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ROBOTIC CATHETER ABLATION OF LEFT VENTRICULAR TACHYCARDIA: INITIAL EXPERIENCE

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Abstract

Objectives—To test the technical feasibility of robotic catheter ablation of left ventricular (LV) tachycardia (VT) using the Hansen Sensei® Robotic system (HRS).

Background—Catheter ablation of VT can be technically challenging due to difficulty with catheter positioning in the LV and achieving stable contact. The HRS has been used in atrial fibrillation but its utility in VT is unclear.

Methods—Twenty-three patients underwent LV VT mapping and ablation with the HRS via a trans-septal, trans-mitral valve approach. Nineteen patients underwent substrate mapping and ablation (18 had ischemic cardiomyopathy, one had an apical variant of hypertrophic cardiomyopathy). Four patients had focal VT requiring LV VT mapping and ablation. Procedural endpoints included substrate modification by endocardial scar border ablation and elimination of late potentials, or elimination of inducible focal VT.

Results—Mapping and ablation were entirely robotic without requiring manual catheter manipulation in all patients and reaching all LV regions with stable contact. Fluoroscopy time of the LV procedure was 22.2 ± 11.2 minutes. Radiofrequency time was 33 ± 21 minutes. Total procedure times were 231 ± 76 minutes. Complications included a left groin hematoma (opposite to the HRS sheath), 1 pericardial effusion without tamponade that was drained successfully, and transient right ventricular failure in a patient with previous left ventricular assist device. At 13.4 ± 6.7 months of follow-up (range 1–19 months), recurrence of VT occurred in 3/23 patients.

Conclusions—Our initial experience suggests that the HRS allows successful mapping and ablation of LV VT.

Keywords

catheter ablation; ventricular tachycardia; robotic navigation; left ventricular assist device; hypertrophic cardiomyopathy

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INTRODUCTION

Ventricular tachycardia (VT) is a cause of significant morbidity and mortality. Therapy with implantable cardioverter-defibrillators (ICD) can significantly reduce the risk of sudden cardiac death. However, ICD shocks can reduce quality of life and are associated with increased mortality. Catheter ablation of VT has been an effective adjunctive therapy for treatment of VT.¹⁻⁴ However, this is a challenging, operator-dependent procedure during which precise catheter manipulation and stable contact during energy delivery are critical.

The Hansen Sensei robotic system (HRS) is approved for cardiac mapping in humans in the United States. It has shown feasibility in the catheter ablation of atrial fibrillation,⁵ with similar outcomes to the conventional (manual) approach.⁶ In addition, by increasing the distance of the operator from the x-ray source, it can significantly reduce radiation exposure of the operator. In general, the ultimate goal of such robotic systems is to increase the stability and precision of catheter positioning, resulting in improved efficacy and increased safety.

The technical feasibility of using HRS for mapping and ablation in the left ventricle (LV) has not been established. The aim of this study was to evaluate the feasibility of catheter ablation of LVVT using a robotic steerable guide.

METHODS

Twenty-three sequential patients at a single institution underwent ablation of LVVT using the HRS. The patient characteristics are described in the Table. Indications for catheter ablation included symptomatic VT or premature ventricular contractions (PVCs), ICD therapies including antitachycardia pacing and shocks, as well as VT storm. Three of the patients had undergone previous VT ablation procedures (without use of the HRS).

