Outcomes of repeat catheter ablation using magnetic navigation or conventional ablation

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Aims
After initial catheter ablation, repeat procedures could be necessary. This study evaluates the efficacy of the magnetic navigation system (MNS) in repeat catheter ablation as compared with manual conventional techniques (MANs).

Methods and results
The results of 163 repeat ablation procedures were analysed. Ablations were performed either using MNS (n = 84) or conventional manual ablation (n = 79). Procedures were divided into four groups based on the technique used during the initial and repeat ablation procedure: MAN–MAN (n = 66), MAN–MNS (n = 31), MNS–MNS (n = 53), and MNS–MAN (n = 13). Three subgroups were analysed: supraventricular tachycardias (SVTs, n = 68), atrial fibrillation (AF, n = 67), and ventricular tachycardias (VT, n = 28). Recurrences were assessed during 19 ± 11 months follow-up. Overall, repeat procedures using MNS were successful in 89.0% as compared with 96.2% in the MAN group (P = ns). The overall recurrence rate was significantly lower using MNS (25.0 vs. 41.4%, P = 0.045). Acute success and recurrence rates for the MAN–MAN, MAN–MNS, MNS–MNS, and MNS–MAN groups were comparable. For the SVT subgroup a higher acute success rate was achieved using MAN (87.9 vs. 100.0%, P = 0.049). The use of MNS for SVT is associated with longer procedure times (205 ± 82 vs. 172 ± 69 min, P = 0.040). For AF procedure and fluoroscopy times were longer (257 ± 72 vs. 185 ± 64, P = 0.001; 59.5 ± 19.3 vs. 41.1 ± 18.3 min, P < 0.001). Less fluoroscopy was used for MNS-guided VT procedures (22.8 ± 14.7 vs. 41.2 ± 10.9, P = 0.011).

Conclusion
Our data suggest that overall MNS is comparable with MAN in acute success after repeat catheter ablation. However, MNS is related to fewer recurrences as compared with MAN.

Keywords
Electrophysiology • Arrhythmia • Repeat • Catheter ablation • Remote magnetic navigation

Introduction
Nowadays, catheter ablation is a well-established technique that has an important role in the treatment of many arrhythmias. It has become the first-line therapy for arrhythmias such as atrioventricular nodal re-entrant tachycardia (AVNRT), circus movement tachycardia (CMT), and cavotricuspid isthmus (CTI)-dependent atrial flutter (AF).1 Furthermore, it is used as therapeutic option for the treatment of atrial fibrillation (AF), atrial tachycardia (AT), and ventricular tachycardia (VT).1 In the past years, the magnetic navigation system (MNS) has been evaluated for treatment of different arrhythmias.2–4

Studies showed that the design of MNS has some advantages such as an atraumatic catheter design that allows safe catheter ablation, a reduced amount of radiation exposure to both the patient and physician, unrestricted and reproducible catheter manoeuvrability, and improved catheter stability.5,6 However, MNS is related to longer procedure times in some cases and may result in more expensive procedures.7 Several studies demonstrated that MNS offers at least equally effective catheter ablation and for particular arrhythmias (e.g. non-structural VT) even improved outcomes as compared with manual ablation.2,8,9 All performed studies evaluated the acute or long-term success and no data are available on the effectiveness of MNS in repeat catheter ablation specifically.

The objective of this study was to evaluate the efficacy of MNS in repeat catheter ablation for different arrhythmias as compared with conventional ablation techniques in a large series of patients.
What’s new

- Previous studies address the use of the magnetic navigation system (MNS) for initial ablation procedures.
- This is the first study that investigated the use of the MNS for repeat ablation procedures.
- The use of the MNS offers comparable acute results as conventional methods.
- For repeat atrial fibrillation procedures MNS is associated with an increased fluoroscopy use.
- For repeat ventricular tachycardia procedures less fluoroscopy was required using MNS.
- For both SVT and AF ablations MNS resulted in more time-consuming procedures.

Because of the prior described advantages of MNS our primary hypothesis was that MNS would lead to higher success rates after prior unsuccessful ablation procedures.

