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Atrial Fibrillation Ablation Using a Robotic Catheter Remote Control System

Initial Human Experience and Long-Term Follow-Up Results

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Objectives We present the initial clinical human experience with the use of a robotic remote navigation system (Hansen Medical, Mountain View, California), to perform left and right atrial mapping and radiofrequency ablation of atrial fibrillation (AF) and atrial flutter (AFL).

Background Catheter ablation is an established curative modality for various arrhythmias. A robotic steerable sheath system (SSS) (Hansen Medical) allows better catheter stability and greater degrees of freedom of catheter movement.

Methods A total of 40 patients (mean age 57 years) with antiarrhythmic drug (AAD)–refractory AF (23 had also concomitant documented typical AFL) were studied. Three-dimensional reconstruction of the corresponding atrial chamber anatomy was performed with the CARTO electroanatomic mapping system (Biosense Webster, Diamond Bar, California or the EnSite NavX system (St. Jude Medical, Minneapolis, Minnesota) in combination with the Artisan catheter (Hansen Medical). In patients undergoing AF ablation, 2 transseptal punctures were performed under intracardiac ultrasound (ICE) guidance, with one of the punctures being performed using SSS. Pulmonary vein antrum isolation was performed with a 3.5-mm thermocool catheter manipulated with the use of the SSS and was verified by circular mapping. Patients were followed clinically for recurrence of arrhythmia with an event transmitter and ambulatory holter monitoring. Clinical recurrence of AF/AFL was defined as AF/AFL episodes >1 min in duration.

Results Pulmonary vein antrum isolation was performed in 40 patients, including 23 with concomitant typical AFL ablation. All pulmonary veins, including the superior vena cava, were successfully isolated. In 23 of 40 patients, cavotricuspid ablation was also performed with bidirectional block obtained. At 1-year follow-up, 34 patients (86%) and 5 patients were free from atrial arrhythmia off AADs and on AADs, respectively.

Conclusions This preliminary human experience suggests that mapping and ablation of AFL and AF using this novel robotic catheter with remote control system is feasible with similar results to conventional approach. (J Am Coll Cardiol 2008;51:2407–11) © 2008 by the American College of Cardiology Foundation

Catheter ablation has been established as a successful curative modality for various kinds of tachyarrhythmias (1,2). Specifically, the various techniques for catheter-based ablation of atrial fibrillation (AF) are evolving rapidly. Ablation targets include anatomic ablation, electrogram-based ablation, and the creation of circular ablation lesion sets around the pulmonary veins (PVs) together with placement of linear ablation lesions in the atria (3–7). However, regardless of strategy, the safety and success of these approaches is operator dependent and require precise catheter manipulation and stable contact during ablation energy delivery.

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Abbreviations and Acronyms

AAD = antiarrhythmic drug
AF = atrial fibrillation
AFL = atrial flutter
CT = computed tomography
ICE = intracardiac echocardiography
PV = pulmonary vein
SSS = steerable sheath system
SVC = superior vena cava
3D = three-dimensional

We have previously reported our experience showing the safety and feasibility of endocardial catheter navigation and mapping by using a robotic catheter remote control system in dogs (8). The aim of this study was to evaluate the safety and efficacy of a robotic steerable guide catheter to perform radiofrequency ablation in the treatment of AF and atrial flutter (AFL) in humans.

Methods

This is a prospective multicenter study. Patients with symptomatic AF with or without documented AFL who had failed at least one antiarrhythmic medication were considered for enrollment. At 12 months after ablation, the data were reviewed and analyzed. Enrollment occurred in 3 centers in Europe: Prague, Coburg, and Bordeaux.

