Remote magnetic with open-irrigated catheter vs. manual navigation for ablation of atrial fibrillation: a systematic review and meta-analysis

Riccardo Proietti1,2*, Valentina Pecoraro3, Luigi Di Biase4,5,6, Andrea Natale4,5, Pasquale Santangeli4,5,7, Maurizio Viecca1, Antonio Sagone1, Alessio Galli1, Lorenzo Moja8, and Ludovica Tagliabue9

1Cardiac Electrophysiology Laboratory, Luigi Sacco Hospital, Via G. B. Grassi, 72, 20156 Milan, Italy; 2Division de Cardiologie, Hôpital Général De Montréal, McGill University, Montreal, Quebec, Canada, H3G 1A4; 3Clinical Epidemiology Unit, IRCCS Orthopedic Institute Galeazzi, 20161 Milan, Italy; 4Texas Cardiac Arrhythmia Institute, St David's Medical Center, Austin, TX 78705, USA; 5Department of Biomedical Engineering, University of Austin, Austin, TX 78705, USA; 6Albert Einstein College of Medicine at Montefiore Hospital, New York 10467, USA; 7Cardiac Arrhythmias Service, Stanford University School of Medicine, 94305 Stanford, CA, USA; 8Department of Biomedical Sciences for Health, University of Milan, 20133 Milan, Italy; and 9Hospital Management Unit, Italian Auxologic Institute, IRCCS, San Luca Hospital, 20149 Milan, Italy

Received 21 December 2012; accepted after revision 19 February 2013; online publish-ahead-of-print 12 April 2013

The aim of this study was to determine the efficacy and safety of remote magnetic navigation (RMN) with open-irrigated catheter vs. manual catheter navigation (MCN) in performing atrial fibrillation (AF) ablation. We searched in PubMed (1948–2013) and EMBASE (1974–2013) studies comparing RMN with MCN. Outcomes considered were AF recurrence (primary outcome), pulmonary vein isolation (PVI), procedural complications, and data on procedure’s performance. Odds ratios (OR) and mean difference (MD) were extracted and pooled using a random-effect model. Confidence in the estimates of the obtained effects (quality of evidence) was assessed using the Grading of Recommendations Assessment, Development and Evaluation approach. We identified seven controlled trials, six non-randomized and one randomized, including a total of 941 patients. Studies were at high risk of bias. No difference was observed between RMN and MCN on AF recurrence [OR 1.18, 95% confidence interval (CI) 0.85 to 1.65, P = 0.32] or PVI (OR 0.41, 95% CI 0.11–1.47, P = 0.21). Remote magnetic navigation was associated with less peri-procedural complications (Peto OR 0.41, 95% CI 0.19–0.88, P = 0.02). Mean fluoroscopy time was reduced in RMN group (−22.22 min; 95% CI −42.48 to −1.96, P = 0.03), although the overall duration of the procedure was longer (60.91 min; 95% CI 31.17 to 90.65, P < 0.0001). In conclusion, RMN is not superior to MCN in achieving freedom from recurrent AF at mid-term follow-up or PVI. The procedure implies less peri-procedural complications, requires a shorter fluoroscopy time but a longer total procedural time. For the low quality of the available evidence, a proper designed randomized controlled trial could turn the direction and the effect of the dimensions explored.

