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Magnetic Versus Manual Catheter Navigation for Ablation of Ventricular Tachycardia: A Systemic Review and Meta-Analysis

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Abstract

Background: This study was conducted to evaluate the efficacy, and procedural complications of remote magnetic navigation (RMN) versus manual catheter navigation (MCN) for ablation of ventricular tachycardia. **Subjects and Methods:** We performed electronic searches on PubMed, The Cochrane Library, EMBASE, EBSCO, Web of Science and CINAHL databases from inception through April 6, 2017, to identify clinical trials comparing RMN with MCN. The primary efficacy outcomes were acute failed ablation and recurrent VT rates. Secondary outcomes in our study were procedural time, fluoroscopic time and procedural complications. **Results:** Six clinical trials, including a total of 582 patients, were identified, of which 324 underwent RMN guided VT ablation, and 258 underwent MCN guided VT ablation. Acute procedural success (or reduced failed VT ablation rates) was significantly improved with RMN group versus MCN group (10% versus 19% respectively, RR 0.56; 95% CI 0.38 – 0.83) with no statistically significant difference in the recurrent VT rates (RR 0.87, 95% CI 0.64-1.19). The total procedure time was not significantly different between the two groups. However, the total fluoroscopy time (Standard mean difference -1.00, 95% CI -1.32 - -0.67; $p<0.001$) was significantly lower and a trend towards reduced procedural complications (RR 0.40, 95% CI 0.16 – 0.99; $p=0.05$) was observed in the RMN group versus MCN group, respectively. **Conclusion:** In this meta-analysis, there was a significant benefit regarding acute VT ablation success rate and a significant reduction in radiation exposure, with a trend towards reduction in procedure-related complication in patients undergoing RMN guided VT ablation versus MCN VT ablation approach.

Keywords: Remote magnetic navigation; Manual catheter navigation; Ventricular tachycardia; Ablation.

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Introduction

With the advent of catheter ablation in clinical electrophysiology in 1980's,[1] it has become a first-line management for various arrhythmias including atrioventricular nodal tachycardia, atrioventricular tachycardia, atrial flutter, and a therapeutic alternative for atrial fibrillation, atrial tachycardia and ventricular tachycardia (VT). Technological advances such as electroanatomical mapping, improved catheter designs and cardiac imaging have evolved rapidly to improve procedural success and patient outcomes.[2] Until recently, all the developments mentioned above were confined to manual catheter navigation (MCN) guided ablations. However, MCN may be technically challenging as the success of MCN depends on arrhythmogenic substrate location, good tissue contact, physician fatigue, and often associated with increased radiation risk. Remote magnetic navigation (RMN) system is a new technology that offers advantages like flexible catheter design and less physical stress and radiation exposure for the physicians as compared to MCN.[3] Since the first published report on RMN,[4] numerous studies have been published assessing safety and efficacy of RMN versus MCN for VT ablation. In the meta-analysis published by Wu et al., RMN guided VT ablation was associated with reduced complications, and shorter procedural and fluoroscopic time as compared to MCN.[5] With increasing evidence (addition of new trials) calls for this meta-analysis to assess the safety and efficacy of RMN guided VT ablation versus MCN approach [Table 1].

Subjects and Methods

The current review was performed according to Cochrane Collaboration and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statements.[6] We searched PubMed, The Cochrane Library, EMBASE, EBSCO, Web of Science and CINAHL databases from the inception through April 6, 2018. All clinical trials evaluating the use of RMN in patients undergoing VT ablation were included in the analysis. We combined the medical subject heading keywords including: ventricular tachycardia, ablation, and remote magnetic navigation. Two reviewers (JG and RG) independently extracted the data from the eligible trials on study design, patient characteristics, acute procedural success, the recurrence rate of VT, procedural complications, total procedural time and fluoroscopy time. Discussion and consensus resolved discrepancies between the two reviewers. Final results were reviewed by senior investigator [Figure 1]. All references of the retrieved articles were examined for further identification of potentially relevant studies. The identified studies were systematically assessed using the inclusion and exclusion criteria described below.

