Randomized trial comparing robotic to manual ablation for atrial fibrillation

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BACKGROUND Catheter ablation of atrial fibrillation (AF) is a physically demanding procedure for the operator, involving radiation exposure, and has limited success rates. Remote robotic navigation (RRN) may offer benefit to the procedure, though only 1 previous small randomized trial has assessed this.

OBJECTIVE This study aimed to investigate the impact of RRN on 1-year single-procedure success rates.

METHODS RRN was compared to manual ablation in a randomized control trial setting by using an intention-to-treat analysis.

RESULTS A total of 157 patients underwent ablation (116/157 (74%) persistent AF; 67/116 (58%) of these long-standing persistent AF). There were no significant differences between the RRN and manual groups with respect to 1-year single-procedure success rates (19/78 (24%) and 26/78 (33%), respectively; $P = .29$), acute wide area circumferential ablation reconnection rates, complication rates, or procedure times. On multivariable analysis, fluoroscopy times were significantly shorter in the RRN group. The number of catheter displacements during ablation was lower in the RRN group, as was subjectively assessed operator fatigue. The crossover rate from RRN to manual ablation was 11/78 (14%), mainly secondary to technical problems with the RRN system. A learning curve was evident for RRN ablation: the fluoroscopy and procedure times were significantly lower after the first 10 cases in an operator's experience.

CONCLUSION This randomized trial showed no difference in the success rate for catheter ablation of AF between a RRN and manual approach. The results highlight the learning curve for RRN ablation and suggest that the use of this technology leads to an improvement in fluoroscopy times, catheter stability, and operator fatigue.

KEYWORDS Atrial fibrillation; Catheter ablation; Remote robotic navigation; Manual ablation; Randomized controlled trial

ABBREVIATIONS **AAD** = antiarrhythmic drug; **AF** = atrial fibrillation; **AT** = atrial tachycardia; **PAF** = paroxysmal atrial fibrillation; **PeAF** = persistent atrial fibrillation; **PV** = pulmonary vein; **RRN** = remote robotic navigation; **WACA** = wide area circumferential ablation

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Introduction

Catheter ablation has become an accepted treatment modality for atrial fibrillation (AF).[1] The procedure is technically and physically demanding for the operator and involves exposure of the patient and operator to radiation.

Remote robotic navigation (RRN; Sensei X system, Hansen Medical Inc, Mountain View, CA) is a technology that may help meet the challenges of AF ablation. Only 1 small randomized trial comparing RRN to manual ablation (30 patients per study arm) has been published, including only patients with paroxysmal atrial fibrillation (PAF), with 6-month success rates of 73% for RRN and 77% for manual ablation ($P = .35$).[2] This as well as other studies suggest a benefit to RRN in terms of fluoroscopy time[2–5] and catheter stability[6] without affecting success rates.[2,4,5]

This prospective randomized study evaluated the hypothesis that the single-procedure AF ablation success rate is greater with RRN than with manual navigation.

Methods

All patients gave informed consent to participate in the study, which was approved by the UK National Research Ethics Service and reported according to CONSORT guidelines.[7] Consecutive patients listed for first-time catheter ablation of AF were allocated to manual or RRN ablation using computer-generated randomization. AF subtypes were classified as PAF, persistent atrial fibrillation (PeAF), or long-standing PeAF according to HRS guidelines,[1] with a recruitment target of 50% patients with PAF and 50% patients with PeAF. Exclusion criteria were age <18 years,

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previous AF ablation, life expectancy <6 months, pregnancy, and procedural contraindications.

Ablation procedure

Procedures were performed in the postabsorptive state under intravenous moderate sedation. In the manual group, 2 transseptal punctures were performed using an Endry's coaxial (Cook Medical, Bloomington, IN) or Brockenbrough (St Jude Medical Inc, Saint Paul, MN) needle. A circular pulmonary vein (PV) mapping catheter and an irrigated ablation catheter of the operator's choice were passed into the left atrium. In the RRN group, a 30-cm 14-F sheath was inserted into the right femoral vein (initially a shorter 14-F sheath was used, but this changed secondary to safety recommendations[8]). The ablation catheter was passed through an Artisan sheath (Hansen Medical Inc) and the assembly advanced under fluoroscopic guidance to the right atrium, with the catheter leading to reduced vascular trauma risk. A single transseptal puncture was performed and the sheath advanced through the septum for dilation and withdrawn, leaving only the outer needle across the septum. The ablation catheter and Artisan sheath were passed either manually or robotically into the left atrium through the transseptal puncture site and the original sheath passed alongside through the same puncture.