Keywords Remote magnetic navigation • Atrial fibrillation ablation • Stereotaxis

Introduction

Electrical pulmonary vein isolation (PVI), obtained through percutaneous trans-catheter radiofrequency ablation, has proven to be a valid therapeutic option to obtain freedom from recurrence of atrial fibrillation (AF).1,2 However, catheter ablation is a demanding procedure for several reasons: in the first place, it relies on an experienced team of electrophysiologists and requires a high level of radiation exposure; secondly, 50% of patients need more than one session to achieve clinical benefits2 and, lastly, procedural complications are experienced by 1 out of 26 patients and the incidence of fatal outcome is reported as 1 per 1000 procedures.3 Remote magnetic navigation (RMN) technologies have been introduced in order to limit some of the drawbacks of manual catheter navigation (MCN) during catheter- ablation of AF and improve the safety and efficacy of ablation procedures.4 Remote magnetic navigation might have several advantages: fine control of small movements, increased precision in reaching the target area, possibility of standardizing the catheter position inside the heart cavities, and need of lower forces to maintain stable tissue contact during ablation. For a time, the application of RMN in performing AF ablation has been limited by the inability to achieve efficacious ablative lesions with the available solid tip catheters.5 Recently, a new open-irrigated catheter for RMN was introduced and preliminary studies showed its efficacy in ablating arrhythmic triggers.6
The aims of this systematic review are (i) to identify and describe all studies that compared RMN performed with the new open-irrigated catheter for AF ablation with MCN and (ii) to evaluate the procedure’s efficacy and safety.

Methods

Eligibility criteria

Randomized, quasi-randomized, and non-randomized controlled studies (NRSs) were included if they met the following criteria: (i) inclusion of patients with AF (either paroxysmal or persistent); (ii) comparison between AF ablation obtained with RMN using an open-irrigated catheter and MCN control system; and (iii) report of results of at least one relevant outcome, including AF or other atrial tachyarrhythmia recurrence rate, PVI success rate, procedure complications, and procedural data (e.g. total duration of the procedure, fluoroscopy time, radiofrequency application duration, and need to switch from RMN to MCN procedure). The term ‘quasi-randomized’ refers to controlled trials that use inappropriate randomization strategies.

Search strategy

Studies were identified by searching electronic databases (PubMed from 1948 to the present and EMBASE from 1974 to the present), scanning reference lists of articles and consulting with experts in the field. We searched also Cochrane and DARE databases for additional records. Search strategy adopted was the same for all the databases and was developed using as key words ‘atrial fibrillation’, ‘ablation’ and ‘remote magnetic navigation’. We limited the search to studies in humans and published in English, French, Italian, or Spanish. The search was performed on 31 January 2013.

Study selection

The literature search was conducted by one investigator (V.P.). Two researchers (R.P. and V.P.) selected independently studies for inclusion according to eligibility criteria. Disagreements between reviewers were resolved by consensus; if no agreement could be reached, it was planned that a third author (L.T.) would decide.

Data extraction

Information was extracted from each included trial about:

(1) Characteristics of trial participants (age, sex, type of AF—paroxysmal or persistent; and co-morbidities, and prior AF ablation) and country where the study was performed;
(2) Outcomes:
   (a) Efficacy
      (i) Primary outcome: AF or other atrial tachyarrhythmia recurrence rate at the end of the follow-up (independently from the length and intensity of the follow-up in each study);
      (ii) Secondary outcome: acute success rate, i.e. in PVI at the end of the procedure;
   (b) Safety: procedural complications included post-operative mortality, frequency of pulmonary vein stenosis, embolic events (i.e. stroke and transient ischaemic attack), pericardial tamponades, and other adverse effects potentially reported by trials’ authors;
   (c) Procedural data: total procedure time, fluoroscopy and radiofrequency times, and need to switch from RMN to MCN.

Two authors (V.P. and L.T.) independently took out data from studies and entered it in a specific extraction form. Disagreements were resolved by discussion; if a consensus was not reached, it was planned that a third author (L.M.) would decide. In case of discordant information reported in the same paper, the most conservative (i.e. less convenient for the experimental RMN group) was included in the review.

Quality assessment

Risk of bias was assessed by two independent reviewers (R.P. and V.P.) using the Cochrane Collaboration’s risk of bias tool. As this instrument was created for evaluating randomized controlled trials (RCTs), we slightly adapted it to NRS. As reported in the Cochrane Handbook, risk of bias assessment parameters for these trials are not well established. We decided to assess the risk of bias in the domains listed below, which could be classified as at ‘high’ or ‘low’ risk of bias or could be defined ‘unclear’, if the information reported in the paper was not enough for judging.