Eligibility criteria

The eligibility criteria for our systematic review and meta-analysis included (1) adult human subjects undergoing VT ablation, (2) reported clinical outcomes of procedural success and recurrent VT. All studies with crossover design, without a comparator arm, studies that did not report our primary outcomes were excluded from our analysis. Abstracts, case reports, conference presentations, editorials, reviews, expert opinions and literature published in Non-English language were excluded from our analysis. We used the longest available follow-up data from individual studies for our analysis.

Outcomes

The primary efficacy outcomes in our study were acute success rate (or failed VT ablation) and recurrent VT rates. Secondary outcomes in our study were procedural time, fluoroscopic time and procedural complications – composite of pericardial effusion or/and tamponade, temporary or permanent atrioventricular block, pacemaker/implantable cardioverter defibrillator damage requiring device or electrode replacement, stroke or transient ischemic attack, major or minor bleeding, and death.

Quality appraisal and publication bias

Assessment of risk of bias for each selected study was performed per PRISMA 2009 guidelines. Qualitative evaluation of bias using the following key parameters were performed for each study: 1) clear definition of study population; 2) clear definition of outcomes and outcome assessment; 3) independent assessment of outcome parameters; 4) sufficient duration of follow-up; 5) selective loss during follow-up; and 6) significant confounders and prognostic factors identified. Evidence of publication bias was investigated using funnel plots and analysed using Egger and Beggs methods (7) and Duval and Tweedie's trim and fill method (8). Sensitivity analysis was performed with the exclusion of one study at a time to asses the effect on overall results.

Statistical Analysis

We performed direct head-to-head comparisons between RMN and MCN using a fixed effects model to estimate pooled risk ratio (RR), standard mean difference (SMD) and 95% confidence intervals (CIs) incorporating within and between study heterogeneity (9). We assessed statistical heterogeneity using the I2 statistic; I2 values >50% indicated substantial heterogeneity (10). In the case of significant heterogeneity, random effects model was used for analysis. All p values were 2-sided, and a p-value of <0.05 was considered significant. Data was analysed using the Cochrane Collaborative software, RevMan 5.3.

Results

A total of 36 studies were identified after exclusion of duplicate or irrelevant references [Figure 1]. After a detailed evaluation of these studies, six trials (1 randomised and 5 non-randomized trials) with a total of 582 patients; of which 324 underwent RMN guided VT ablation, and 258 were treated with MCN guided VT ablation.[11-16] The mean age of the participants was 53 years, 58% were males and the mean follow-up period was 19 months. Characteristics of included studies are described in [Table 1].

Table 1: Characteristics of included studies

Study name	Di Biase et al[11]	Bauernfeind et al[12]	Szili-Torak et al[13]	Dinov et al[14]	Zhang et al[15]	Kawamura et al[16]
Country	USA	Netherlands	Netherlands	Germany	China	USA
Study design	CCS	PCS	CCS	RCS	RCT	RCS
No. of patients (Study/Control)	110/92	54/29	72/41	50/52	15/15	23/29
Age (mean yrs) (Study/Control)	56/58	N/A	51/49	69/66	41.7/46.5	49/45
Male sex (n) (Study/Control)	75/52	N/A	49/33	46/42	4/4	7/16
LVEF (mean %) (Study/Control)	40/44	N/A	N/A	32.3/31.8	64.6/65.2	57/55
Hypertension (n) (Study/Control)	64/54	N/A	N/A	42/44	N/A	4/17
Diabetes (n) (Study/Control)	17/13	N/A	N/A	21/20	N/A	9/10
Follow-up period (months) (Study/Control)	11.8/18.7	N/A	20/20	13/14	22.1/22.1	24/26

CCS=Case-control study; PCS=Prospective cohort study; RCS=Retrospective cohort study; RCT=Randomized controlled trial; LVEF=Left ventricle ejection fraction

Table 2: Sensitivity analysis by exclusion of 1 trial at a time for primary and secondary outcomes

