®JAFIB

Featured Review

Journal of Atrial Fibrillation

www. jafib.com

Atrial Fibrillation Ablation Using Magnetic Navigation Comparison With Conventional Approach During Long-Term Follow-Up

Tolga AKSU, MD[1], Serdar BOZYEL, MD[1], Ebru GOLCUK, MD[1], Kývanc YALIN, MD[2], Tumer Erdem Guler, MD[1]

[1]Kocaeli Derince Education and Research Hospital, Department of Cardiology, Kocaeli/Turkey. [2]Kolan Hospital, Department of Cardiology, Istanbul, Turkey.

Abstract

Atrial fibrillation (AF) ablation targeting the circumferential isolation of pulmonary veins (PVI) is an established therapeutic alternative in symptomatic AF patients resistant to anti-arrhythmic medications. The procedure is technically challenging and multiple difficulties must be overcome in order to achieve a successful outcome. The magnetic navigation system (MNS) is a remote catheter control technology which has advantages such as a traumatic catheter design improving the procedural safety, a reduced amount of radiation exposure to both the patient and physician, unrestricted and reproducible catheter maneuverability that allows the access to difficult anatomical situations, and an improved catheter stability leading to better energy delivery. Due to these advantages, MNS is increasingly being used for AF ablation and both acute and chronic success rates are comparable with the conventional technique. The new developments in navigation systems, catheters and new three-dimensional mapping systems are very promising to obviate these concerns. However, MNS is related to longer radiofrequency (RF) application duration and procedure time.

Introduction

AF is a major cardiovascular challenge in modern society and its medical, social and economic aspects are all set to worsen over the coming decades. It is associated with a five-fold risk of stroke and a three-fold incidence of congestive heart failure, and higher mortality. Hospitalization of patients with AF is also very common.

RF catheter ablation is an established therapeutic alternative in symptomatic AF patients, resistant to anti-arrhythmic medications, as it has been proved more effective than antiarrhythmic drug therapy in maintaining sinus rhythm.[1] The procedure is technically challenging and the operators must be experienced, especially in manipulating catheters in difficult clinical situations, which may lead to long, tiring and potentially risky procedures. It requires catheter maneuverability to access target regions and catheter stability in difficult anatomical regions and reproducibility of the catheter location.[2]

Key Words:

Atrial Fibrillation, Ablation, Magnetic Navigation.

Disclosures:

None.

Corresponding Author:

Dr.Tolga AKSU, MD

Kocaeli Derince Education and Research Hospital,

Department of Cardiology,

Kocaeli/Turkey.

A major limitation of conventional method is caused by the manual catheters that are limited in their freedom of movement by their predefined curve. In certain anatomic situations, this will make maneuvering within the heart extremely difficult, and anatomic regions of interest cannot be reached at all. In addition, manipulation of a stiff manual catheter can have a high risk of complications. When moving the catheter, high contact force (CF) is often applied and can be at risk of perforating the atrial wall.[3] Operators are not always able to make an adequate estimation on the CF, which is applied during ablation with manual method, thus causing different forces to be applied between target areas in the PVs and left atrium (LA). Since good CF is related to effective ablation lesions, lower forces will result in fewer transmural lesions.[4] These inadequate ablation lines will be predominant sites of reconduction or occurrence of new macro-reentrant arrhythmias.[5] Length of the procedure (at times more than 4 hours) may lead to a loss of concentration. This decreased concentration that is associated with large amount of fluoroscopy exposure for both operator and patient, along with complication rates has always been a concern.

MNS was introduced to limit some of the drawbacks of manual catheter navigation during ablation of AF and improve the safety and efficacy of the procedures.MNS (Niobe ES, Stereotaxis Inc., MO, USA) is a remote catheter control technology that has several advantages such as fine controlling 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 to prevent complications and improve lesion formation. This system has been used for 10 years and widespread using for AF ablation began in 2008 with the availability of irrigated magnetic catheters. Data consistently show that MNS using either non-irrigated or irrigated catheters results in remarkably low complication rates, along with satisfying short and mid-term success rates.[6-9]

On the other hand, there are some limitations related to the MNS as compared with conventional catheter ablation. It needs longer time to set up. The operator must commute frequently between the remote control room and operation room to change the circular mapping catheter position when it is unstable and the sheath position to facilitate accessing the target with the magnetic catheter. These processes would lead to longer total procedural duration. The limited CF may limit the lesion size, which might lead to more-frequent PV reconnection after PVI. The necessities of the expensive hardware, specially designed ablation catheters and a second long sheath for the ablation catheter lead to a higher procedural cost. Observation and evaluation of the patient's state are relatively difficult since the operator stays in the remote room. During conventional ablation procedure, the operator can estimate the force of the tissue contact by the tactile feedback during catheter manipulation. In contrast, no tactile feedback of the catheter tip contacting the atrial wall can be perceived by the operator using it. Besides, manipulating the magnetic ablation catheter may be slower as compared with manually controlled catheters resulting in longer procedure times.[10]

As expected for a new developing technology, there are major differences in magnetic navigation systems, catheters and sheaths, a new three-dimensional mapping system and these advancements have improved the procedure related outcomes. We conducted a systematic review of the available published literature on the effectiveness and safety of AF ablation using magnetic navigation comparison with conventional approach during long-term follow-up.