The domains included were:

(1) Study designs, i.e. if the study was retrospective or prospective, awarding a low risk of bias to prospective trials.
(2) Methods used for study cohorts’ selection, i.e. if participants were allocated consecutively to study groups or not. We meant ‘consecutively allocation’ the situation where the patients receiving AF ablation in a defined period were all treated with RMN or MCN procedures, and we considered it at low risk of bias. On the contrary, in ‘non-consecutively allocation’ the patients receiving AF ablation in a defined period could have been treated either with RMN or MCN but allocation criteria to the groups were not explicit; this system was defined at high risk of bias.
(3) Control of known confounding factors at baseline, i.e. if compared groups were similar at the beginning of the study, considering at low risk of bias the trials that performed this control.
(4) Blinding of outcomes’ assessors, evaluating at low-risk blinded studies.
(5) Attrition (incomplete outcome data): percentages of losses to follow-up in the trial and if methods were applied for dealing with attrition.

Two investigators (L.T. and V.P.) trained in using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) method assessed each outcome for the confidence in the estimates of effect of the body of evidence (quality of evidence) and produced the draft evidence profiles accordingly. The completed evidence summary and GRADE assessment were discussed and reviewed by a third author (L.M.). In GRADE approach factors that affect negatively the confidence in the estimate of effect include risk of bias, imprecision, indirectness (directness includes generalizability and applicability), inconsistency of results (heterogeneity), publication bias, dose—effect responses, magnitude of effect, and issues of residual plausible confounding. The confidence in the estimate of effect is categorized into four levels, ranging from very low to high.

Summary measures

Odds ratio (OR) was the primary measure of treatment or side effect; 95% confidence intervals (CIs) for OR were calculated. Mean difference (MD) and its 95% CIs were used for continuous outcomes. We assumed that latent clinical heterogeneity was ubiquitous and expected to involve a majority of observational studies, with inherently more variability than RCTs; indeed, we combined the studies using the random-effects model described by DerSimian and Laird. For the meta-analysis of peri-procedural complications, we used fixed-effect Peto OR, giving to the low incidence of the outcome. Heterogeneity was assessed by Q (χ²) and I² statistics. The I² statistic indicated...
RMN with open-irrigated catheter vs. manual navigation for AF ablation

the percentage variability due to between-study (or inter-study) variability, as opposed to within-study (or intra-study) variability. An \( I^2 \) value > 50% was classified as a substantial presence of heterogeneity.\(^\text{11}\) All analyses were performed with the RevMan software.

**Results**

**Study selection**

Our literature search identified 122 references. Exclusion of duplicates and irrelevant references left 100 records. Of these, 82 studies were discarded because after reviewing the abstracts it appeared that these papers clearly did not meet the eligibility criteria. The full text of the remaining 18 citations was examined in detail. It appeared that 11 studies did not meet the inclusion criteria: 8 studies considered different interventions\(^\text{12–19}\) and 3 did not demonstrate to have a control group.\(^\text{20–22}\) Finally, seven trials were included (Figure 1).\(^\text{23–29}\)

**Study characteristics**

We included six published NRS\(^\text{23–28}\) and one RCT, available only as abstract presentation.\(^\text{29}\) Main features of the seven trials are summarized in Table 1. Overall, 941 participants were considered, with the number of participants ranging from 64 to 356. Two NRSs were published in 2010\(^\text{16,28}\) and four in 2011,\(^\text{24,25,27,28}\) while the RCT\(^\text{29}\) was available only as meeting abstract. Clinical follow-up length varied from 3 to 12 months. Follow-up intensities differed among studies.