Methods

Patients

A total of 163 repeat catheter ablation procedures were included in this study. The median age of the study population was 55.0 years [interquartile range (IQR), 42.0–65.0 years] and 64% was male. Sixty-seven patients had ablation for AF, 16 for AT, 18 for CTI-dependent AFI, 15 for AVNRT, 18 for CMT, 28 for VT, and 1 for atiroventricular junction (AVJ) ablation. These arrhythmias were combined in three subgroups: supraventricular tachycardias (SVTs, n = 68), AF (n = 67), or VTs (n = 28). Three types of AF were classified according to the ESC 2010 guidelines:1 paroxysmal (self-terminating AF within 7 days), persistent (AF lasts longer than 7 days or required termination by cardioversion), and long-standing persistent (AF being persistent for 12 months or longer). In the AF subgroup 48 patients suffered from paroxysmal AF, 15 patients had persistent AF, and 4 patients had long-standing persistent AF (Table 1).

The mean left atrium (LA) size of AF patients was comparable for MNS and manual conventional technique (MAN) patients (43.1 ± 6.4 vs. 44.9 ± 6.4 mm, P = 0.282). Ablation was performed either using MNS (84 patients) or conventional manual techniques (group MAN, 79 patients). Only patients who underwent repeat catheter ablation for the identical arrhythmia as targeted in the initial procedure were included in this study. Data of patients with either an unsuccessful initial procedure or recurrence after an initially successful ablation were analysed. Investigators were not involved in the decision as to whether a patient was scheduled in the MNS-equipped laboratory or MAN-equipped laboratory. Patient age, gender, and number of SVT, AF, and VT were equally distributed between the two groups (Table 1). The ablation procedures were performed by the same group of electrophysiologists experienced with both manual and MNS techniques.

Electrophysiology studies—ablation strategy

Written informed consent for the ablation procedure was obtained from all patients. Resting 12-lead electrocardiogram, and laboratory tests, a chest X-ray image and a two-dimensional echocardiography were acquired from all patients within the month prior to and 48 h following the procedure. A transoesophageal echocardiogram was performed if considered necessary. Standard peri-procedural medication protocols were followed in all patients. For AVNRT, AT, CMT, and elective VT patients were instructed to stop taking antiarrhythmic drugs for a period of at least four half-lives prior undergoing the procedure. In cases of AF, AVJ ablation, and emergency VT ablation medication remained unchanged. The procedures were performed during a fasting state, using local or general anaesthesia.

The left heart could be accessed via the retrograde aortic route or trans-septal puncture (TSP) based on the operator’s preference. Generally, left-sided ventricular arrhythmias were performed via the retrograde approach (MNS 100%, MAN 75%; P = ns), left-sided atrial arrhythmias always via TSP, and left-sided accessory pathways distributed between the two methods (MNS 14% TSP, group MAN 67% TSP; P = ns). Intracardiac echocardiography was used to guide TSPs in both groups.

The endpoints of procedural success were defined as the elimination of accessory pathway conduction for CMT, the elimination of inducibility and no more than single echo beats for AVNRT, complete AV block for AVJ ablation, and bidirectional isthmus block for CTI-dependent AFI. The endpoint for paroxysmal and persistent AF was complete electrical pulmonary vein isolation (PVI) and, if necessary, additional linear lesions to achieve sinus rhythm. For long-standing persistent AF, first all PVs were isolated, linear lines were created (first roof line, then mitral line, and lastly posteroinferior line), and electrogram-based ablation in the LA and coronary sinus was performed. After restoration of sinus rhythm bidirectional block was assessed at every line using differential pacing methods. Atrioventricular node ablation was not part of this protocol. Additional linear ablation was performed in 19 patients and was higher for the MNS group than the MAN group (39.4 vs. 17.6%, P = 0.044). For VT patients, if the VT was inducible, non-inducibility of the clinical VT was the endpoint, if only ventricular extrasystoles (VESs) were present, then the complete abolishment of VESs assessed by 24 h telemetry counted as acute success.
Magnetic navigation system-guided ablations

Magnetic-guided ablation procedures were performed using the Stereotaxis Niobe Magnetic Navigation System (Stereotaxis, Inc.) in an electrophysiology (EP) lab equipped with a Siemens Axiom Artis (Siemens) fluoroscopy system. The principles and use of the MNS has previously been described. The Niobe II MNS consists of two permanent magnets situated on both sides of the patient. The system uses a computer-controlled workstation (Navigant, Stereotaxis, Inc.) to allow changes of the magnetic field orientation in order to navigate the ablation catheter. Combined field strength of 0.08 or 0.1 T was used. During the procedures the following ablation catheters were used: for AVNRT, AVJ, and CMT the Celsius RMT (4 mm) (Biosense Webster); for AF the Navistar RMT ThermoCool (Biosense Webster); and for AT and VT the Navistar RMT DS (8 mm) or NaviStar RMT ThermoCool (Biosense Webster). However, after the thermoden catheter became available the 8 mm tip catheter was no longer used because of char formation. Electroanatomical mapping was performed using the CARTO RMT (Biosense Webster, Inc.) system.