Patients were eligible to enter the study if they had experienced symptomatic AF episodes for ≥3 months and had failed to respond to at least 1 antiarrhythmic medication. Patients with the following criteria were excluded: 1) age <18 and >75 years; 2) previous history of AFL or AF ablation; 3) previous history of open-heart surgery; or 4) contraindication for long-term anticoagulation treatment. Each patient signed an informed consent approved by the institutional ethic committee at the corresponding hospital. Forty patients were enrolled in the study. The end points of the study were feasibility of isolation of the PVs and superior vena cava (SVC), achieving bidirectional isthmus block in patients with concomitant typical AFL, and the recurrence of arrhythmia in patients at 12 months after ablation while they were not receiving antiarrhythmic drugs (AADs).

Robotic system. The robotic system (SenseiRobotic Catheter System, Hansen Medical, Mountain View, California) consists of a physician workstation that includes the instinctive motion controller (Fig. 1), a remote catheter manipulator (Fig. 1), and a setup joint that is mounted on a table at the patient's side. The remote catheter manipulator directly controls a robotic hollow catheter (Artisan Catheter, Hansen Medical) consisting of an internal steerable guide sheath system (SSS, Artisan Catheter) (Fig. 1). This robotic hollow catheter is in reality a hollow robotically steered sheath that can house any mapping or ablation catheter. The physician workstation is placed at a remote location from the patient's table. The control is provided via a master and slave electromechanical system: the operator movements at the instinctive motion controller (Fig. 1) are updated constantly with resultant seamless motion of the catheter (Fig. 1). Using this system, the operator can perform catheter control in 3 dimensions and also allows for tight bend radius.

Three-dimensional (3D) mapping. Mapping was done in an effort to study the potential integration of this robotic system with available mapping systems. In all patients, 3D reconstruction of the corresponding atrial chamber anatomy was performed with the CARTO electroanatomic mapping system (Biosense Webster, Diamond Bar, California; 22 patients) or the EnSite NavX system (St. Jude Medical, Minneapolis, Minnesota; 18 patients) (Fig. 1). Registration with the 3D computed tomography (CT) was performed in patients in whom CARTO was used and side-by-side synchronization was performed in the cases where NAvX was used.

Procedure. Patients were brought to the electrophysiology laboratory in the post absorptive state. A multipolar catheter was placed into the coronary sinus. The Acunav (Siemens Acuson, Mountain View, California) intracardiac echocardiography (ICE) catheter was placed via the left femoral vein and was positioned in the right atrium. This placement was used to facilitate catheter manipulation, monitor circular mapping catheter position, and guide transseptal puncture.

After manually placing the SSS in the inferior right atrium, the position of the SSS was registered into the robotic catheter remote control system. This registration involved the use of 2 orthogonal fluoroscopic views of the heart (anterior-posterior and lateral) to allow the saving the position of the SSS in 3D space.

AF ablation. The SSS was inserted via a 14-F sheath in the right femoral vein and advanced manually into the right atrium under fluoroscopic visualization. In patients undergoing AF ablation, 2 transseptal punctures were performed under ICE guidance. The first transseptal puncture was performed manually. We used ICE to confirm the appropriate puncture site. Through this transseptal puncture, a long sheath was advanced into the left atrium, and a circular mapping catheter was introduced into the left atrium. We performed the second transseptal puncture with the Sensei system by using a transseptal sheath and dilator (Hansen Medical, Inc.); a custom-made transseptal needle (Hansen Medical, Inc.) was advanced through a dilator lumen.

After the septum was punctured, the SSS and dilator were advanced robotically in the LA and the dilator replaced with a 3.5-mm thermocool catheter (Navistar, Biosense-Webster) that was then inserted into the SSS with approximately 1 cm of the ablation catheter exposed (Fig. 1). This catheter was used for ablation. Systemic anticoagulation was initiated just before the first transseptal puncture with the use of intravenous heparin with a target ACT of approximately 400 s. A fixed radius decapolar Biosense LASSO circular mapping catheter (Biosense Webster) was used for mapping the PV antra. With this configuration, the final setup before initiation of ablation included the following: A robotically controlled steerable sheath housing the ablation catheter (this is performed by a physician at the console) and a manually controlled circular mapping catheter handled and moved by a second physician at the procedure tableside. Ablation along the PV's antrum, which encompasses the