**Risk of bias within studies**

Risk of bias evaluation is reported in Figure 2. Many items were judged as unclear (reported in yellow) because the paper of the studies did not report enough information for a proper evaluation. In most trials many dimension were at high risk of bias (red).

Table 2 is the GRADE evidence profile that summarizes the findings and the quality of the evidence available. All outcomes were graded at very low quality for the absence of criteria for evaluating the risk of bias indirectness or imprecision.

**Atrial fibrillation and atrial tachyarrhythmia recurrences rate (primary outcome)**

The proportion of patients with recurrences of AF or other atrial tachyarrhythmia was evaluated at the end of the follow-up periods in six trials, including 853 patients.\(^\text{23–26,28,29}\) The follow-up in the studies lasted from 3 to 12 months, and the trials were heterogeneous for the intensity and the follow-up methods. We excluded from the analysis of the outcome the study by Solheim et al.\(^\text{27}\) that reported it as an overall effect in the trial population and not separately for the two comparison groups. The recurrence rate of AF and atrial tachyarrhythmia was not statistically superior in RMN than MCN group (OR 1.18, 95% CI 0.85 to 1.65, \( P = 0.32\); Figure 3).

**Pulmonary vein isolation**

Six studies, including 854 patients, evaluated PVI success at the end of the procedure.\(^\text{23–28}\) Pulmonary vein isolation success rate was not statistically higher with RMN than MCN procedure (OR 0.41, 95% CI 0.11 to 1.47, \( P = 0.17\)). Substantial heterogeneity was present in the comparison (\( I^2 = 77\%\), \( P = 0.002\); Figure 4).

**Complications**

All the seven studies reported data on procedure complications, assessed in 941 participants.\(^\text{23–29}\) Major complications, including deaths, pulmonary vein stenosis, embolic events, and/or pericardial tamponade, were rare events and occurred in 7 of 349 patients in the RMN group (2.2%) and in 26 of 592 (4.7%) in the MCN group. The difference between the two groups was statistically significant (Peto OR 0.41, 95% CI 0.19 to 0.88, \( P = 0.02\), \( I^2 = 28\%\); Figure 5). If we only consider cardiac tamponades, the outcome is statistically lower in RMN group (2 events in 349 patients vs. 17 in 592; Peto OR 0.29, 95% CI 0.11 to 0.81). Only two events of TIA/stroke (one in each interventional group) were reported.

**Procedural data**

All the seven studies reported data about total procedural duration and fluoroscopy time.\(^\text{23–29}\) In RMN group, total procedure time was significantly longer (MD 60.91 min, 95% CI 31.17 to 90.01, \( P < 0.00001\)) while total fluoroscopy time was significantly reduced (MD –22.22 min, 95% CI –42.48 to –1.96, \( P = 0.03\)). A substantial heterogeneity was found for both outcomes (\( I^2 = 94\%\) and 99%, respectively). Data about radiofrequency current application duration were reported in 4 studies, including 678 patients:\(^\text{23,25,26,29}\) in RMN group the time was longer (MD 16.98 min, 95% CI 6.77 to 27.28, \( P = 0.001\); \( I^2 = 86\%\)). Only one study reported information about the need to switch to MCN during RMN procedure in 11% of cases, in order to achieve PVI.\(^\text{25}\)
Discussion

The evidence favouring or disfavouring RMN compared with manual navigation are mixed and come for low-quality trials. Our primary finding is that procedure for AF ablation performed with RMN and new open-irrigated catheter is not statistically superior to MCN procedure in achieving mid-term freedom from recurrent atrial tachyarrhythmia. The main advantages of RMN include a statistically significant reduction in the incidence of major complications (deaths, pulmonary vein stenosis, embolic events, or pericardial tamponades) and a decrease in the time of patient’s exposure to fluoroscopy. Considering that recent studies showed that repetition of ablation procedure is necessary in a high percentage of patients to obtain satisfying freedom from AF recurrence, the lower rate of complications and exposure to radiation could be interpreted as a relevant advantage. However, the duration of RMN procedure takes 1 h more on average, potentially impacting on workflow and service delivery.