Manual-guided ablations

Procedures in the manual group were performed in an EP lab equipped with a Siemens Megalix (Siemens) fluoroscopy system. Electroanatomical mapping was performed using CARTO (Biosense Webster) or the EnSite NavX system (St Jude Medical, Inc.). The following ablation catheters were used: for AVNRT, AVJ, and CMT the Celsius RMT B–D curve 4 or 8 mm tip (Biosense Webster); for AF, AT, and VT the Biosense Webster Navistar ThermoCool (Biosense Webster). The Arctic Front cryoballoon catheters (Medtronic Inc.) were used for cryo-isolation of the PVs; Freezor Max (Medtronic Inc.) catheters were used in cases when complete electrical isolation could not be achieved with the balloon. For recurrent AVNRT a Cryocath 4 or 6 mm catheter was used as well when it was judged that cryoenergy was the appropriate choice. Ablation parameters were excluded from analysis, if the repeat procedure was performed using cryoenergy.

Crossovers

Crossover from the magnetic navigation catheter to manual navigation catheter was allowed if preferred by the operator. Any crossover was counted as an acute failure for the MNS group. However, no crossover occurred during this study and therefore it was not taken into account in the analysis.

Data collection and analysis

Procedures were divided into four groups based on the technique used during the initial and repeat ablation procedure: MAN–MAN (n = 66), MAN–MNS (n = 31), MNS–MNS (n = 53), and MNS–MAN (n = 13). Direct post-procedural success rates were analysed and subgroup analysis was performed for the subgroups SVT, AF, and VT. Acute success was assessed according to the criteria described before. Procedural parameters such as total application, fluoroscopy and procedure time, and the number of radiofrequency (RF) applications were analysed as well. Procedure time was defined as the time between the first subcutaneous injection application of lidocaine to the groin and the removal of all catheters from the patient’s body. A waiting time of 30 min was included.

Follow-up

During a follow-up period of 19 ± 11 months recurrence rates were assessed between the overall group and the subgroups. Follow-up visits were scheduled for all patients at the outpatient clinic of the Department of Cardiology, Erasmus MC, starting at 3 months after the procedure, and every 3 months thereafter, except for CMT, AF, and AVNRT patients, when other than the first follow-up, visits were scheduled only if the symptoms recurred.

Statistics

Normality of distribution was determined by using the Kolmogorov–Smirnov test. Continuous variables were expressed as mean ± SD, if normally distributed, and compared with the Student’s t-test for independent samples. In case of non-normal distribution of data, medians and IQRs were reported and the Mann–Whitney U test was used for data comparison. Categorical data were expressed as percentages and compared with the χ² test or Fisher’s exact test when appropriate. Event-free survival rates were determined using the Kaplan–Meier method and differences were evaluated by the log-rank test. Statistical analysis was performed using SPSS 15.0 (SPSS Inc.). Statistical significance was defined as P < 0.05 (two-tailed).

Results

Overall

Repeat procedure using magnetic navigation system

When a repeat procedure was performed using MNS, independent of the approach used during the previous procedure, similar success rates were achieved as compared with MAN (89.0 vs. 96.2%, P = 0.078; Figure 1). However, when a procedure was successful, significantly fewer recurrences were experienced in the MNS group (25.0 vs. 41.4%, P = 0.045; Figure 2). During these procedures the median number of RF applications was higher when using MNS compared with MAN [19, IQR (6–58) vs. 6.5, IQR (3–21), P = 0.002]. No differences were observed for application time [720 s, IQR (245–1710 s) vs. 581 s, IQR (113–1201 s), P = 0.116], fluoroscopy time (37.4 ± 26.3 vs. 36.6 ± 17.5 min, P = 0.859), and total procedure time (199 ± 87 vs. 164 ± 61 min, P = 0.063). Figures 3 and 4 represent the freedom of recurrence for the overall groups of MNS and MAN and the four subgroups, respectively. After analysing the survival curves no significant difference was reached between the groups.