Trial excluded	Relative risk (RR) or Standard difference in means (SMD)	RR or SMD (after exclusion)	Significant change from overall result
Acute success rate (failed VT ablation rate)			
Di Biase et al 2010	0.56 (0.38 to 0.83)	0.48 (0.29 to 0.80)	No
Bauernfeind et al 2011	0.56 (0.38 to 0.83)	0.63 (0.34 to 1.17)	Yes
Szili-Torak et al 2012	0.56 (0.38 to 0.83)	0.58 (0.25 to 1.36)	Yes
Dinov et al 2012	0.56 (0.38 to 0.83)	0.54 (0.24 to 1.22)	Yes
Zhang et al 2013	0.56 (0.38 to 0.83)	0.49 (0.32 to 0.74)	No
Kawamura et al 2016	0.56 (0.38 to 0.83)	0.60 (0.30 to 1.20)	Yes
Recurrent ventricular tachycardia			
Di Biase et al 2010	0.87 (0.64 to 1.19)	0.78 (0.55 to 1.10)	No
Bauernfeind et al 2011	0.87 (0.64 to 1.19)	0.82 (0.60 to 1.13)	No
Szili-Torak et al 2012	0.87 (0.64 to 1.19)	0.89 (0.63 to 1.25)	No
Dinov et al 2012	0.87 (0.64 to 1.19)	0.91 (0.60 to 1.38)	No
Zhang et al 2013	0.87 (0.64 to 1.19)	0.82 (0.61 to 1.12)	No
Kawamura et al 2016	0.87 (0.64 to 1.19)	0.84 (0.61 to 1.14)	No
Procedural Complications			
Di Biase et al 2010	0.40 (0.16 to 0.99)	0.33 (0.12 to 0.92)	No
Szili-Torak et al 2012	0.40 (0.16 to 0.99)	0.46 (0.16 to 1.31)	Yes
Dinov et al 2012	0.40 (0.16 to 0.99)	0.35 (0.07 to 1.63)	Yes
Zhang et al 2013	0.40 (0.16 to 0.99)	0.46 (0.15 to 1.40)	Yes
Total procedural time			
Di Biase et al 2010	-0.09 (-0.53 to 0.35)	-0.19 (-0.67 to 0.29)	No
Bauernfeind et al 2011	-0.09 (-0.53 to 0.35)	0.05 (-0.39 to 0.49)	No
Szili-Torak et al 2012	-0.09 (-0.53 to 0.35)	0.03 (-0.43 to 0.49)	No
Dinov et al 2012	-0.09 (-0.53 to 0.35)	-0.14 (-0.69 to 0.41)	No
Zhang et al 2013	-0.09 (-0.53 to 0.35)	-0.21 (-0.67 to 0.26)	No
Kawamura et al 2016	-0.09 (-0.53 to 0.35)	-0.06 (-0.58 to 0.46)	No
Total fluoroscopy time			
Di Biase et al 2010	-1.00 (=1.32 to -0.67)	-1.16 (-1.39 to -0.94)	No
Bauernfeind et al 2011	-1.00 (=1.32 to -0.67)	-0.98 (-1.37 to -0.60)	No
Szili-Torak et al 2012	-1.00 (=1.32 to -0.67)	-0.98 (-1.36 to -0.59)	No
Dinov et al 2012	-1.00 (=1.32 to -0.67)	-0.94 (-1.30 to -0.59)	No
Zhang et al 2013	-1.00 (=1.32 to -0.67)	-0.97 (-1.33 to -0.62)	No
Kawamura et al 2016	-1.00 (=1.32 to -0.67)	-1.05 (-1.44 to -0.67)	No

