Novel robotic catheter manipulation system integrated with remote magnetic navigation for fully remote ablation of atrial tachyarrhythmias: a two-centre evaluation

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Aims
Studies have shown that remote magnetic navigation is safe and effective for ablation of atrial arrhythmias, although optimal outcomes often require frequent manual manipulation of a circular mapping catheter. The Vdrive robotic system (‘Vdrive’) was designed for remote navigation of circular mapping catheters to enable a fully remote procedure. This study details the first human clinical experience with remote circular catheter manipulation in the left atrium.

Methods and results
This was a prospective, multi-centre, non-randomized consecutive case series that included patients presenting for catheter ablation of left atrial arrhythmias. Remote systems were used exclusively to manipulate both the circular mapping catheter and the ablation catheter. Patients were followed through hospital discharge. Ninety-four patients were included in the study, including 23 with paroxysmal atrial fibrillation (AF), 48 with persistent AF, and 15 suffering from atrial tachycardias. The population was predominately male (77%) with a mean age of 60.5 ± 11.7 years. The Vdrive was used for remote navigation between veins, creation of chamber maps, and gap identification with segmental isolation. The intended acute clinical endpoints were achieved in 100% of patients. Mean case time was 225.9 ± 70.5 min. Three patients (3.2%) crossed over to manual circular mapping catheter navigation. There were no adverse events related to the use of the remote manipulation system.

Conclusions
The results of this study demonstrate that remote manipulation of a circular mapping catheter in the ablation of atrial arrhythmias is feasible and safe. Prospective randomized studies are needed to prove efficiency improvements over manual techniques.

Keywords
Ablation • Catheter ablation • Electrophysiology • Robotics • Tachyarrhythmias

Introduction
Remote magnetic navigation (RMN) is an increasingly popular tool for facilitating complex electrophysiology procedures. Numerous publications have evaluated the system and demonstrated an excellent efficacy and safety profile for a variety of arrhythmias and other applications in interventional cardiology.1–8 Recently, a number of studies have focused on the utility of RMN technique for atrial fibrillation (AF) procedures.5–8

A common AF ablation strategy is circumferential pulmonary vein isolation (PVI). In these procedures, block lines are created to inhibit electrical conduction between the left atrium (LA) and the pulmonary veins (PV).9 Following the ablation procedure, a circular mapping catheter (‘Lasso’, Biosense Webster, Inc, Diamond Bar, CA, USA) is often used to evaluate PV conduction simultaneously at multiple circumferential points and confirm successful abatement of electrical conduction.5–8 Until recently, however, these catheters could only be manipulated manually from the...
patient’s bedside. This interrupts the remote workflow of the procedure by requiring the operator to move frequently from the remote RMN workstation to the procedure room in order to manually adjust the non-magnetic Lasso catheter. Without a means of remotely manipulating the circular mapping catheter, inefficiencies are introduced into the procedure and the utility of the RMN approach is substantially undermined.

The Vdrive robotic catheter manipulation system (‘Vdrive,’ Stereotaxis, Inc., Saint Louis, MO, USA) was developed to overcome the procedural difficulties associated with manipulating Lasso catheters in remote procedures. Vdrive consists of a controller with which the operator can manipulate a compatible catheter remotely from the magnetic workstation via a robotic drive unit. This has the potential to enable more fully remote PVI procedures, reduce procedure time, and further reduce the operator’s fluoroscopy exposure. In the present study, we detail the first human series employing remote circular catheter manipulation in the LA.

Methods

This prospective, multi-centre, non-randomized case series included patients presenting to our centres for catheter ablation of left atrial arrhythmias. Ninety-four were included in this study. Two patients were excluded from analysis due to completely missing procedural data.

All patients signed written informed consent.

Magnetic navigation system

The Niobe magnetic navigation system (MNS) (Stereotaxis) has been described in detail elsewhere. Briefly, the MNS is a fully integrated workstation for navigating proprietary catheters that have very small magnets placed into their distal tips. The orientation of these devices is controlled by precise manipulation of the field generated by two large neodymium-iron-boron magnets that are mounted on mechanical positioners near the head of the patient. Rotation and translation of these magnets maintain a net magnetic field of 0.08–0.1 T within a 20 cm diameter sphere in the patient’s upper thorax. Although these are permanent magnets, they may be stowed and retracted away from the patient when not in use. The operator interfaces with the system via the Navigant Navigation Work Station software interface (NWS) (Stereotaxis), and the system is fully integrated with both fluoroscopy and electroanatomic mapping.

Vdrive robotic catheter manipulation system

The Vdrive is a remote navigation platform that allows physicians to manoeuvre specialized diagnostic catheters from a fully integrated remote interface (Figure 1). The system consists of a robotic drive unit, a remote controller, and a catheter-specific disposable set that interfaces the drive unit with a compatible catheter. The first available disposable set is designed to accept Lasso 2515 and Lasso NAV 2515 circular mapping catheters (Biosense Webster) without modification.