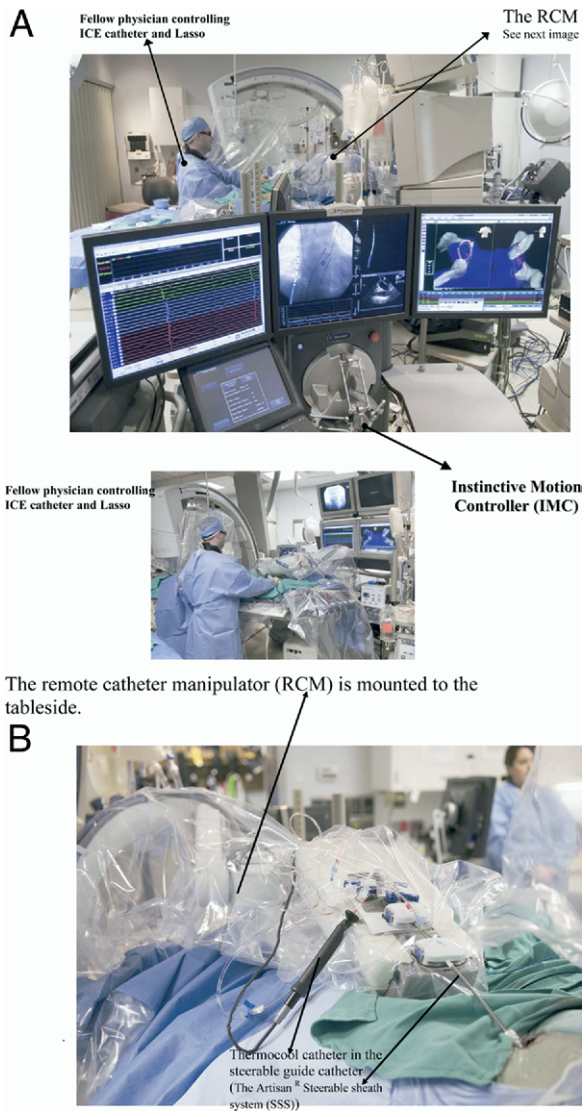

Figure 1 **The Sensei Robotic Catheter System**

The entire system is depicted. **(A)** The workstation, including the master consol, is mobile and can be moved to an area remote from the patient and fluoroscopy. It can depict electrograms, intracardiac echo images, fluoroscopy, and also 3-dimensional navigation images. The instinctive motion controller device is located on the master consol. The physician operator maneuvers the handle guided by the images on the consol (intracardiac echocardiography, fluoroscopy, and electroanatomical maps) to guide the catheter within the body. **(B)** The remote catheter manipulator (RCM) is mounted to the tableside and connected to the catheter, which is placed inside the cardiovascular system. Movement of the instinctive motion controller is transmitted by the use of motion logic to the RCM, which in turn maneuvers the catheter. The RCM mounts at the bedside and directs the catheter using the steerable catheter/sheath units. With the use of interpreted motion logic, it is able to smoothly transmit the operator's motions of the master input device to the catheter. The Artisan steerable sheath system consists of a steerable guide catheter inside a steerable sheath, which allows the transmission of the operator's movements (via the RCM) to direct the catheter. This complex system allows for motion in 3 dimensions in response to the operator's hand motion.

posterior wall and septal portions of the right PVs, was performed with the Artisan robotic system until disappearance of local PV potential with the end point of electrical isolation of all PV antra as well as SVC isolation at the level of the SVC-right atrial junction.

Radiofrequency power was set at 30 W with a maximum temperature limit of 45°C with irrigation using heparinized saline infusion (2,000 IU/l) at a rate of 30 ml/min via the Cool Flow pump (Biosense Webster). At the end of the procedure, systemic anticoagulation was discontinued and partially reversed with intravenous protamine before removal of vascular sheaths. Three months after ablation, all patients underwent a CT scan so that they could be examined for the presence of PV stenosis.