MNS With Open-Irrigated Catheter

It has been demonstrated that the use of a solid-tip (non-irrigated) magnetic catheter for AF ablation resulted in thrombus formation leading embolic events due to char formation at the catheter tip. In addition, AF ablation has been limited by the inability to achieve efficacious ablative lesions with these catheters.[6,7] The report by Di Biase et al clarified that electric PVI was not completed in most of the PVs when using the non-irrigated tip 4-mm CARTO RMT catheter and needed additional manual ablation even with high RF delivery settings (55°C with a maximum power of 50 W). Furthermore, the charring of the catheter tip was observed in 33% of the patients.[6] Since 2008, a first generation open-irrigated magnetic catheter (ThermoCool RMT; Biosense Webster) has been utilized, improving catheter efficacy and safety. Miyazaki et al evaluated the feasibility and efficacy of irrigated tip ablation catheter and no tip charring and related embolic events reported during Lasso-guided electric PVI using MNS, which stands as a substantial improvement in non-irrigated catheter.[10]

The first-generation open-irrigated magnetic catheter was revised and a study was undertaken by Chun et al by comparing the first-generation irrigated magnetic catheter with a second-generation irrigated catheter. Modifications included increasing the internal luminal diameter to improve uniformity of flow of irrigation fluid, adjusting the irrigation port location, and reducing internal clearances to maximize thermal conductivity, whereas inter-electrode spacing and RF settings were identical to the original catheter. The initial ablation success rate was 93% in the second-generation catheter group. During global follow-up, 70% of patients were in sinus rhythm and no complications were observed with the second-generation catheter. In addition, no 'char' formation was detected in this group of patients. Although first-generation irrigated MNS catheters improved catheter performance, two thromboembolic events associated with catheter tip char formation occurred.[11] A recent meta-analysis of six non-randomized and one randomized clinical trials including 349 patients reported the outcomes of AF ablation with MNS when using open-irrigated catheter. Major complications, including deaths, PV stenosis, embolic events, and/or pericardial tamponade, were rare events and occurred in 7 patients (2.2%) and only one thromboembolic event was reported.[12]

Remote Magnetic Catheter And Sheath Manipulation Systems

Circumferential continuous ablation lines aim to electrically disconnect the PV antrum from the body of the LA and are considered the cornerstone of the ablation procedure. A concrete ablation line necessitates lesion continuity and transmurality.MNS was lacking efficacy in creating continuous linear ablation lesions outside the PVs due to reduced maximal force applied, making patients more prone to AF recurrence. Maximal CF provided by magnetic catheters was inferior to that obtained with conventional catheters in experimental studies (26.8 vs. 45.4 g).[10] CF in magnetic catheters is limited by the maximum force resulting from the interaction of the magnetic fields of the catheter and the external magnets. Also, the flexibility of the magnetic catheter shaft results in deterioration of the maximal force applied to the tissue. When a circular mapping catheter is used in the PVs, the operator needs to leave the control room in order to manually manipulate this mapping catheter. Although some groups perform catheter ablation of AF without the use of a circular mapping catheter, it can be used to evaluate complete PVI at the end of the ablation procedure. Given that manipulation of the catheter needs to be performed several times, it could be more time consuming than during a manual ablation procedure.

The mentioned disadvantages concern the catheter-only advancement system (CAS) with a fixed curve sheath. Since 2012, the Vdrive system (Stereotaxis Inc.) has been introduced that it allows the physicians to maneuver both a magnetic ablation catheter as well as an otherwise manual circular mapping catheter (V-Loop, Stereotaxis) remotely from a radiation shielded control room.[13] The catheter can be advanced, retracted, rotated and deflected. The loop size of the circular mapping catheter can be modified as well. The Vdrive can be used for navigation between PVs, mapping of the chambers and identifying gaps with segmental isolation. Nölker et al reported that the first human clinical experience of Vdrive system in 94 patients demonstrated that the use of this system is feasible and safe for the ablation of atrial arrhythmias. 100% of the patients achieved the clinical end point of complete PVI and there were no adverse events related to the use of the system. Only three patients (3.2%) required crossover due to deeper placement of the sheath not allowing to reach to the vein, a suboptimal initial setup of the Vdrive and impossibility for counter-clockwise rotation due to safety limits of the system.[13]

MNS can be demanding in some cases, especially on the subject of the right inferior PV, because of anatomical complexities and the relationship of the ostium of the right inferior PV to the insertion of the transseptal sheath to the LA.[10] Mapping on the right side of the LA was proved more complex and caused prolongation of ablation and procedure times. It is considered that for the mapping and ablation especially of the right inferior PV, the proximal ablation catheter magnets may remain withdrawn inside the transseptal sheath even if the latter is kept back into the right atrium.[11] To overcome this difficulty, Choi et al. retracted the sheath in the lower inferior vena cava after a more anterior transseptal puncture in manual catheter navigation patients in an effort to ease accessibility to the anterior-septal parts of the LA and the right PVs.[14]