To prepare the Vdrive for use, the disposable components are applied to the Vdrive and the distal end of the catheter is fed through the telescoping catheter support tube and a standard sheath. The handle of a compatible catheter is attached to the disposable handle clamps and a sterile drape is placed over the unit. The system is fully integrated with the Navigant Workstation and was used in conjunction with either the EnSite Velocity (St Jude Medical, Sylmar, CA, USA) or Carto RMT electroanatomic mapping systems.

Mapping and ablation procedure

Remote systems were used exclusively to manipulate both the circular mapping catheter and the ablation catheter from the control room. A quadripolar or decapolar catheter was introduced through the right femoral vein and positioned in the coronary sinus. A transseptal sheath was placed and a Lasso circular mapping catheter was positioned at the LA. The Lasso catheter was used to acquire baseline LA-to-PV conduction data. A 3.5 mm irrigated-tip mapping and ablation catheter (Navistar RMT Thermocool, Biosense-Webster) or a catheters (Biosense Webster). The operator controls catheter motion by manipulating the remote controller (Figure 2) from the remote workstation. The drive unit then transmits these commands directly to the catheter handle. Operations governed by the remote controller include: advancement, retraction, rotation, deflection, loop size increase, and loop size decrease. Fluoroscopy was used to navigate the circular catheter using the Vdrive system.
5 mm irrigated gold-tip catheter (Trignum G, Biotronik, Berlin, Germany) was introduced into the femoral vein and positioned at the LA. Three-dimensional electroanatomical mapping was performed with either the EnSite Velocity or Carto RMT platforms in conjunction with the RMN system.

For image integration multi-slice computed tomography or intraprocedural rotational angiography (DynaCT Cardiac, Siemens, Erlangen, Germany) could be used as guiding imaging techniques.

During the ablation procedure, radiofrequency catheters were limited to the range of 25–45 W and were perfused with a 0.9% saline solution at a rate of 17–30 mL/min. Radio frequency application was ceased whenever tissue temperature exceeded 48 °C. Radio frequency energy was either applied continuously during catheter dragging for up to 120 s, with a 15–20 s application duration per lesion, or was applied point by point for a maximum of 30 s per lesion.

Successful PVI was confirmed using the Lasso catheter. If electrical conduction was detected, the region was remapped and any gaps were relabeled. If the operator was unable to navigate the Lasso catheter properly after several attempts, they had the option of crossing over from Vdrive to manual circular mapping catheter navigation.

The clinical endpoint was defined as complete PVI confirmed by entrance block of all PV.

**Statistical analysis**

Data mean ± standard deviation was used to describe continuous variables with normal distribution. Descriptive statistical analysis was performed using the SPSS 15.0 software (SPSS Inc., Chicago, IL, USA).

**Results**

**Patient characteristics**

Patient clinical and demographic characteristics are summarized in Table 1. Of the 94 patients included in this study, 23 had paroxysmal AF, 48 had persistent AF, and 15 had left atrial tachycardias [perimtrial flutter (n = 9); focal tachycardias (n = 6)]. The population was predominantly male (76.6%) with a mean age of 60.5 ± 11.7 years. Patients had a mean left atrial diameter of 46.5 ± 7.0 mm and a mean left ventricular ejection fraction of 52.2 ± 9.1%. Fifteen patients (16.0%) had failed one or more previous PVI attempt.

**Ablation and mapping procedure**

Procedure data are summarized in Table 2. The intended clinical endpoints were achieved in 100% of patients. No patients required crossover from the magnetic ablation catheter to a manual equivalent. Mean procedure and ablation times were 225.9 ± 70.5 and 41.0 ± 20.9 min, respectively. A mean 29.7 ± 13.6 min of fluoroscopy was required. Three operators reported mean radiation doses of 5073.4 ± 2077.7 μGy m². Three patients (3.2%) required crossover to manual circular mapping catheter navigation in order to adequately assess conduction at the right inferior PV. This could be traced back to difficulties reaching the vein due to a sheath placed too deep (n = 1), a suboptimal initial setup of the Vdrive (n = 1) and impossibility for counter-clockwise rotation due to safety limits of the system.

In all other patients, the Vdrive was used exclusively to navigate the Lasso catheter for PV mapping.

**Complications**

One patient developed pulmonary oedema after the procedure. The duration of the procedure in this patient had been 360 min. A pulmonary embolism was developed in one patient. The procedure time in this patient had been 300 min. Both procedures were longer than the average procedure time. One patient experienced cardiac tamponade requiring intervention during this study (1.1%). The patient recovered immediately after pericardiocentesis and no open heart surgery was required. Therefore, the cause of the cardiac tamponade remains unclear, at least it did not directly coincide with manipulation of the circular catheter. An inguinal haematoma was noted in one patient.