In each case, general endotracheal anesthesia was administered. Routine catheters included quadripolar catheters at the bundle of His and RV apex, a coronary sinus catheter, an intracardiac ultrasound catheter. 3D mapping was performed using the CARTO-3 electroanatomic mapping system (Biosense-Webster, Diamond Bar, CA, USA) in 14 cases. In 9 cases, the Nav-X (St. Jude Medical) system was used. Prior to trans-septal puncture, a left ventricular geometry was obtained with the ultrasound catheter using CartoSound in cases where the CARTO-3 was used. The LV was accessed via a trans-septal approach in all cases. Heparin intravenous bolus was administered just prior to trans-septal puncture in all cases, and thereafter an ACT of 350 to 400 seconds was targeted. A trans-septal puncture was performed conventionally under ultrasonographic and fluoroscopic guidance using a Preface® sheath (Cordis, Johnson and Johnson). A J-tipped wire was placed in a left-sided pulmonary vein and the trans-septal sheath and dilator were pulled back into the right atrium. The Hansen Artisan steerable sheath system was de-aired and prepped. It consists of an articulating 11.5 F inner guide extendable to up to 10.5 cm, advanced over a steerable 14F outer guide. An open-irrigated ablation catheter (NaviStar Thermocool catheter, Biosense-Webster) was loaded into the steerable sheath. The sheath and catheter were introduced to the right atrium via a 30 cm long 14 French sheath. Alignment was performed. The catheter was driven across the septum adjacent to the wire using the steerable sheath under fluoroscopic guidance in multiple fluoroscopic projections and using intracardiac ultrasound guidance using an Acunav (Siemens) intracardiac echocardiographic catheter (ICE). The IntelliSense contact pressure sensor was turned on and monitored after trans-septal crossing. Crossing the mitral valve was facilitated by counterclockwise rotation of the steerable sheath system. Catheter manipulation within the left ventricle used the Hansen remote catheter manipulator, placed remotely at a workstation located within the same room

as the patient's table. Manipulation was guided by single-plane fluoroscopy in the LAO or RAO projection and with the aid of the 3D electroanatomic mapping system and ultrasonographic guidance.

Two patients underwent epicardial mapping and one of these two patients underwent (manual) epicardial ablation in addition to robotic endocardial ablation. Induction of VT was performed using programmed stimulation. If tolerated, it was mapped in patients with focal VT. In patients with substrate-directed ablation (n=19), induced VT was terminated by pacing or cardioversion and used as a template for pace-mapping. 3D mapping of the endocardial substrate for scar (defined by bipolar voltage amplitudes less than 1.5 mV⁷) and for late potentials was performed.⁸ Ablation targeted the scar border zone particularly at sites of matching pace-maps, as well as sites within low voltage areas with late potentials, double potentials, wide fractionated potentials during sinus or paced rhythm.^{2, 7, 8} In three patients, entrainment maneuvers were performed during hemodynamically tolerated VT. Catheter ablation used 30 to 50 Watts, targeting tip temperatures to 42°C (limited to 47°C), and used 30 mL/min irrigation rate, typically 60 seconds per site.

RESULTS

Study Population

The patient characteristics are shown in the Table. They were predominantly male, and represented unselected consecutive patients that required LV VT ablation, and all patients' procedures attempted were successfully completed robotically. Eighteen of the 23 patients had ischemic cardiomyopathy. The average age of the patients was 64 years, ranging from 26 to 83. The average left ventricular ejection fraction was 33%. The indication for the ablation procedure included ICD shocks in eleven patients, one of whom had VT storm (up to 12 shocks in 1 day). Four additional patients had frequent symptomatic (near-syncope) VT episodes treated successfully with anti-tachycardia pacing. Five patients had VT associated with syncope without prior ICD implant and underwent VT ablation followed by ICD implant. Three patients had symptomatic left ventricular PVCs.

Substrate-based ablation

In general, there was little difficulty with maneuvering the catheter to any left ventricular position desired. All patients with substrate-based ablations underwent detailed maps of the entire LV geometry, and the HRS reached all areas without difficulty. As shown in the Table, a wide range of scar locations were present in the patient series. Given the limited length of the HRS, concerns about potential difficulties reaching the LV apex existed *a priori*. However, we were able to reach the apex in all cases without difficulty, including 4 cases with apical scars. Figure 1 shows an example of a substrate-based ablation in a patient with LVVT arising from a previous septal and antero-apical myocardial infarction. A detailed map of the septal and apical scar was created. Because the VT was initially tolerated, entrainment maneuvers were performed and concealed entrainment was demonstrated at the lateral edge of the apical scar, with perfect matching of the VT morphology in the electrocardiogram and short stimulus-to-QRS delays, consistent with a location close to the exit site of the tachycardia circuit. During tachycardia, recordings from inside the apical scar showed mid diastolic potentials. Ablation along the entire edge of the scar as well as sites of delayed potentials during sinus rhythm eliminated VT inducibility.