Steerable sheath technology has emerged as a measure to optimize catheter-tissue contact and improve catheter guidance into all cardiac structures. The use of this technology has been reported to increase catheter stability, tissue contact, and improve ablation outcome. Piorkowski et al. demonstrated that steerable sheath technology has a significant impact on clinical outcome after AF ablation, without compromises regarding safety. In particular, they reported on a significantly higher single procedure success in patients ablated with a steerable sheath (76% vs. 53% in those ablated with a non-steerable sheath after 6 months follow-up). After stepwise multivariable logistic regression analysis, only steerable sheath utilization emerged as independent predictor of treatment success, providing more sufficient and stable catheter-to-tissue contact in all ablation target sites, the latter leading to the formation of broader and deeper tissue lesions.[15]

The latest generation of MNS system can be coupled with a new advancement system that fully controls both the catheter and a robotic deflectable sheath. The V-CAS deflect system (Stereotaxis Inc.) is a remote navigation platform that consists of a robotic drive unit, a remote controller, and a catheter-specific disposable set that interfaces the drive unit with both the robotic sheath and the magnetic catheter. The operator controls both deflectable sheath and catheter motion by manipulating the remote controller. The drive unit then transmits these commands directly to the catheter handle. Operations governed by the remote controller include advancement, retraction, rotation, deflection, looping, and unlooping movements. The first experience on remotely controlled steerable sheath coupled with magnetic navigation in the setting of AF ablation was reported by Errahmouni et al. They reported that V-CAS deflect fastens right pulmonary vein isolation with significant reduction of the procedure duration and radiofrequency delivery time compared to standard magnetic navigation (catheter-only advancement).They used the sheath to provide an anchoring point for the magnetic catheter inside the LA, in a region opposite to the ablation target site. Thus, a longer length of the magnetic catheter is available for alignment with the magnetic field, improving navigation and tissue contact.[16]

Efficacy Of The Magnetic Navigation Systems

The several studies have demonstrated equal clinical efficacy of AF ablation procedure performed with MNS when compared with conventional method. Shurrab et al in their meta-analysis of 1647 patients in fifteen studies demonstrated that MNS has similar rates of success outcomes when compared to manual catheter ablation for AF. In comparison between MNS and conventional groups, a tendency towards higher acute success was noted with the conventional group but with similar long-term freedom from AF (95% vs. 97%, OR 0.25 (95% confidence interval [CI] 0.06; 1.04, p = 0.057); 73% vs. 75%, OR 0.92 (95% CI 0.69; 1.24, p = 0.59), respectively). A significantly shorter fluoroscopic time was achieved with MNS (57 vs. 86 min, standardized difference in means (SDM)–0.90 (95% CI–1.68;–0.12, p = 0.024)). On the other hand, longer total procedure and ablation times were noted with MNS (286 vs. 228 min, SDM 0.7 (95% CI 0.28; 1.12, p = 0.001); 67 vs. 47 min, SDM 0.79 (95% CI 0.18; 1.4, p = 0.012), respectively).[17]A reasonable fraction of the procedure time was utilized during the ablation.[8,18] To realize equally effective ablation lesions, more RF current needs to be delivered as compared with the conventional approach. In prior studies, it was suggested that the MNS was not sufficiently effective in making ablation lines.[6,19] This statement was based on using a 4 or 8-mm non-irrigated MNS ablation catheter. However, these results were partially confirmed based on longer RF application times while using an irrigated MNS catheter.[9] Data suggest that MNS requires a longer total application time than manual procedures and is therefore less effective at creating linear lesions; however, the long- term outcome is equivalent.[8,9]

Catheter based CF sensing technology gives detailed information regarding contact between the catheter tip and myocardium. CF-guided CPVI improves long-term outcome of manual PVI. The TOCCATA study investigated a new force-sensing RF ablation catheter to measure the real-time CF within ablation. The authors stated that the CF during PVI predicts AF recurrence at 1-year follow-up. The patients treated with an average CF of 10 g had AF recurrences and the patients treated with a CF of >20 g had no AF recurrences.[20] The CF applied by the MNS on the endocardial surface is substantially lower than when using conventional ablation catheters.[3] The study by Solheim et al. looked at Troponin T (TnT) level as a sensitive measure for myocardial injury, comparing MNS utilizing either an irrigated or non-irrigated catheter to conventional manual-irrigated catheters in AF ablation procedures. They demonstrated a significant correlation between total ablation time and post-ablation levels of TnT. Lower number of TnT and longer total ablation times were noted with MNS. Remote magnetic catheters may create more discrete and predictable ablation lesions measured by myocardial enzymes and may require longer total ablation time to reach the procedural endpoints in contrast to manual catheters that are likely to be less stable as suggested by the study with higher number of TnT as the catheters are sliding; brushing the endocardium during ablation causing more myocardial damage. There were no differences in success rates between groups, suggesting that MNS is still effective with less myocardial damage.[18] Conversely, we found that cryobaloon ablation for paroxysmal AF resulted in an greater increase in TnI levels and TnI level was the only independent predictor of AF recurrence in multivariate analysis.[21] As a better control of RF energy delivery optimizes the ablation procedure, a CF sensor should be included in the next generation of magnetic catheters.