It is important to remark the low quality of the trials included and the high heterogeneity inter-studies. Most of existing studies are small and not randomized, conducted with various kind of methodology for assessing the outcomes, and include heterogeneous population of patients with either paroxysmal or persistent AF. The follow-up varies from 3 to 12 months (with a median of 6) and differs for intensity schemes: as 6 months is a limited time to have atrial tachyarrhythmia recurrences manifesting, the lack of difference between RMN and MCN might be either due to the short period of observation or, in other words, the AF recurrence rates might be different but we were unable to observe it and could be driven by the spontaneous remission of the arrhythmia, or the data could be blended by the absence of comparability between follow-up evaluations. Also the assessment of electrical PVI varied among studies: some authors created a ‘virtual circular PV mapping catheter’ using specifically the Niobe system with a pre-defined magnetic vector, while others utilized a circumferential mapping catheter (Lasso, produced by Biosense-Webster). This might have an impact on our capacity to detect differences between groups. The quality of reporting in the studies did not allow us to evaluate if the type of ablation could impact the clinical or the electrical success of procedures, because not enough

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Country</th>
<th>Number of participants</th>
<th>Mean age (years)</th>
<th>Male (%)</th>
<th>Paroxysmal AF (%)</th>
<th>Previous AF ablation (%)</th>
<th>Follow-up length (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arya et al.</td>
<td>Published NRS</td>
<td>Germany</td>
<td>356</td>
<td>57.9 ± 10.9</td>
<td>66</td>
<td>69</td>
<td>35 (AF or flutter ablation)</td>
<td>6</td>
</tr>
<tr>
<td>Choi et al.</td>
<td>Published NRS</td>
<td>Korea</td>
<td>111</td>
<td>56 ± 11</td>
<td>76.3</td>
<td>67</td>
<td>Not reported</td>
<td>3</td>
</tr>
<tr>
<td>Luthje et al.</td>
<td>Published NRS</td>
<td>Germany</td>
<td>161</td>
<td>62 ± 10</td>
<td>50</td>
<td>33</td>
<td>22</td>
<td>12</td>
</tr>
<tr>
<td>Miyazaki et al.</td>
<td>Published NRS</td>
<td>France</td>
<td>74</td>
<td>58.5 (SD not reported)</td>
<td>80</td>
<td>100</td>
<td>Not reported</td>
<td>12</td>
</tr>
<tr>
<td>Natale and coworkers</td>
<td>Unpublished RCT (abstract)</td>
<td>USA</td>
<td>87</td>
<td>61 ± 11</td>
<td>61</td>
<td>61</td>
<td>Not reported</td>
<td>120 ± 34 days</td>
</tr>
<tr>
<td>Solheim et al.</td>
<td>Published NRS</td>
<td>Norway</td>
<td>88</td>
<td>58 ± 8</td>
<td>83</td>
<td>63</td>
<td>28</td>
<td>12</td>
</tr>
<tr>
<td>Sorgente et al.</td>
<td>Published NRS</td>
<td>Belgium</td>
<td>64</td>
<td>56 (SD not reported)</td>
<td>80</td>
<td>68.5</td>
<td>0</td>
<td>12</td>
</tr>
</tbody>
</table>

NRS, non-randomized study; RCT, randomized controlled trial; SD, standard deviation; AF, atrial fibrillation.

Figure 2 Risk of bias table. Red (−) = high risk of bias; yellow (?) = unknown risk of bias; green (+) = low risk of bias.
details are available for breaking down results according to AF type (paroxysmal or persistent) or ablation extension. Previous papers reported the inability to achieve PVI with solid tip catheters available for RMN technology, because a very high percentage of charring of the catheter tip was found, limiting the viability of the technology. In 2007 an open-irrigated magnetic catheter was put on the market. We approached this research field assuming that 5 years were a sufficient time span to cumulate evidence.