Figure 1 Overall acute success rates and after initial MAN or MNS ablation procedures.
After initial manual conventional technique procedure
For the two groups that included patients who had a prior manual ablation there was no difference in acute success depending on the use of MNS or MAN during the repeat procedure (93.3 vs. 98.5%, \( P = 0.229 \)). Recurrence rate was comparable as well between MAN–MNS and MAN–MAN (26.1 vs. 44.0%, \( P = 0.114 \)). When a patient experienced any recurrence, the time until this event was comparable for the two groups (3.9 + 3.2 vs. 3.0 + 2.5 months, \( P = 0.411 \)). Using MNS for the repeat procedure is associated with a higher number of RF applications [41, IQR (9–68) vs. 5.5, IQR (3–21), \( P = 0.001 \)] and more use of fluoroscopy (49.6 ± 24.8 vs. 36.3 ± 18.3 min, \( P = 0.007 \)). When the use of fluoroscopy was corrected for the type of arrhythmia this difference could be explained by a significantly lower fluoroscopy use during MAN ablation in AF (40.0 ± 16.6 vs. 61.3 ± 16.8 min, \( P < 0.001 \)). Other arrhythmias did not contribute to this difference. Total RF application time (1575 ± 1563 vs. 801 ± 853 s, \( P = 0.052 \)) and procedure time (219 ± 102 vs. 174 ± 68 min, \( P = 0.057 \)) was not statistically different between MNS and MAN.

After initial magnetic navigation system procedure
If a patient underwent a prior MNS procedure there was no difference in acute success if the repeat procedure was executed using MNS or MAN (86.5 vs. 83.3%, \( P = 0.539 \)). No difference was observed in recurrence rate (26.3 vs. 14.3% , \( P = 0.445 \)) and the time until recurrence (3.9 ± 4.3 vs. 0.3 ± 0.6 months, \( P = 0.185 \)). When procedural parameters were compared between the MNS–MNS and MNS–MAN group there was no statistical difference in total number of RF applications [17, IQR (5–41) vs. 9.4, IQR (1–23), \( P = 0.215 \)], total RF application time (942 ± 946 vs. 622 ± 684 s, \( P = 0.512 \)), fluoroscopy time (32.4 ± 25.1 vs. 40.7 ± 24.5 min, \( P = 0.444 \)), and procedure time (194 ± 79 vs. 160 ± 76 min, \( P = 0.417 \)).

Supraventricular tachycardia
In the subgroup with patients suffering from SVT, a lower acute success was observed using MNS compared with MAN (87.9 vs. 100.0%, \( P = 0.049 \); Figure 5). The recurrence rate for this subgroup was comparable for MNS and MAN (17.2 vs. 31.4%, \( P = 0.155 \); Figure 6). In the SVT subgroup, repeat ablation procedures using MNS were associated with comparable numbers of total RF applications (15.1 ± 18.9 vs. 10.3 ± 10.5, \( P = 0.251 \)) and longer procedure time (205 ± 82 vs. 172 ± 69 min, \( P = 0.040 \)). No difference was observed for total RF application time [317 s, IQR
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Figure 5 Acute success rates for SVT, AF, and VT. The asterisk indicates P < 0.05.

Figure 6 Recurrence rates for SVT, AF, and VT.

(195–740 s) vs. 537 s, IQR (143–976 s), P = 0.670] and fluoroscopy time (42.4 ± 27.1 vs. 36.7 ± 19.7 min, P = 0.206).

**Atrial fibrillation**

In patients with AF, MNS achieved comparable acute success rates as MAN (90.9 vs. 100%, P = 0.114) with equal recurrence rates (26.7 vs. 32.4%, P = 0.413). For patients who underwent PVI alone, success rates were comparable for MNS and MAN patients (95.0 vs. 100.0%, P = 0.417). The time until recurrence was comparable for both groups (5.1 ± 4.2 vs. 3.0 ± 2.5 months, P = 0.177). When procedural parameters were analysed MNS was associated with longer fluoroscopy times (59.5 ± 19.3 vs. 41.1 ± 18.3 min, P < 0.001) and longer procedures (257 ± 72 vs. 185 ± 64 min, P = 0.001).

**Ventricular tachycardia**

Patients who were classified in the VT subgroup had comparable rates for acute success and recurrence when compared between MNS and MAN (87.5 vs. 66.7%, P = 0.230; 16.7 vs. 40.0%, P = 0.330, respectively). There was no difference between MNS and MAN for the median number of RF applications (13.0 vs. 9.0, P = 0.392), total RF application time [481 s, IQR (214–990 s) vs. 270 s, IQR (51–1200 s), P = 0.495], and procedure time (181 ± 100 vs. 190 ± 62 min, P = 0.891). During these procedures, MNS was associated with decreased fluoroscopy use (22.8 ± 14.7 vs. 41.2 ± 10.8 min, P = 0.011).