The lower CF is compensated by the better catheter stability provided by the MNS.[22-24] The magnetic catheter remains stable despite complex atrial anatomy or cardiorespiratory movement. Because of the constant magnetic vector, the location of the ablation catheter will not change during an application. Besides, the MNS allows better perpendicular alignment of the catheter tip which improves energy delivery.[25,26] It has been shown that stability combined with lower CF can produce efficacious lesions.[27] The magnetic stability of the catheter provides constant wall contact of the catheter tip with less variation in CFs, whereas, conventional techniques show intermittent or variable CFs. This decreased variation of CF will create more transmural and larger volume lesions at comparable forces. Magnetic catheters also deliver RF energy with a lower mean temperature and with less variability of temperature during ablation, thus enhancing tissue energy transfers.[28] In studies to date, MNS was compared only to conventional manual ablation without CF guidance. One may hypothesize that manual-PVI guided by contact force is probably more effective than MNS.

Until 2012, the workflow of MNS was made difficult by the need for the operator to commute frequently between the control room and the procedure room in order to manipulate each class of catheter. This introduced inefficiencies into the procedures as it would be necessary for the operator to repeatedly relocate and rescrub, or to require the assistance of another operator at the patient's tableside. In addition to lengthening procedures, this exposed the operator to additional radiation, thereby undermining an important advantage of the MNS. The authors of previously published studies point out that their long procedure times may be due to the need to frequently move between the control room and the patient bedside in order to manually navigate the circular mapping catheter.[8,10] The study by Nolker et al showed that using of Vdrive system minimizes the time consumed during the procedure for relocating a circular catheter. Mean fluoroscopy time was higher than has been reported for magnetic PVI procedures, but lower than previous manual data.[8,10] However, this study incorporated the initial experience of the new Vdrive technology, both procedure and fluoroscopy times may be expected to shorten as the operators become more familiar with the system following the initial learning curve.

There are difficult regions where the MNS cannot provide sufficient CF, resulting in lower energy delivery. These are exactly the most difficult regions to use manual ablation catheters. In these cases, switching to a manually controlled ablation catheter is common. Especially, mapping and ablation of the right inferior PV due to anatomical complexities was proved more complex and caused prolongation of ablation and procedure times.[10,11] V-CAS Deflect system allows looping the robotic deflectable sheath inside the LA and this fastens right pulmonary vein isolation with significant reduction of the procedure duration and radiofrequency delivery time compared to standard magnetic navigation (fixed curve sheath and a catheter-only advancement system).[16]

Longer procedure time can also be explained by a slower navigation speed of the LA and other chambers using MNS compared with experienced manual navigators. The separate movements of changing the magnetic vector, movements of the magnets and subsequently catheter movement, will increase the time spent on navigating the catheter and thus the procedure and ablation time. On this road, a significant improvement was made with Niobe ES (Epoch) system (Stereotaxis, Inc., St. Louis, MO, USA), which increases the speed of the magnetic catheter with respect to the earlier version, can be coupled with the V-drive system. This system advances soft catheter control to a new level, dramatically improving catheter response times, providing responsive real-time control and offering new computer-assisted catheter movements that allow physicians to master difficult techniques with the click of a mouse. Fast 125 ms response to navigator commands potentially enabling shorter procedure times. Wissner et al compared procedural data using the EPOCH system with using the 2.generation system for catheter ablation of AF. Median procedure duration was 142 (105-170) min and median total fluoroscopy time was 7.5 (3-14) min. They were able to reduce the procedure time by 100 minutes, reduce fluoro time by 11 minutes, while achieving 100% acute isolation. Compared to the 2.generation magnetic navigation system, using of the EPOCH system resulted in a dramatic reduction in procedure duration.[29]

Electroanatomical mapping systems (Carto XP, Cartomerge, Carto 3; Biosense Webster, Diamond Bar, CA, USA and NavX; St. Jude Medical, Inc., St. Paul, MN, USA) and the integration of 3D cardiac images (magnetic resonance imaging or computed tomography scan) show great potential for reducing both procedure and X-ray exposure times. Manipulation of the catheter does not need continuous fluoroscopy and it is generally used only to confirm tip localization prior to application. The main progress was made over the past years with the Carto 3 mapping system. In Carto XP mapping system visualization was possible only for the ablation catheter tip by means of electromagnetic technology. The inability to visualize multiple catheters required routine validation of the Lasso catheter position by means of fluoroscopy, thereby prolonging radiation exposure.[29-32] The Carto 3 system combines the electromagnetic technology with new advanced catheter location technology that enables visualization of multiple catheters without fluoroscopy.[33] The data showed that the combination of MNS and Carto 3 system significantly reduced the both patient and operator X-ray exposure.[34]

Since MNS is so well implemented into modern electrophysiology, understanding of the usefulness for repeat catheter ablation is very important for clinical practice. For repeat AF ablation procedures, MNS has been related to fewer recurrences when compared with manual conventional technique. The study by Akca et al investigated the effectiveness of MNS in repeat catheter ablation and they stated 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. When procedural parameters were analyzed 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 ¼ 0.001). MNS is comparable with manual ablation 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.[35]