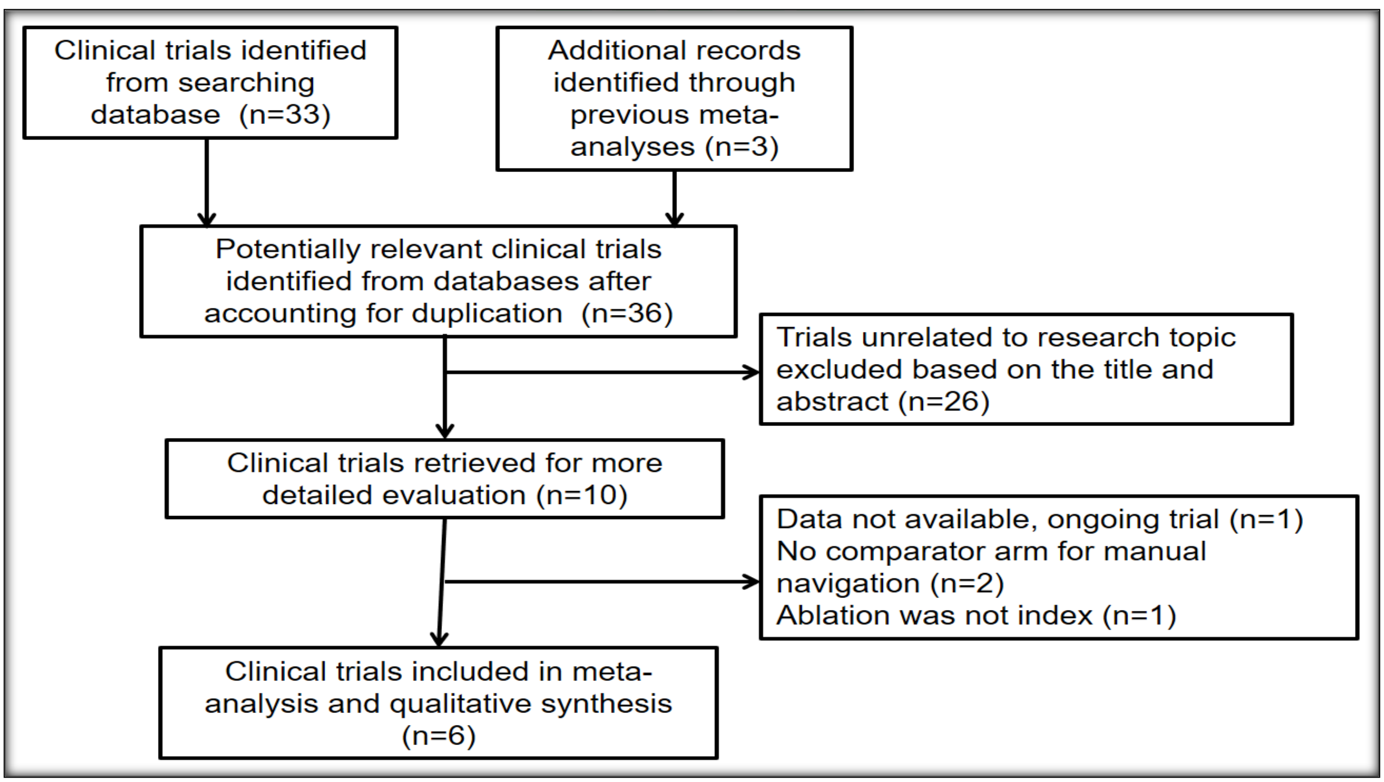

Figure 1: Process of study selection for trials (PRISMA Statement)