Other regions of the LV were similarly easy to reach and ablate robotically. Figure 2 shows an example of an inferior wall scar leading to VT. A detailed map of the inferior wall scar was generated. Perfect pace-maps were obtained when pacing from both the inner part of the scar as well as from the scar's edge, with long and short stimulus-to-QRS times,

respectively. Signals from these locations during VT preceded the QRS with delays that matched the stimulus-to-QRS delays during pacing, and late potentials were present during sinus rhythm. An ablation strategy consisting of ablation along the scar edge and in areas of late potentials during sinus rhythm rendered the VT non-inducible. Once the catheter was navigated to a desired location in the LV, it remained stable. Once a targeted area was reached, immobilizing the catheter system at the control console resulted in a stable catheter position that was not affected by blood flow, heart motions, or respiratory motions. This allowed demonstration of ablation lesion formation with ICE. Figures 3 and 4 show examples. In Figure 3, a detailed map of an anteroapical and apical scar had been performed. The catheter was positioned in the distal septum in direct apposition to the myocardial tissue, where it remained stable. Within 15 seconds of radiofrequency application, increased echogenicity of the myocardium adjacent to the catheter tip was present. In Figure 4, substrate-based mapping and ablation of LVVT arising from an inferolateral scar is shown, with the ablation catheter positioned in the mid-lateral wall at the edge of the scar. Catheter position was stable, and radiofrequency application led to increased echogenicity of the adjacent myocardium as monitored by ICE.

Catheter ablation of VT in the presence of a left ventricular assist device (LVAD) can be particularly challenging,⁹ due to the presence of the LVAD inflow cannula in the apex and its continuous suctioning in an underfilled LV. We performed a substrate-based ablation of LVVT in a patient with an LVAD. Figure 5 shows details of that procedure. Catheter navigation was performed uneventfully, reaching all regions of the underfilled LV, including in areas around the LVAD inflow cannula, and allowing an extensive ablation of the inferior wall scar.

Substrate-based ablation was also performed in nonischemic heart disease. One patient with the apical variant of hypertrophic cardiomyopathy posed a particular challenge to catheter manipulation. The LV hypertrophy had led to near complete cavity obliteration and he had developed progressive dilation and scarring of the apex. Reaching the apex was difficult due to the cavity obliteration. The HRS was successfully advanced into the LV apex, and scar mapping of the LV cavity was performed. Radiofrequency applications were delivered at the edge of the scar, as well as in sites of delayed potentials within the apical scar. Reaching the most distal tip of the apex was not difficult. Because the scar's border zone coincided with the distal end of the mid-cavity obliteration, ablation lesions were delivered with the catheter tip in closed apposition to surrounding myocardium, leading to increased echogenicity. Figure 6 shows details of this procedure. Additionally the ablation catheter was disengaged from the robotic sheath, and advanced further so that the sheath served as an anchor to allow additional manual manipulation of the catheter (Figure 6C).

Focal VT mapping and ablation

Four patients underwent focal LV ablation of idiopathic outflow VT (1) or symptomatic, frequent premature ventricular complexes (3). The patient with LVOT tachycardia had previously undergone 3 ablation attempts, which had failed due to difficulty in mapping the VT and in achieving stable catheter contact in the LVOT. Reaching the most basal and septal LVOT with the HRS via a trans-septal, trans-mitral approach required bending the robotic catheter, but was not difficult and was stable, allowing for a detailed activation map, perfect pace-map, and successful ablation. Supplemental Figure online shows details of this procedure.