Safety Of The Magnetic Navigation Systems

Catheter ablation as a treatment for AF is often associated with a substantial risk of major complications that are major limitations of these techniques, as shown by Cappato et al. in their registry of AF ablation procedures undertaken in 521 centers in 24 countries. Although AF ablation was shown to be efficacious in approximately 80% of cases, with an average of 1.3—1.7 procedures per patient, the rate of reported major complications was 4.5% of cases, with 1% vascular accidents and 1.3% tamponade.[36] Tamponade is the most commonly reported major complication.[36–38] When moving the catheter, high CFs are often applied and can be at risk of perforating the atrial wall. The safety concerns including pericardial effusion/tamponade, stroke/TIA, radiation exposure and the atrial–esophageal fistulae (AEF) have been increased considerably by the introduction of MNS. To date, this issue has been evaluated and the overall complication rate was found similar between MNS and conventional groups. Proietti et al. in their meta-analysis of 941 patients in seven trials demonstrated an odds ratio (OR) of 0.41[95% CI 0.19–0.88, P ¼ 0.02] in favour of MNS regarding major complications.[12]

Cases of pericardial tamponade due to the magnetic catheter are very rare in the literature. In a study evaluating MNS in AF ablation with irrigated catheter, two cardiac tamponades were reported that they occurred subacutely, in one case 30 min after the end of an uneventful procedure, in the other subject several hours after an uncomplicated ablation in the MNS group.[9] These complications were related to repetitive ablation at the perforation site and not to acute perforation with the magnetic catheter tip. Magnetic catheters are soft and flexible which make mechanical complications less likely to occur. Lower applied CF is leading to reduced shear atrial wall stress and deformation, preventing pericardial effusion and tamponade. There is significant decrease in the risk of significant pericardial complication with the use of magnetic catheters as reported in a metaanalysis when compared to manual technique (0.3% vs. 2.5%, p = 0.005).[17]

Early reports on MNS in AF using non-irrigated ablation catheters describe char formation at the catheter tip after LA ablation.[6,7] Some patients had thrombus formation and experienced embolic events. The concern of catheter charring with the subsequent risk of embolism was initially prominent in the non-irrigated magnetic catheters or first generation irrigated tip magnetic catheters. Once the second-generation irrigated magnetic catheters were available, this problem was solved, and no tip charring and related embolic events occurred.[11]

Cumulative absorbed radiation dose during a lifetime of exposure could become a concern for healthcare professionals involved in fluoroscopically driven procedures. Decreased use of fluoroscopy for both the patient and operator is one of the main advantages of the MNS. Fluoroscopy time was reduced by 29 min in MNS as compared to conventional groups, with an average reported fluoroscopy time of 57 min in MNS versus 86 min in control groups.[17] Soft and flexible magnetic catheter can be safely manipulated without the need of fluoroscopic guidance, given the very low risk of causing perforations. The use of integrated 3D mapping systems can be used for localization of the catheter without continuous fluoroscopy. The computerized drive systems minimizing radiation exposure enable the operators to manipulate both ablation and circular mapping catheter remotely from the control room. Also, the positional stability of magnetic catheter leads to use less fluoroscopy for monitoring its movement during ablation.

Atrial-esophageal fistula (AEF) is one of most disastrous complications of AF ablation. Some data have suggested that MNS is related to changes in esophageal temperatures causing acute esophageal injury. These esophageal lesions all demonstrated complete remission within 14 days and were comparable for MNS and conventional approaches.[39] Danon et al conducted the first international survey among MNS operators for assessment of the prevalence of AEF. Data from parallel survey of AEF among Canadian interventional electrophysiologists (CIE) using only manual catheters served as control. Fifteen RMN operators (who performed 3637 procedures) and 25 manual CIE operators (7016 procedures) responded to the survey. The maximal energy output in the posterior wall was higher in the operator using RMN (33 ± 5 vs. 28.6 ± 4.9 W; $p = 0.02$). Other parameters including using of preprocedural images, irrigated catheter, pump flow rate, esophageal temperature monitoring were similar. AEF was reported in 5 of the 7016 patients in the control group (0.07 %) but in none of the MNS group ($p = 0.11$).[40] In our previous study, we evaluated the frequency of gastroparesis in the patients who underwent catheter ablation for AF by cryoballoon or RF and defined the risk factors for gastroparesis.[41] Totally 104 patients were treated with PVI with 2 different technologies: cryoballoon in 58 patients (group 1) and open-irrigated tip RF catheter in 46 patients (group 2). Gastroparesis was seen in 7 cases (6 cases in group 1 and 1 case in group 2, respectively). Management was conservative, and the patients have no residual symptoms at 6-month follow-up.

