GRADE system, four studies were considered as low evidence and seven as very low evidence (Table 1). Three main VT subtypes were studied: VT in ICMP, NICMP and SNH. Additionally, studies on SRVT in patients with ICMP, NICMP or both are analyzed.

In Table 1 an overview of the extracted data is presented. As the article by De Torres et al. did not report a recurrence rate, we contacted the authors in order to obtain the missing data [42].

3.1 Overall success rate

Overall success rates ranged from 52% to 86% for studies assessing VT ablation in ICMP, NICMP and SNH. Two studies reported crossover to manual irrigated tip catheters in 14% and 48% of procedures, respectively [22, 38]. Thirty-four of 65 ablation procedures (52%) by Di Biase et al. (2009) utilized only non-irrigated tip RMN ablation catheters. The remaining procedures required the use of manual ablation catheters in order to achieve procedural success. Di Biase et al. (2010) report manual crossover in 15 cases (14%).

3.2 Ischemic cardiomyopathy

For ablation of VT in ICMP, success rates ranging from 71% to 80% were achieved [6, 20, 39]. Arya et al. and Haghjoo et al. report success rates of 80% using the irrigated RMN ablation catheter. In both studies 20% of the cases resulted in partial

Table 1 Data from included publications

Publication	GRADE score	RMN catheter type	Number of VT ablation procedures/VT type			Acute succes				Manual crossover	Follow-up (months)	Recurrence				Complications
			ICMP	NICMP	SNH	ICMP	NICMP	SNH	Overall			ICMP	NICMP	SNH	Overall	
Di Biase et al. 2010 (USA)	Low	Irrigated	33	14	63	–	–	–	86% (95/110)	14% (15/110)	11.8	30% (10/33)	14% (2/14)	8% (5/63)	15% (17/110)	Total heartblock (n=1)
Di Biase et al. 2009 (USA)	Low	Non-irrigated	44 SR		21	36% (16/44)		86% (18/21)	52% (34/65)	SR: 64% (28/44) SNH: 14% (3/21)	12	–	–	–	40%	Groin hematoma (n=2)
Arya et al. 2010 (GER)	Low	Irrigated	30	–	–	80% (24/30)	–	–	–	0%	7.8	25% (6/24)	–	–	–	No
Aryana et al. 2007 (USA)	Low	Non-irrigated	17	ARVC (n=3) HCM (n=2) DCM (n=3) CS (n=2)	–	71% (12/17)	ARVC: 100% (3/3) DCM: 50% (1/2) CS: 50% (1/2)	–	–	92% (22/24)	7	27% (3/11)	CS: 50% (1/2)	–	–	Right ulnar nerve palsy (n=1) DVT (n=1)
Konstantinidou et al. 2011 (GER)	Very low	Non-irrigated	–	–	13	–	–	92% (12/13)	–	0%	8.4	–	–	17% (2/12)	–	No
Thornton and Jordaens 2006 (NL)	Very low	Non-irrigated	–	–	7	–	–	100% (7/7)	–	0%	12	–	–	14% (1/7)	–	No
Haghjoo et al. 2009 (GER)	Very low	Irrigated	5	–	–	80% (4/5)	–	–	–	0%	4.2	0%	–	–	–	No
Thornton et al. 2006 (NL)	Very low	Non-irrigated	–	–	1	–	–	100% (1/1)	–	0%	12	–	–	0%	–	No
De Torres et al. 2008 (NL)	Very low	Non-irrigated	–	–	1	–	–	100% (1/1)	–	0%	12	–	–	0%	–	No
Schwagten et al. 2009 (NL)	Very low	Non-irrigated	–	–	3	–	–	100% (3/3)	–	0%	6	–	–	0%	–	No
Burkhardt et al. 2006 (USA)	Very low	Non-irrigated	–	–	1	–	–	100% (1/1)	–	0%	1 day	–	–	–	–	No

ARVC arrhythmogenic RV cardiomyopathy, *CS* cardiac sarcoidosis, *DCM* dilated cardiomyopathy, *DVT* deep venous thrombosis, *HCM* hypertrophic cardiomyopathy, *LVOT* left ventricular outflow tract, *NICMP* non-ischemic cardiomyopathy, *RV* right ventricle, *RVOT* right ventricular outflow tract, *SNH* structural normal heart, *SR* scar-related success, defined as inducibility of non-clinical VT following the ablation procedure [20, 39]. Manual crossover was never necessary to achieve procedural success in these studies. Aryana et al. report a 71% success rate for VT ablation in patients with ICMP [6].

Di Biase et al. report an acute success rate of 36% for SRVT ablation [38]. This study combines the ICMP and NICMP populations into a single cohort. In 64% of the procedures the non-irrigated tip RMN ablation catheter was unable to achieve acute success, so the procedure was crossed-over to manual technique.

3.3 Non-ischemic cardiomyopathy

Aryana et al. evaluated the use of RMN for VT ablation in patients with NICMP and report an acute success rate of 50% in patients with cardiac sarcoidosis after two VT ablation procedures [6]. In patients with ARVC and DCMP acute success was achieved in 100% and 50% of procedures, respectively. Because of lack of VT inducibility, successful catheter ablation could not be performed in HCMP population.

3.4 Structurally normal heart

Success rates for RMN ablation in patients with SNH vary from 86% to 100% [7, 11, 38, 40–43]. Di Biase et al. report manual crossover in 14% of cases. Thornton et al., Konstantinidou et al., De Torres et al., Schwagten et al. and Burkhardt et al. completed all cases without crossover to manual catheters.