AF ablation. After PV and SVC isolation were performed, the circular ablation catheter was withdrawn. Ablation along the posterior cavotricuspid isthmus was performed in 23 patients with the robotic system in conjunction with the 3.5-mm thermocool catheters (Navistar, Biosense-Webster). Bidirectional block was confirmed with 3D mapping and proximal coronary sinus/posteriolateral right atrial pacing.

Follow-up. Follow-up was scheduled at 1, 3, 6, and 12 months. An event recorder was used in all patients to monitor events during the first month and was repeated at 3 months. During the monitoring period, patients were asked to record any symptoms and once weekly, even if they were asymptomatic. Additional event recorder monitoring was considered beyond the 3-month period for patients with recurrence of symptoms. All patients had a spiral CT scan after 3 months. Patients resumed oral anticoagulation therapy with warfarin on the evening of the procedure and oral anticoagulation therapy was continued for at least 6 months. Antiarrhythmic drugs were continued for a 2-month period. A 2-month blanking period was used in which episodes of AF occurring within that time period were not considered procedure failures.

Results

Study population. Between January 2005 and July 2006, 40 patients were enrolled in the study. The characteristics of the study population are described in Table 1. A total of 40 patients (29 men/11 women, mean age 57 ± 20 years) with AF were included in this study. Twenty-three patients also had documented typical AFL. These patients had failed to respond to an average of 2 ± 1 AADs. The mean left ventricular ejection fraction was 58 ± 12%. Atrial fibrillation was paroxysmal in 75% and recently persistent in 25%.

Pulmonary vein antrum isolation (which includes ablation along the posterior wall and septal aspect of the right PVs) was performed in 40 patients. Concomitant AFL ablation was also performed in 23 of these 40 patients. All PVs in addition to the SVC were successfully isolated.

All ablations were performed with the robotic system. The procedure was assessed using fluoroscopy and also image integration with CARTO and NAvX. Total procedure time

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Table 1 Baseline Demographics of Patients (n = 40)

Age, yrs, mean ± SD	57 ± 8
Left atrial size, cm, mean ± SD	4.1 ± 0.8
Duration of AF, months, mean ± SD	48 ± 12
Paroxysmal AF	29
Recently persistent AF	11
Structural heart disease/hypertension	10% (10/40)
Ejection fraction, %, mean ± SD	58 ± 12

AF = atrial fibrillation.

was 163 ± 88 min, ablation time was 89.6 ± 43 min, and fluoroscopy time was 64 ± 33 min (Table 2). The average radiation exposure at the procedure table was 149 versus 13 microseiverts at the physician workstation ($p < 0.05$).

Procedural complications. Two patients undergoing pulmonary vein isolation developed pericardial tamponade requiring pericardiocentesis with no other sequelae (procedure was aborted in one patient after manual transseptal).

Long-term follow-up. At 12 months follow-up, 34 patients were free from atrial arrhythmia off AADs and 5 were arrhythmia free on previously ineffective AADs. No patients developed PV stenosis.

Discussion

This report demonstrates the safety of robotically performed transseptal puncture in addition to atrial ablation for AF and AFL. The efficacy is similar to results reported with the use of the conventional approach. Furthermore, there does not appear to be any increased risk of perforation or intracardiac damage associated with this remote navigational system.

Clinical importance of remote control. Endocardial navigation by the use of conventional manual steerable diagnostic and ablation catheters and transseptal puncture by the use of standard equipment can be challenging and time consuming. This challenge is partly related to the variability of the cardiac anatomy as well as operator's skills and experience in catheter navigation. This remote robotic manipulation system offers an opportunity to overcome the limitations of manual control. In addition, it provides precise as well as stable positioning, which would potentially improve the efficacy and safety of ablation procedures. In this case series, the robotic console was close to the table because of space constraints. Specifically designed electrophysiologic laboratory space can allow accommodation of the robotic console in a location away from radiation. Having the physician in a remote area at the workstation will reduce the physician's radiation exposure during long procedures of electrophysiologic study and catheter ablation. Also, in our case series where we used a strategy of verification of isolation with the circular mapping catheter, there was a need for a second physician to manipulate the mapping catheter at the bedside. With the use of other strategies, such as anatomically based ablation, there would be no need for a separate mapping catheter. In the future, it is possible that both the ablation and mapping catheter can be controlled in tandem with 2 coordinated robotic steerable guides.