The presence of implantable cardiac devices makes the operator unwilling to carry out a MNS procedure. Electromagnetic interference with pacemaker (PM) or implantable cardioverter defibrillator (ICD) systems may cause temporary or permanent system malfunction of implanted devices. A study involving 121 devices (77 PMs, 44 ICDs) were exposed to an activated MNS at the maximal magnetic field strength of 0.1 Tesla, showed that the risk of interference was very small, as 95% of devices did not show any interference with the programme variables, battery status or registered data.[42] Another study involving 31 patients with devices (5 PMs, 26 ICDs) demonstrated that MNS system can be performed safely in patients with implanted devices with no significant effects on device system integrity. After the procedure, no statistically significant difference either in atrial or right ventricular sensing and impedance were observed.[43] In another study, 18 patients with implanted devices [12 PM, 3 ICD, 1 CRT-P, 2CRT-D] were evaluated and no relevant changes in lead parameters or device programming were observed after the MNS procedure. No interference was noted in ICD/CRT-D devices (tachycardia detection off) and in 2 PMs, whereas 10 PMs and 1 CRT-P switched to asynchronous stimulation for 1.8 ± 0.3 h ($63 \pm 13\%$ of RMN duration) without clinical adverse effects.[44] The use of MNS is generally safe in patients with implanted devices, however, risks and benefits of the utilization of the MNS system should carefully be weighed for every single patient. the safety of this technology in patients with PMs and ICDs and the effect on the integrity of these implanted devices and le

Conclusions

MNS offers an equivalent efficacy to the manual technique for AF ablation with better safety profile associated with a significant reduction in fluoroscopy time and radiation exposure, but also with longer procedure time. However, the new developments with the release of the latest version of the Niobe ES (Epoch) system with its robotic arms (Vdrive system), the later versions of 3D mapping systems might decrease the procedure time to a level closer to manual catheter ablation procedures and resolve the concern about the high cost of installing the system. As a different ablation modality, conventional cryoballoon ablation by single-shot technique, easier for the operator and shorten procedure time beyond the learning curve. Finally, the system provides a special benefit for the operator by reducing the level of physical constraint during the long procedure and fatigue at the end of the day.

References

1. Camm AJ, Lip GY, De Caterina R, Savelieva I, Atar D, Hohnloser SH, Hindricks G, Kirchhof P; ESC Committee for Practice Guidelines-CPG; Document Reviewers. 2012 focused update of the ESC guidelines for the management of atrial fibrillation: an update of the 2010 ESC guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association. Europace. 2012; 14: 1385–413.
2. Pappone C, Vicedomini G, Manguso F, Gugliotta F, Mazzone P, Gulletta S, Sora N, Sala S, Marzi A, Augello G, Livolsi L, Santagostino A, Santinelli V. Robotic

magnetic navigation for atrial fibrillation ablation. J. Am. Coll. Cardiol. 2006; 47: 1390–1400.