### Table 2. GRADE evidence profile for remote magnetic navigation (RMN) system with open-irrigated catheter compared with manual navigation control (MCN) for atrial fibrillation ablation

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>No of Participants (studies) Follow up (FU)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Relative effect (95% CI)</th>
<th>Anticipated absolute effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Risk with MCN navigation</td>
</tr>
<tr>
<td>Atrial tachyarrhythmia recurrence</td>
<td>853 (6 studies) FU 3-12 months</td>
<td>⊗⊗⊗⊗ VERY LOWb,c,e due to risk of bias, indirectness, imprecision</td>
<td>OR 1.18 (0.85 to 1.65)</td>
<td>30 per 100⁹</td>
</tr>
<tr>
<td>Pulmonary vein isolation</td>
<td>854 (6 studies) FU 3-12 months</td>
<td>⊗⊗⊗⊗ VERY LOWb,c,d,e due to risk of bias, indirectness, inconsistency, imprecision</td>
<td>OR 0.41 (0.11 to 1.47)</td>
<td>89 PVI per 100⁹</td>
</tr>
<tr>
<td>Major complications</td>
<td>941 (7 studies) FU 3-12 months</td>
<td>⊗⊗⊗⊗ VERY LOWb,d due to risk of bias, indirectness</td>
<td>OR 0.41 (0.19 to 0.88)</td>
<td>44 per 100⁹</td>
</tr>
</tbody>
</table>

CI, Confidence interval; OR, Odds ratio.
GRADE Working Group grades of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.
*Baseline risk is pooled from the event rates in the control groups of studies included in the meta-analysis.
*See risk of bias table.
Centers pioneering the use of RMN system might be scarcely representative of care provided in other centers.
Unexplained heterogeneity across studies.
*Wide Confidence Intervals.

**Figure 3** Remote magnetic navigation vs. MCN; outcome: atrial tachyarrhythmia recurrence.
sustaining technology dissemination, moving it from an early adoption perspective (i.e. research purpose) to a consolidated use (i.e. routine). As often happens for medical devices, we retrieved only a limited number of low-quality studies, all NRS. Although results from NRSs are generally accepted as basis for taking clinical decisions, they are inherently susceptible to bias, with retrospective ones at the lower rank in the hierarchy of evidence. Most of the NRSs included in our review were at high risk of bias, and only few of them had basic positive features, such as consecutive prospective recruitment and a defined follow-up of a minimum 6 months. If we had limited the review to NRS at low risk of bias, only one trial would have been included. Indeed, the findings revealed by our meta-analysis cannot be clearly distinguished from bias. Reaching definitive recommendations about the net benefit of RMN requires collaboration among cardiac electrophysiology centres to implement a RCT enrolling a high number of patients. Given the incidence of AF and the burden of the disease, this should be achievable. The exact number would depend on the type of design adopted. We recommend a superiority trial with at least two primary outcomes: atrial tachyarrhythmia recurrences and major complications rates.

Choosing a longer follow-up, the analysis of other clinically relevant outcomes, such as the frequency of strokes or other embolisms and the frequency of use of long-term anticoagulation could be even more significant. If a non-inferiority RCT is planned, we still recommend to use a superiority approach for major complications. The median follow-up of patients enrolled should be at least 1 year. Non-randomized studies could provide data about special populations and incidence of complications. However, these studies should be registered to reduce reporting and publication bias. When the clinical benefit in reducing problems related to the arrhythmias will be clear, advantages concerning the lower radiation exposition in using RMN AF catheter ablation should be taken into account. Promising results merge from our review, although characterized by a high statistical heterogeneity. In a hypothetical group of 1000 patients, the use of RMN instead of MCN would be expected to prevent \( \approx 27 \) complications (number needed to treat = 37) and would be expected to cumulatively prevent more than 367 h of fluoroscopy. Thus, the net benefit of RMN might be justified, particularly in young adult patients (e.g. 45–54 years old). This subpopulation is considerable in