**Discussion**

Remote magnetic navigation has become a widely accepted means of treating a variety of arrhythmias, including AF. Numerous publications demonstrate that the technology may be associated with significant safety benefits for the patient and the physician. The risk of major complications has been shown in some studies to be lower in RMN procedures relative to manual technique and RMN requires significantly less fluoroscopy.®

Certain procedures can benefit from combined magnetic–manual approach that seeks to take advantage of specialized manual diagnostic catheters in conjunction with the highly flexible and precise magnetic ablation catheters. Until recently, the workflow of these combined procedures was made difficult by the need for the operator to commute frequently between the NWS 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 bedside. In addition to lengthening procedures, this exposed the operator to additional radiation, thereby undermining an important

### Table 1 Baseline patient characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
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<tbody>
<tr>
<td>Male sex (%)</td>
<td>76.6</td>
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<tr>
<td>Age (years)</td>
<td>60.5 ± 11.7</td>
</tr>
<tr>
<td>Persistent AF (%)</td>
<td>56.5</td>
</tr>
<tr>
<td>Left atrial diameter (mm)</td>
<td>46.5 ± 7.0</td>
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<tr>
<td>LVEF (%)</td>
<td>52.2 ± 9.1</td>
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</tbody>
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AF, atrial fibrillation; LVEF, left ventricular ejection fraction

### Table 2 Ablation and mapping procedure data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute ablation efficacy rate (%)</td>
<td>100%</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>225.9 ± 70.5</td>
</tr>
<tr>
<td>Ablation time (min)</td>
<td>41.0 ± 20.9</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>29.7 ± 13.6</td>
</tr>
<tr>
<td>Radiation dose (μGy²)</td>
<td>5073.4 ± 2077.7</td>
</tr>
<tr>
<td>Vdrive-to-manual crossover (%)</td>
<td>3.2</td>
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advantage of the RMN system. The new Vdrive platform has the potential to overcome these difficulties by simplifying the workflow of remote procedures. The system allows the operator to manipulate both a magnetic ablation catheter as well as an otherwise manual circular mapping catheter remotely from a radiation-shielded control room. This enables a fully remote procedure that is not limited strictly to the use of the magnetic mapping and ablation catheter.

The present study offers the first prospective multi-centre data on various procedural parameters associated with Vdrive procedures. We were able to achieve the desired clinical endpoints in 100% of patients. The remote circular catheter manipulation system was used for remote navigation between veins, stabilization of the circular mapping catheter, creation of chamber maps, and gap identification with segmental isolation. Identification of gaps in the circular conduction block lines was augmented by the system's ability to make small precise changes in the position and orientation of the circular mapping catheter.

Our mean procedure time of 225.9 ± 70.5 min is similar to what has been previously reported for magnetic PVI procedures. Miyazaki et al. reported a mean procedure time of 246 ± 50 min in a sample of 30 patients with paroxysmal AF. These authors note that their long procedure times may be due in part to the need to frequently move between the RMN control room and the patient bedside in order to manually navigate the circular mapping catheter. Arya et al. report a mean procedure duration of 223 ± 44 in a patient sample that was equally distributed between paroxysmal and persistent AF. They point out that magnetic PVI procedures are subject to ‘interruption delays’ ranging from 23 to 52 min, owing to the remote nature of the procedures which allows the operators to engage in unrelated or non-essential tasks during magnetic procedures.

Mean fluoroscopy time was higher than has been reported for magnetic PVI procedures, but lower than previous manual data. However, this study incorporates the initial experience of both hospitals with 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. Moreover, intraprocedural DynaCT cardiac replacing pre-procedural computed tomography or magnetic resonance imaging contributed to fluoroscopy time and radiation exposure in a significant proportion of the patients.

One patient experienced tamponade. Although this event is not expected to have been related to the use of the Vdrive circular catheter manipulation system, this possibility cannot be definitively excluded. All catheter ablation procedures carry the risk of complications, among them cardiac tamponade is responsible for a minor proportion of deaths associated with catheter ablation performed for treatment of AF. The rate of tamponades in this study is less than the amount of tamponades reported by Cappato et al. in a survey on complications of catheter ablation procedures for treatment of AF.

Costs

Use of the Vdrive adds ~€600 over classical Lasso manipulation. This cost is likely to be reduced in the future due to planned multi-use functionality of the disposable portion of the unit, and is at least partially offset by the reduction in times related to the magnetic ablation case.

Study limitations

This was not a randomized study. Randomized studies are needed to further evaluate the comparative efficacy of Vdrive procedures. Moreover, the study incorporates the operators’ first experience with the Vdrive and does not evaluate learning-curve trends. It is unclear to what extent the results would differ from the data presented if the operators had more extensive experience with the new technology. Two patients have been excluded from analysis due to incomplete data sets; no complications were recorded in these patients.

In conclusion, the results of this study demonstrate that remote manipulation of a circular mapping catheter in the ablation of atrial arrhythmias is feasible and safe. The Vdrive system enabled fully remote procedures with minimal need for manual cross over. Prospective randomized studies with long-term follow-up are needed to prove efficiency improvements relative to manual techniques.

Conflict of interest: G.N. and T.S.-T. are consultants of Stereotaxis, Inc., St Louis, MO, USA.

References