3. Kuck KH, Reddy VY, Schmidt B, Natale A, Neuzil P, Saoudi N, Kautzner J, Herrera C, Hindricks G, Jaïs P, Nakagawa H, Lambert H,Shah DC. A novel radiofrequency ablation catheter using contact force sensing: Toccata study. Heart. Rhythm. 2012; 9: 18–23.
4. Okumura Y, Johnson SB, Bunch TJ, Henz BD, O'Brien CJ, Packer DL. A systematical analysis of in vivo contact forces on virtual catheter tip/tissue surface contact during cardiac mapping and intervention. J. Cardiovasc. Electrophysiol. 2008;19: 632–640.
5. Pappone C, Manguso F, Vicedomini G, Gugliotta F, Santinelli O, Ferro A, Gulletta S, Sala S, Sora N, Paglino G, Augello G, Agricola E,Zangrillo A, Alfieri O, Santinelli V. Prevention of iatrogenic atrial tachycardia after ablation of atrial fibrillation: a prospective randomized study comparing circumferential pulmonary vein ablation with a modified approach. Circulation. 2004; 110: 3036–3042.
6. Di Biase L, Fahmy TS, Patel D, Bai R, Civello K, Wazni OM, Kanj M, Elayi CS, Ching CK, Khan M, Popova L, Schweikert RA,Cummings JE, Burkhardt JD, Martin DO, Bhargava M, Dresing T, Saliba W, Arruda M, Natale A. Remote magnetic navigation: human experience in pulmonary vein ablation. J. Am. Coll. Cardiol. 2007; 50:868–874.
7. Katsiyiannis WT, Melby DP, Matelski JL, Ervin VL, Laverence KL, Gornick CC. Feasibility and safety of remote-controlled magnetic navigation for ablation of atrial fibrillation. Am. J. Cardiol. 2008; 102: 1674–1676.
8. Arya A, Zaker-Shahrak R, Sommer P, Bollmann A, Wetzel U, Gaspar T, Richter S, Husser D, Piorkowski C, Hindricks G. Catheter ablation of atrial fibrillation using remote magnetic catheter navigation: a case– control study. Europace. 2011; 13: 45–50.
9. Luthje L, Vollmann D, Seegers J, Dorenkamp M, Sohns C, Hasenfuss G, Zabel M. Remote magnetic versus manual catheter navigation for circumferential pulmonary vein ablation in patients with atrial fibrillation. Clin. Res. Cardiol. 2011; 100: 1003–1011.
10. Miyazaki S, Shah AJ, Xhaët O, Derval N, Matsuo S, Wright M, Nault I, Forclaz A, Jadidi AS, Knecht S, Rivard L, Liu X, Linton N, Sacher F, Hocini M, Jaïs P, Haïssaguerre M. Remote magnetic navigation with irrigated tip catheter for ablation of paroxysmal atrial fibrillation. Circ. Arrhythmia. Electrophysiol. 2010; 3: 585–589.
11. Chun KR, Wissner E, Koektuerk B, Konstantinidou M, Schmidt B, Zerm T, Metzner A, Tilz R, Boczor S, Fuernkranz A, Ouyang F, Kuck KH. Remote-controlled magnetic pulmonary vein isolation using anewirrigated-tip catheter in patients with atrial fibrillation. Circ. Arrhythm. Electrophysiol. 2010; 3: 458–464.
12. Proietti R, Pecoraro V, Di Biase L, Natale A, Santangeli P, Viecca M, Sagone A, Galli A, Moja L, Tagliabue L. Remote magnetic with open-irrigated catheter vs. manual navigation for ablation of atrial fibrillation: a systematic review and meta-analysis. Europace. 2013; 15: 1241–1248.
13. Nölker G, Gutleben KJ, Muntean B, Vogt J, Horstkotte D, Dabiri Abkenari L, Akca F, Szili-Torok T. Novel robotic catheter manipulation system integrated with remote magnetic navigation for fully remote ablation of atrial tachyarrhythmias: a two-centre evaluation. Europace. 2012; 14: 1715–1718.
14. Choi MS, Oh YS, Jang SW, Kim JH, Shin WS, Youn HJ, Jung WS, Lee MY, Seong KB. Comparison of magnetic navigation system and conventional method in catheter ablation of atrial fibrillation: is magnetic navigation more effective and safer than conventional method? Korean. Circ. J. 2011; 41: 248–252.
15. Piorkowski C, Eitel C, Rolf S, Bode K, Sommer P, Gaspar T, Kircher S, Wetzel U, Parwani AS, Boldt LH, Mende M, Bollmann A, Husser D, Dagres N, Esato M, Arya A, Haverkamp W, Hindricks G. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: a prospective, randomized study. Circ. Arrhythm. Electrophysiol. 2011; 4: 157–165.
16. Errahmouni A, Latcu DG, Bun SS, Rijo N, Dugourd C, Saoudi N. Remotely controlled steerable sheath improves result and procedural parameters of atrial fibrillation ablation with magnetic navigation. Europace. 2015 Feb 5. pii: euu388.
17. Shurrab M, Danon A, Lashevsky I, Kiss A, Newman D, Szili-Torok T, Crystal E. Robotically assisted ablation of atrial fibrillation: a systematic review and meta-analysis. Int. J. Cardiol. 2013; 169: 157-165.
18. Solheim E, Off MK, Hoff PI, De Bortoli A, Schuster P, Ohm OJ, Chen J. Remote magnetic versus manual catheters: evaluation of ablation effect in atrial fibrillation by myocardial marker levels. J. Interv. Card. Electrophysiol. 2011; 32: 37–43.
19. Vollmann D, Lüthje L, Seegers J, Hasenfuss G, Zabel M. Remote magnetic catheter navigation for cavotricuspid isthmus ablation in patients with common-type atrial flutter. Circ. Arrhythm. Electrophysiol. 2009; 2: 603–610.
20. Reddy VY, Shah D, Kautzner J, Schmidt B, Saoudi N, Herrera C, Jaïs P, Hindricks G, Peichl P, Yulzari A, Lambert H, Neuzil P, Natale A, Kuck KH. The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. Heart Rhythm. 2012; 9: 1789-1795.
21. Aksu T, Golcuk SE, Guler TE, Yalin K, Erden I. Prediction of mid-term outcome after cryo-balloon ablation of atrial fibrillation using post-procedure high-sensitivity troponin level. Cardiovasc. J. Afr. 2015; 17: 26:1-6.
22. Ernst S, Ouyang F, Linder C, Hertting K, Stahl F, Chun J, Hachiya H, Bänsch D, Antz M, Kuck KH. Initial experience with remote catheter ablation using a novel magnetic navigation system: Magnetic remote catheter ablation. Circulation. 2004; 109: 1472–1475.
23. Davis DR, Tang AS, Gollob MH, Lemery R, Green MS, Birnie DH. Remote magnetic navigation-assisted catheter ablation enhances catheter stability and ablation success with lower catheter temperatures. Pacing. Clin. Electrophysiol. 2008; 31: 893–898.
24. Ricard P, Latcu DG, Yaici K, Zarqane N, Saoudi N. Slow pathway radiofrequency ablation in patients with avnrt: Junctional rhythm is less frequent during magnetic navigation ablation than with the conventional technique. Pacing. Clin. Electrophysiol. 2010; 33: 11–15.
25. Faddis MN, Blume W, Finney J, Hall A, Rauch J, Sell J, Bae KT, Talcott M, Lindsay B. Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation. Circulation. 2002; 106: 2980–2985.
26. Thornton AS, De Castro CA, van Deel E, van Beusekom HM, Jordaens L. An in vivo comparison of radiofrequency cardiac lesions formed by standard and magnetically steered 4 mm tip catheters. Neth. Heart J. 2010, 18: 66–71.
27. Kuck KH. Comparison of catheter stability between magnetically guided and manual cooled-tip ablation catheters. Presented at Heart Rhythm. San Fransisco, CA, USA, 14–17 May 2008.
28. Wissner E, Deiss S, Maurer T, Botros M, Kuck KH. Dramatic reduction in procedure duration using the 3. generation magnetic navigation system for catheter ablation of atrial fibrillation. J Cardiovasc Electrophysiol. (2015), The Boston AF Symposium 2015 Abstracts. Journal of Cardiovascular Electrophysiology, 26: 581–596. doi: 10.1111/jce.12644.
29. Bertaglia E, Bella PD, Tondo C, Proclemer A, Bottoni N, De Ponti R, Landolina M, Bongiorni MG, Corò L, Stabile G, Dello Russo A,Verlato R, Mantica M, Zoppo F. Image integration increases efficacy of paroxysmal atrial fibrillation catheter ablation: results from the CartoMerge Italian Registry. Europace. 2009; 11: 1004-1010.
30. Rotter M, Takahashi Y, Sanders P, Haïssaguerre M, Jaïs P, Hsu LF, Sacher F, Pasquié JL, Clementy J, Hocini M. Reduction of fluoroscopy exposure and procedure duration during ablation of atrial fibrillation using a novel anatomical navigation system. Eur. Heart. J. 2005; 26: 1415-1421.
31. Sporton SC, Earley MJ, Nathan AW, Schilling RJ. Electroanatomic versus fluoroscopic mapping for catheter ablation procedures: a prospective randomized study. J. Cardiovasc. Electrophysiol. 2004; 15: 310-5.
32. Stabile G, Scaglione M, del Greco M, De Ponti R, Bongiorni MG, Zoppo F, Soldati