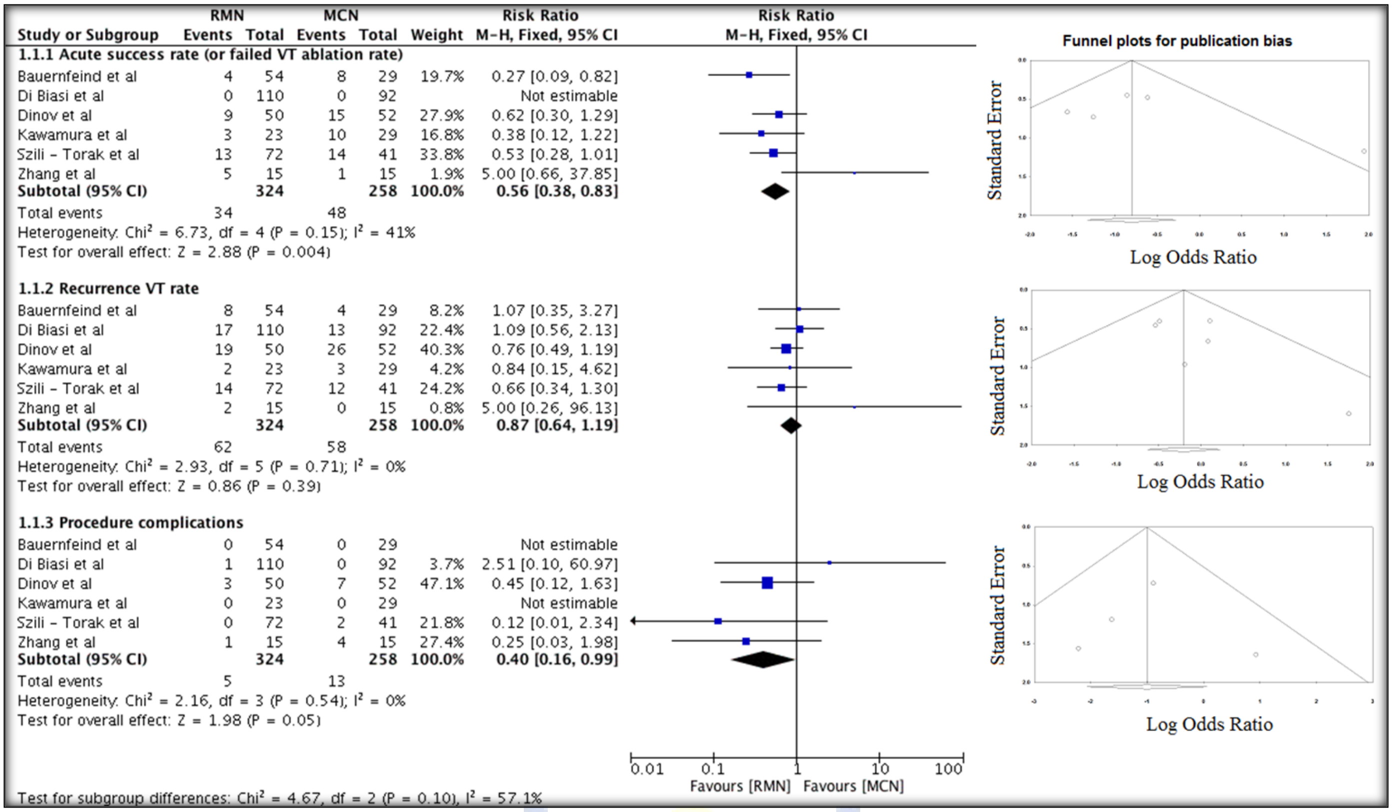

Figure 2: Forest plots demonstrating acute success rate (or failed VT ablation), recurrence of ventricular arrhythmia and procedural complications in patients undergoing remote magnetic navigation versus manual catheter navigation guided ventricular tachycardia ablation.

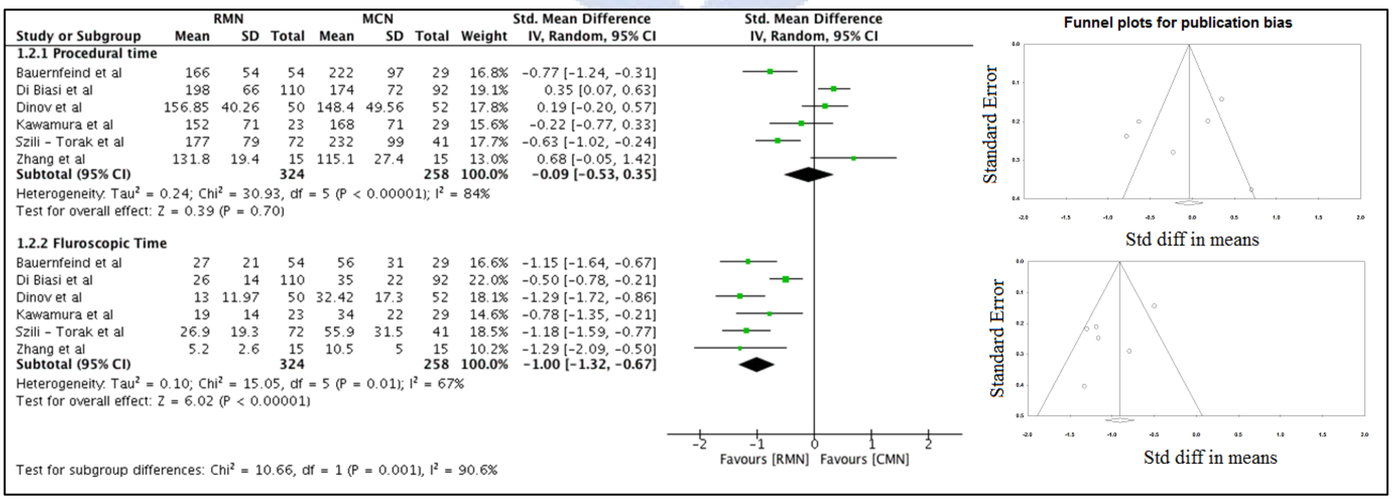

Figure 3: Forest plots demonstrating total procedure time and fluoroscopy time in patients undergoing remote magnetic navigation versus manual catheter navigation guided ventricular tachycardia ablation.