---

**Table:**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>RMN Events</th>
<th>Total</th>
<th>MCN Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds ratio Peto fixed, 95% CI</th>
<th>Odds ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arya 2011</td>
<td>61</td>
<td>70</td>
<td>285</td>
<td>286</td>
<td>16.3%</td>
<td>0.02 [0.00, 0.19]</td>
<td></td>
</tr>
<tr>
<td>Choi MS 2011</td>
<td>34</td>
<td>41</td>
<td>63</td>
<td>70</td>
<td>23.4%</td>
<td>0.54 [0.17, 1.67]</td>
<td></td>
</tr>
<tr>
<td>Luthje 2011</td>
<td>96</td>
<td>107</td>
<td>47</td>
<td>54</td>
<td>24.3%</td>
<td>1.30 [0.47, 3.57]</td>
<td></td>
</tr>
<tr>
<td>Miyazaki 2010</td>
<td>26</td>
<td>30</td>
<td>44</td>
<td>44</td>
<td>11.4%</td>
<td>0.07 [0.00, 1.28]</td>
<td></td>
</tr>
<tr>
<td>Solheim 2011</td>
<td>10</td>
<td>23</td>
<td>22</td>
<td>65</td>
<td>24.6%</td>
<td>1.50 [0.57, 3.97]</td>
<td></td>
</tr>
<tr>
<td>Sorgente 2010</td>
<td>35</td>
<td>35</td>
<td>29</td>
<td>29</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>306</td>
<td>548</td>
<td>100.0%</td>
<td></td>
<td>0.41 [0.11, 1.47]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 4** Remote magnetic navigation and MCN; outcome: PVI.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>RMN Events</th>
<th>Total</th>
<th>MCN Events</th>
<th>Total</th>
<th>Weight</th>
<th>Peto odds ratio Peto fixed, 95% CI</th>
<th>Peto odds ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arya 2011</td>
<td>1</td>
<td>70</td>
<td>11</td>
<td>286</td>
<td>28.4%</td>
<td>0.48 [0.11, 2.03]</td>
<td></td>
</tr>
<tr>
<td>Choi MS 2011</td>
<td>0</td>
<td>41</td>
<td>9</td>
<td>70</td>
<td>30.0%</td>
<td>0.18 [0.04, 0.74]</td>
<td></td>
</tr>
<tr>
<td>Luthje 2011</td>
<td>5</td>
<td>107</td>
<td>1</td>
<td>54</td>
<td>20.0%</td>
<td>2.18 [0.39, 12.22]</td>
<td></td>
</tr>
<tr>
<td>Miyazaki 2010</td>
<td>0</td>
<td>30</td>
<td>1</td>
<td>44</td>
<td>3.7%</td>
<td>0.19 [0.00, 10.08]</td>
<td></td>
</tr>
<tr>
<td>Natale 2011</td>
<td>0</td>
<td>43</td>
<td>0</td>
<td>44</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solheim 2011</td>
<td>0</td>
<td>23</td>
<td>0</td>
<td>65</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sorgente 2010</td>
<td>1</td>
<td>35</td>
<td>4</td>
<td>29</td>
<td>17.9%</td>
<td>0.22 [0.04, 1.38]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>349</td>
<td>592</td>
<td>100.0%</td>
<td></td>
<td>0.41 [0.19, 0.88]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 5** Remote magnetic navigation vs. MCN; outcome: major complications.
terms of AF prevalence\textsuperscript{30} and at higher risk for malignancies if exposed to prolonged radiation.