**Discussion**

This is the first study that reports on the effectiveness of MNS for repeat catheter ablation. For the efficacy during initial ablation procedures the MNS has been well investigated.\(^{17–19}\) However, since this system is so well implemented into modern electrophysiology, understanding of the usefulness for repeat catheter ablation is very important for clinical practice. Our data suggests that the use of MNS offers comparable success rates after repeat catheter ablation as MAN for the overall study population. In this group, MNS results in fewer recurrences after long-term follow-up. Furthermore, after subgroup analysis MNS leads to similar acute and long-term success as manual ablation, independent of what technique has been used during the initial procedure. For the ablation of recurrent SVT’s, MNS procedures resulted in a lower acute success than manual-guided procedures.

As a result of the improved catheter manoeuvrability and stability using MNS, our hypothesis was that MNS would lead to higher success rates after prior unsuccessful ablation procedures. Based on the findings of this study our conclusion is that MNS does not increase efficacy for repeat catheter ablation. Future improvements of this system could enhance the efficacy of the system by implementing a force-sensing catheter that is currently not available. This might lead to more effective ablation procedures by providing feedback regarding lesion formation. However, when the MNS procedures were successful the effect sustained over time and this is reflected in the decreased recurrence rate in the overall population.

The findings of our study demonstrate that MNS is associated with lower acute success in treatment of recurrent SVT. However, in the MNS group a significant higher percentage of the patients had ATs and the MAN group included more AVNRTs. The difference in complexity in the ablation of these arrhythmias could have influenced the acute success rate. Subgroup analyses on AT or AVNRT specifically would lead to too small groups that have very less value for clinical practice.

**Clinical implications**

The outcomes of this study have important clinical implications for the use of MNS in repeat catheter ablation. Since the acute outcomes of MNS are comparable with MAN the question rises if the magnetic system has advantages for use during repeat procedures. In some particular situations the special capabilities of the MNS could be beneficial during the ablation procedure. For example, when the site of origin is very difficult to approach or could not be reached at all using manual ablation catheters (e.g. right inferior PV) the superior manoeuvrability of the magnetic catheter could allow navigation to this specific site. Other groups have published these advantages of the MNS in tip delivery as well.\(^{14,15}\) However, for repeat catheter ablation in a large series of a mixed patient population this advantage could not be demonstrated. Therefore, more research is required to evaluate the true value of MNS in repeat procedures for complex atrial arrhythmias.
Certainly more purposes of the MNS could be mentioned for repeat catheter ablation despite the similar acute outcome. Many reports have demonstrated the improved safety using MNS. For complex situations or an unknown cardiac anatomy in congenital heart disease patients the atrumatic catheter design could be valuable. In addition, the use of fluoroscopy could be important to decide whether to choose MNS or MAN for repeat procedures. In children with an unsuccessful procedure that requires a repeat procedure fluoroscopy could be an important concern and the cumulative radiation dose should be reduced as much as possible. Therefore, the decreased total fluoroscopy time could be determinate to use the magnetic approach in children with VT.

Limitations
In this study, no randomization was performed for direct comparison of magnetic and manual catheter ablation therapy. We used our prospective registry for the evaluation of the acute and long-term outcomes of repeat ablation procedures. Our data demonstrate the use of MNS in this specific patient population, but randomized trials are required to evaluate the true value of the magnetic system.

Today, enhanced MNSs are available (EPOCH, Stereotaxis) that might allow faster and more effective catheter ablation. Furthermore, for this study no deflectable sheath was used during MNS procedures, which might have influenced procedural success. Novel developments on the field of remote magnetic navigation and the use of steerable sheaths could lead to improved outcomes of catheter ablation. However, further clinical evaluation is necessary to reveal the true value of this system. Furthermore, a higher percentage of AT and fewer AVNRT were included in the MNS group as compared with MAN. This mix of different arrhythmia complexity could have influenced the acute success and recurrence rates. Since subgroup analyses for AT and AVNRT in this study would not lead to valuable clinical recommendations, more research is necessary in this field of arrhythmias.

Conclusion
Our data suggest that the use of MNS leads to similar acute and long-term success as manual ablation, independent of what technique has been used during the initial procedure. Overall, MNS is comparable with MAN in acute success of repeat catheter ablation and may reduce recurrences on the long term. Therefore, it may be considered as an alternative technique although it has the potential to prolong procedure times.

Conflict of interest: T.S.T. is a consultant of Stereotaxis, Inc., St Louis, MO, USA.

References