Primary outcome

There was a significant difference in acute procedural success (or reduced failed VT ablation rates) with RMN guided VT ablation versus MCN strategy, 34 events (10%) versus 48 events (19%), respectively (RR 0.56; 95% CI 0.38 – 0.83). No significant heterogeneity was observed (I2 =41%). No statistically significant difference in the recurrent VT rates was observed between RMN and MCN guided VT ablation, 62 events (19%) versus 58 events (22%) respectively, (RR 0.87; 95% CI 0.64 – 1.19), (I2=0%) [Figure 2].

Secondary outcomes

The total procedure time was not significantly different between RMN and MCN groups (standard mean difference -0.09, 95% CI -0.53 – 0.35; p=0.70, I2=84%). However, the total fluoroscopy time was significantly lower in the RMN group compared to MCN (Standard mean difference -

1.00, 95% CI -1.32 - -0.67; p<0.001, I2=67%) [Figure 3]. There was a trend towards reduced procedural complications in RMN group versus MCN (1.5% versus 5%, respectively, RR 0.40, 95% CI 0.16 – 0.99; p=0.05). The statistical heterogeneity was small (I2= 0%) [Figure 2].

Discussion

Catheter-based ablations have become a mainstay of treatment for cardiac arrhythmias, with high success rate and reduced complications. Manual catheter navigation can be technically challenging for VT ablation especially in patients with difficult to reach arrhythmogenic substrate (due to lack of optimal catheter curves especially in patients with dilated heart or complex congenital heart disease or rotated cardiac anatomy), compromised catheter positioning and inadequate tissue contact resulting in ineffective ablation.[17] Therefore, an alternative ablation strategy as effective as MCN guided VT ablation with improved safety is essential. Herein, we present the largest meta-analysis demonstrating the safety and efficacy of RMN guided VT ablation versus MCN approach. The main findings in our study was 1) significant improvement in acute success rate (or acute failed ablation) with RMN guided VT ablation versus MCN approach; 2) non-significant trend towards reduced procedural complications and; 3) non-significant difference in the procedural time with significant reduction in fluoroscopic time between the two groups.

One of the possible explanations for acute ablation success (i.e. reduction in acute failed ablation) could be due to floppy and atraumatic ablation catheter design (not limited to preformed catheter curves) in RMN guided approach allowing increased freedom of movement in the cardiac chambers and easy accessibility to the desirable site for ablation – thereby better tissue contact and effective lesions.[17,18] A non-significant difference in the procedural time with significant reduction in fluoroscopic time was observed between the two groups despite the increased learning curve for the electrophysiologist as well as laboratory staff. This could potentially reduce both physician and patient related radiation-induced disease in the future. In addition to atraumatic catheter design and manoeuvrability, stored magnetic vectors and software based auto mapping provides additional benefit in reduction of radiation exposure and fluoroscopic time without requiring re-imaging after each repositioning unlike MCN VT ablation approach.[18,19]

Given the lack of literature, a randomised controlled trial MAGNETIC VT (NCT02637947) will provide valuable information if substrate-based VT ablation with RMN is clinically advantageous than MCN approach.[20] A total of 386 patients will be enrolled and randomised into 1:1 fashion between RMN and MCN at up to 20 centres. The primary outcome of the study is freedom from any recurrent VT up to 12 months.

One of the major limitations of the current meta-analysis includes the paucity of randomised data and reliance on retrospective trials. So far only 1 RCT has been done, and hence imperfection of study design may limit data interpretation in our analysis. Also, the overall results could have been driven from the data from trials observed with sensitivity analysis [Table 2]. In addtion, operator experience, small sample size and lack of availability of data from included trials may have also limited further evaluation of the source of heterogeneity in our analysis.

Conclusion

In this meta-analysis, there was a significant benefit regarding acute VT ablation success rate and a significant reduction in radiation exposure, with a trend towards reduction in procedure-related complication in patients undergoing RMN guided VT ablation versus MCN VT ablation approach.

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