Ablation was generally performed in a temperature-controlled mode (temperature limited to 48°C and power to 30 W). The aim of each ablation was reduction in local bipolar electrogram amplitude by >80% or until <0.1 mV,[9] or, failing this, delivery of energy for up to a minute. Procedures were guided by 3-dimensional navigation systems: EnSite Classic or EnSite Velocity (St Jude Medical Inc) and CARTO XP or CARTO 3 (Biosense Webster Inc, Diamond Bar, CA).

The ablation protocol was the same in the 2 study arms. For PAF, wide area circumferential ablation (WACA) was performed to encircle ipsilateral PVs in pairs. If patients were in atrial tachycardia (AT) after WACA, the AT was mapped and ablated, but if in AF, they were electrically cardioverted. A cavotricuspid isthmus line was added only in patients with a history of typical atrial flutter. The end point for WACA was entry and exit block, which was assessed using the PV mapping catheter. Evidence of exit block was sought by pacing the PV catheter within the WACA line and confirming no conduction to the LA, although it was accepted that PV capture could not be documented in all cases. Acute WACA reconnection was assessed after a 1-hour waiting time from the completion of that WACA, with veins reisolated if necessary.

In patients with PeAF, after WACA, fractionated electrograms were targeted throughout the left atria and then right atria (as described previously[10]) until all were abolished or sinus rhythm restored. If patients remained in AF, linear lesions were added at the mitral isthmus and roof. A cavotricuspid isthmus line was added in patients with a history of typical right atrial flutter. If at any point AF organized into AT, it was mapped and ablated. If sinus rhythm was not restored after these lesions, the patient was electrically cardioverted. The PVs were rechecked at the end of the case in sinus rhythm and reisolated where necessary. Linear lesions were checked and further lesions delivered where necessary to achieve block.

During ablation, catheter stability was assessed in a semiquantitative manner similar to that described previously.[11] If during ablation, the catheter position shifted, and this dislodgment was sufficient for the operator to prematurely terminate the ablation procedure or significantly readjust ablation catheter location, it was recorded as a catheter displacement. Catheter motion secondary to respiratory motion was not counted as displacement. At procedure completion, operators assessed their level of fatigue on a subjective scale ranging from 1 to 5, with 1 being no fatigue and 5 very fatigued.

Four operators participated in the study. At the study's commencement, the operators had performed a median of 400 (range 100–700) AF ablation procedures and 10 (range 2–20) RRN AF ablation procedures. No randomization was performed with respect to operator. To explore the presence of an RRN learning curve, procedures were coded in terms of how far along in each operator's experience they were undertaken, on the basis of how many RRN ablation procedures they had performed before the trial. Therefore, if an operator had performed 5 RRN ablation procedures before the trial, their first case in the trial was coded as case 6 in their learning curve.

For RRN cases, contact force measurement was done with the sheath-based IntelliSense system native to the RRN platform and ablation procedures were performed at 5–40 g of force.

Follow-up

Antiarrhythmic drugs (AADs), including amiodarone, were discontinued predischarge, and all patients followed up at 3, 6, and 12 months. If the electrocardiogram at 3 months did not demonstrate AF/AT, a 7-day Holter monitor test was arranged before 6-month follow-up (unless the patient had a permanent pacemaker). Postprocedure, a 3-month blanking period was used. Patients with a recurrence of symptoms and/or documented AT/AF after this period were offered a repeat procedure. Complications were recorded from the time of the procedure until discharge and at follow-up visits. Complications prospectively investigated included cerebrovascular events, vascular access complications, pericardial effusion, tamponade, PV stenosis, the need for blood transfusion or surgery, hospital admission (or prolongation of hospital stay), and death. Complication severity is reported according to Heart Rhythm Society guidelines.[1]

End points

The primary study end point was single-procedure success rate at 12 months, with success defined as freedom from symptomatic AF or asymptomatic AF or AT lasting ≥30