3.5 Recurrence rates

Following acutely successful ablation procedures, 0–30% of ICMP patients experienced recurrence [6, 20, 22, 39]. Recurrence rates ranging from 14% to 50% are reported for the NICMP population [6, 22]. Recurrence rates ranged from 0% to 17% for patients with SNH after VT ablation procedures [11, 22, 40–43]. Thornton et al. note one patient (14%) who experienced non-sustained VT after an acutely successful catheter ablation procedure. Because this patient had sustained VT prior to ablation, the procedure was considered as partial success [40].

Di Biase et al. reported an overall recurrence rate of 40% in a mixed sample of patients treated with 4 mm RMN, 8 mm RMN and manual catheters. The same group reported an overall recurrence rate of 15% in 2010. For the RMN subgroup, VT recurrence was 14% and 27% for patients that were crossed over to manual technique [22].

3.6 Complications

Four complications were associated with VT ablation procedures. Di Biase et al. noted heart block in one patient with a right bundle branch block (RBBB) [22]. Two additional patients developed groin hematomas [38]. Another study reports an uncomplicated bilateral lower-extremity deep venous thrombosis in one patient [6]. This thromboembolic complication occurred during left-sided ablation with a non-irrigated tip catheter, so the risk of similar events is likely to be reduced by using irrigated tip RMN ablation catheters [44]. Aryana et al. report a case of right ulnar nerve palsy after an epicardial RV mapping procedure. It is unclear whether the palsy is caused by an embolic stroke or was a result of long immobilization under general anesthesia [6].

3.7 Crossover to manual ablation

In this systematic review the use of RMN in ablation of VT has been investigated. Several groups report use of RMN ablation to treat patients with ICMP, but these results are quite varied [6, 20, 38, 39]. Three groups reported favorable success rates between 71% and 80%. Two of 15 ablation procedures (13%) by Aryana et al. utilized only non-irrigated tip RMN ablation catheters. The remaining procedures required the use of manual irrigated tip ablation catheters in order to achieve acute procedural success. Di Biase et al., however, achieved a rate of only 36% for SRVT ablation procedures. This low success rate may not accurately reflect the potential of RMN as the study employs only non-irrigated RMN catheters and showed a low threshold for manual crossover [38]. The most recent trial by Di Biase et al. (2010) with irrigation demonstrated a considerable lower crossover rate of 14%. Previous research has shown that catheter irrigation improves ablation efficacy and decreases the risk of thrombotic events [44]. However, very scarce data are available on SRVT using an irrigated ablation catheter.

3.8 Idiopathic VT

RMN is most effective when used in patients with SNH and is successful in 86% to 100% of these procedures [7, 11, 38, 40–43]. The usefulness of RMN in ablation of idiopathic VTs has been investigated by several groups. Although they evaluate RMN in a relatively small sample of patients, these studies demonstrate the feasibility of RMN for successful ablation of RVOT, LVOT, left fascicular and aortic cusp VT. Still, more evidence is needed to assess the efficacy and safety of RMN in different subtypes of idiopathic VT.

3.9 Future studies or areas of investigation

This review showed successful results in patients with ARVC, DCMP and sarcoidosis [6]. However, these groups included a minimal number of patients, and more research is needed in this patient population. Therefore, we call for more research on the use of RMN in ablation of VT in NICMP.

The safety and efficacy of RMN in ablation of VT is evaluated in multiple studies. Schwagten et al. report on the superior capabilities of RMN in VT ablation [45]. A higher rate of acute success (97% vs. 81%, p=0.03) and lower rate of arrhythmia recurrence (14% vs. 50%, p<0.01) were achieved in RMN procedures compared to manual catheter ablation.

The use of RMN compared to manual procedures has been evaluated for multiple arrhythmias, including VT [13]. Bauernfeind et al. evaluated the safety and long-term efficacy of RMN in a large number of patients. These data showed that the use of RMN reduced the occurrence of major complications (0.34 vs 3.2%, p=0.01) without compromising efficacy compared to manual ablation. Further, RMN was significantly more successful for VTs (93 vs 72%, p<0.05). In this population both SNH and SR VT were studied; however, the superiority of RMN in SNH VT was largely responsible for the difference. Di Biase et al. (2010) stated that procedure times were longer using RMN, although with decreased use of fluoroscopy. To achieve similar results, a statistically greater number of RF lesions needed to be applied in RMN group. However, Bauernfeind et al. report both decreased procedure times and fluoroscopy times using RMN. This could be explained by the steep learning curve for the RMN system. This demonstrates that new methods are needed to increase efficacy of ablation compared to conventional manual techniques. However, no randomized studies have been executed to prove superiority.

3.10 Limitations of the study

In this review we evaluated the safety and efficacy of RMN in VT ablation. Several studies show advantages of RMN for VT ablation, although this is based on low quality evidence according to the GRADE system. High quality randomized studies are needed for more consistent evidence to assess the efficacy and safety of RMN in ablation of VT.

4 Conclusion

The available data on RMN suggests that it is an effective and safe method for ablation of VT with relatively low recurrence and complication rates. RMN has been used to achieve successful outcomes in various patient populations and VT subtypes. SNH VT appears to have the best outcome using RMN in comparison to ICMP and NICMP VT. In case of NICMP extremely limited data are available for the effectiveness of RMN. Although these are promising results, more comparative and randomized studies are necessary to assess superiority. The true value of RMN for VT ablation remains still unknown.

Disclosure Tamas Szili-Torok is a consultant of Stereotaxis, Inc., St. Louis, MO, USA.

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