E, Marazzi R, Marini M, Gaita F, Iuliano A, Bertaglia E. Reduced fluoroscopy exposure during ablation of atrial fibrillation using a novel electroanatomical navigation system: a multicentre experience. Europace. 2012; 14: 60-65.

33. Scaglione M, Biasco L, Caponi D, Anselmino M, Negro A, Di Donna P, Corleto A, Montefusco A, Gaita F. Visualization of multiple catheters with electroanatomical mapping reduces X-ray exposure during atrial fibrillation ablation. Europace. 2011; 13: 955-962.
34. Da Costa A, Ben H'dech M, Romeyer-Bouchard C, Bisch L, Gate-Martinet A, Levallois M, Isaaz K. Remote controlled magnetic pulmonary vein isolation usinga new three-dimensional non-fluoroscopic navigation system: A single centre prospective study. Arch. Cardiovasc. Dis. 2013;106:423-32.
35. Akca F, Theuns DA, Abkenari LD, de Groot NM, Jordaens L, Szili-Torok T. Outcomes of repeat catheter ablation using magnetic navigation or conventional ablation. Europace. 2013; 15: 1426–1431.
36. Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J, Kim YH, Klein G, Natale A, Packer D, Skanes A, Ambrogi F, Biganzoli E.Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. Circ. Arrhythm. Electrophysiol. 2010; 3:32–38.
37. Dagres N , Hindricks G, Kottkamp H, Sommer P, Gaspar T, Bode K, Arya A, Husser D, Rallidis LS, Kremastinos DT, Piorkowski C. Complications of atrial fibrillation ablation in a high-volume center in 1,000 procedures: still cause for concern? J. Cardiovasc. Electrophysiol. 2009; 20: 1014–1019.
38. Spragg DD, Dalal D, Cheema A, Scherr D, Chilukuri K, Cheng A, Henrikson CA, Marine JE, Berger RD, Dong J, Calkins H. Complications of catheter ablation for atrial fibrillation: incidence and predictors. J. Cardiovasc. Electrophysiol. 2008; 19: 627–631.
39. Konstantinidou M, Wissner E, Chun JK, Koektuerk B, Metzner A, Tilz RR, Rillig A, Fuernkranz A, Wohlmuth P, Ouyang F, Kuck KH. Luminal esophageal temperature rise and esophageal lesion formation following remote-controlled magnetic pulmonary vein isolation. Heart. Rhythm. 2011; 8: 1875–1880.
40. Danon A, Shurrab M, Nair KM, Latcu DG, Arruda MS, Chen X, Szili-Torok T, Rossvol O, Wissner EE, Lashevsky I, Crystal E. Atrial fibrillation ablation using remote magnetic navigation and the risk of atrial-esophageal fistula: international multicenter experience. J Interv Card Electrophysiol. 2015 May 3.
41. Aksu T, Golcuk S, Guler TE, Yalin K, Erden I. Gastroparesis as a Complication of Atrial Fibrillation Ablation. Am. J. Cardiol. 2015; 116: 92-97.
42. Jilek C, Tzeis S, Reents T, Estner HL, Fichtner S, Ammar S, Wu J, Hessling G, Deisenhofer I, Kolb C. Safety of implantable pacemakers and cardioverter defibrillators in the magnetic field of a novel remote magnetic navigation system. J. Cardiovasc. Electrophysiol. 2010; 21: 1136-1141.
43. Eitel C, Hindricks G, Sommer P, Wetzel U, Bollmann A, Gaspar T, Piorkowski C, Arya A. Safety of remote magnetic navigation in patients with pacemakers and implanted cardioverter defibrillators. J. Cardiovasc. Electrophysiol. 2010; 21: 1130-1135.
44. Lüthje L, Vollmann D, Seegers J, Sohns C, Hasenfuss G, Zabel M. Interference of remote magnetic catheter navigation and ablation with implanted devices for pacing and defibrillation. Europace. 2010; 12:1574-1580.