In contradistinction to the magnetic navigation system that requires specific compatible magnetic-guided catheters, the robotic system is an open platform system whereby any mapping or ablation catheter of appropriate size can be introduced into the remotely steerable catheter/sheath. The magnetic navigation system requires continuous alteration and adjustment of the magnetic field and then advancement of the catheter in that direction. With the use of this system, a continuous uninterrupted motion of the ablation catheter can be achieved with the use of the instinctive motion controller (9–14).

Radiation exposure. Because of the remote location of the workstation from the fluoroscopy, radiation exposure to the physician is significantly reduced. Our early experience showed an average of 12-fold reduction in radiation dosage between a bedside dosimeter and one located at the workstation, 3 to 4 m away. Again, as noted earlier, the workstation was close because of space constraints. This difference will be more prominent as the workstation is moved further away to the control room, out of the actual procedure room. Experience with other remote navigation system using remote magnetic navigation showed similarly a substantial reduction in radiation dose at the control station. Furthermore, because of better catheter stability and easier navigation with the robotic system, total fluoroscopy time and radiation exposure might be reduced; however, further head to head studies are needed to be able to answer this question (9–14).

Overall safety. There was one incidence of pericardial effusion related to the ablation procedure. This procedure was done with a thermocool catheter, with flow rates at 30 ml/min and power at 50 W resulting in a steam pop. The pericardial effusion occurred after PV isolation and while the operator ablated along the roof of the posterior wall with greater power than specified. We believe that, with better catheter contact and stability offered by the system, the effectiveness of ablation is increased, and one would need to reduce flow rates and maximum power in these situations. Further studies will be needed to evaluate the optimum ablation energy parameters while using a robotic system at different pressure levels and compare those to the parameters used with conventional manually operated catheters. Such a contact pressure sensor has been developed by the manufacturer (Intellisense, Bothell, Washington) and is currently being tested. This sensor was not available at the time of our study, but it will allow for the further evaluation

Table 2 Procedural Parameters Results for the Robotic System

Duration, min	Total	Atrial Fibrillation	Atrial Flutter
Procedure time	163 ± 88	189 ± 88	126 ± 56
Ablation time	89.6 ± 43	106 ± 25	56 ± 54
Fluoroscopy time	64 ± 33	83 ± 15	37 ± 35

of adequate and optimal tissue contact during navigation mapping and ablation. The second incidence of pericardial effusion was not related to ablation or the robotic system and occurred with the manual transseptal puncture.

Study limitations. In the present study, we did not compare the mapping time using the computer-controlled system to the current conventional manual method. Furthermore, the procedural timing reported in the current study reflects our initial attempts and might be expected to improve with the further experience of the operator with the system. A larger series and also longer follow-up will be needed to further assess the safety and efficacy of this technology.

Conclusions

This preliminary human experience suggests that mapping and ablation of AFL and AF with the use of this novel robotic catheter with remote control system is feasible, with similar results compared with the conventional approach. Furthermore, the use of the robotic catheter remote control system for transseptal puncture and endocardial navigation is safe and feasible. With improved catheter stability and contacts with such systems, more investigation is needed to evaluate whether different energy output parameters are needed as compared to manual and conventional ablation catheters. Moreover, its usefulness in decreasing procedure time and improving procedural success compared with current approaches requires further evaluation in randomized clinical trials. Also in the future, a comparison between this technology and remote magnetic navigation may be warranted.

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