Limitations

Systematic reviews of rapidly developing technology, particularly when focused on devices rather than a medical therapy, face a number of challenges.\textsuperscript{31} Similarly to the field of surgical interventions, the number of RCTs in electrophysiology is likely to be limited\textsuperscript{31} and NRSs comprise a large part of the data. A great limitation of our work is that the meta-analysis is the results of only NRSs. The choice to include NRSs has been made to complement the limited evidence available from RCTs. As reported above, NRSs are by definition more susceptible to distortions and, furthermore, studies comparing the efficacy of RMN vs. MNC in AF ablation included in our review are at high risk of bias. Moving from our results, the effect of RMN-guided procedures with the open-irrigated catheter in AF rates reduction and in PVI achievement is not statistically significant. We cannot exclude that in a properly designed RCT some of the dimensions that we explored turn on to be statistically significant or, on the contrary, the RMN technology definitively shows a lack of clinical efficacy.

Another limitation of our review is that the external validity of the results is uncertain. We observed large inter-study heterogeneity and, moreover, the published studies disproportionately reflect the experience of ‘pioneering’ centres, specialized in RMN-guided AF ablation that can achieve better success rates compared with standard ones. However, trials included in the review come from the experience of centres in a range of different countries and health-care systems: since avoided bias, the geographical variability could permit to be more confident in the external validity of the results.

Finally, as the trials included in the meta-analysis were conducted in patients with paroxysmal or persistent AF and subgroup analysis cannot be performed, the results cannot be applied in a particular clinical condition.

Conclusions

The net benefit and effectiveness of RMN-guided AF ablation with an open-irrigated catheter compared with manual navigation is not easy to predict and cannot be clearly distinguished from bias. Our results are limited by the existing trials which are small and not randomized, and heterogeneity prevents firm conclusions. RMN did not show to be superior to MNC in controlling AF recurrences after a period of follow-up of 6–12 months, but seems to be associated with fewer complications and a decreased radiation exposure. However, in order to obtain stronger evidence, it is necessary to devise a randomized study where the two procedures are evaluated following a rigorous pre-defined protocol.

Conflict of interest: none declared.

References


EP CASE EXPRESS

doi:10.1093/europace/eut037
Online publish-ahead-of-print 20 March 2013

Pacemaker lead-induced severe tricuspid valve stenosis: complete percutaneous extraction under extracorporeal life support

Romain Cassagneau, Peggy Jacon, and Pascal Defaye*

Arrhythmia Department, University Hospital, 38043 Grenoble, France

*Corresponding author. Tel: +33 476768888; fax: +33 476765623, Email: PDefaye@chu-grenoble.fr

A 55-year-old man developed heart failure due to severe lead-induced tricuspid valve stenosis, 16 years after implantation of a pacemaker. After undergoing percutaneous extraction of three leads under extracorporeal life support, he regained a normal functional status and tricuspid and right ventricular functions, without requiring surgical repair.

A 55-year-old, non-pacemaker-dependent man, who had undergone implantation of a DDD pacemaker in 1985, developed advanced heart failure and syncope requiring three hospitalizations 16 years later. On chest roentgenogram (Figure 1), the atrial lead looped across the tricuspid valve (TV), one right ventricular (RV) lead looped across the pulmonary valve, and a second RV lead was non-functional. Echocardiography and cardiac catheterization showed the presence of severe TV stenosis. An attempt was made to extract all leads transvenously in an operating suite with surgical back-up. However, a laser sheath could not be advanced across the superior vena cava, which was occluded by an old, calcified thrombus. Manual traction precipitated the development of cardio-circulatory collapse requiring extracorporeal life support, which was continued until extraction of the leads by femoral approach, 72 h later. The atrial lead was extracted with a 16F Needle’s Eye Snare® catheter, while the RV leads were extracted using a custom-made lasso. Over the following year, the patient’s clinical status improved markedly, and the mean tricuspid gradient and RV systolic function normalized.

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/pacemaker-lead-induced.pdf

Figure 1

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2013. For permissions please email: journals.permissions@oup.com.