Three patients underwent ablation of frequent, symptomatic PVCs. In one patient, these occurred in the setting of LV non-compaction cardiomyopathy. The patient had undergone two previous ablation attempts at another institution. The PVCs were mapped to the outflow tract, with signals from the right ventricle outflow tract (RVOT) preceding the QRS with

identical delay to those of the LVOT. Ablation was performed robotically at both the RVOT and the subaortic LVOT, with successful elimination of the ventricular ectopy. Figure 8 shows details of this procedure.

Acute results and ablation outcomes

Inducibility of VT was tested in 18/23 patients (5 of the patients with substrate-based ablations were not tested due to poor hemodynamic tolerance). All 18 patients were noninducible for the clinical VT at the end of the procedure by programmed extrastimulation at coupling intervals that had previously induced VT prior to ablation. In the focal VT patients, extrastimulation, burst pacing and isoproterenol were used for inducibility testing. One patient with focal PVCs had only temporary PVC suppression and required a repeat procedure (see above).

With an average of 13.4 ± 6.7 months of follow-up (range 1–19), three of the eighteen patients have had ICD therapies after ablation—in all cases, there was a significant reduction in the frequency of episodes. One patient expired 18 days after the ablation procedure after developing refractory pump failure and cardiogenic shock.

Procedural parameters

As seen in the Table, fluoroscopy time of the LV procedure was 22.2 ± 11.2 (range 8.6 to 34.1) minutes. Radiofrequency time was 33.5 ± 21.8 (range 7.5 to 61.8) minutes. Total procedure times were 231 ± 76 (range 155 to 470) minutes. All patients were ablated with a single ablation catheter. Manipulation of the catheter was entirely robotic without cross over to a pure manual or magnetic approach. In the patient with apical hypertrophy in whom some ablation was performed manually with the catheter still inserted in the robotic sheath.

Complications

One patient developed a femoral hematoma extending to the retroperitoneum that originated on the opposite side as the Hansen sheath. This originated in the arterial line puncture, was felt not to be caused by use of the Hansen system, and was managed conservatively. Another patient developed a pericardial effusion without tamponade. This effusion was slow to develop and was noted near the end of LV endocardial mapping and ablation. The patient was hemodynamically stable and a pericardial drain was placed. After obtaining pericardial access and draining the effusion, epicardial LV mapping was performed (without using the Hansen sheath system). This did not reveal sites with late potentials or a significant epicardial substrate, and no epicardial lesions were delivered. The pericardial drain was removed subsequently without further intervention.

In the patient with an LVAD, progressive right ventricular failure developed during the procedure. This was documented by ICE and responded to transient extracorporeal membrane oxygenation. The patient eventually recovered and was discharged with his LVAD and without VT recurrence.

Additionally, two patients experienced transient hypotension due to interference with mitral valve closure (and mitral regurgitation) when the Artisan robotic catheter was looped to map the basal inferior wall. Retracting slightly the catheter loop into the left atrium (with the tip still in the LV) so that the mitral valve could close corrected the hypotension.

Radiofrequency power was titrated to a maximal temperature of 47°C , and reaching up 50°C at sites where electrogram attenuation was not achieved or where temperatures remained below 36°C . There were no steam pops detected during ablation.

DISCUSSION

We report here our initial experience on the use of the HRS system in the LV for VT ablation in 23 consecutive patients. Our experience suggests the feasibility and safety of using this robotic system in performing LV endocardial mapping and ablation. The HRS is currently FDA-approved for manipulation and control of mapping catheters in EP procedures. The bulk of its use has been limited to the treatment of atrial fibrillation.^{5, 6, 10–12} In this setting, benefits have been reported in terms of reduction of fluoroscopy,^{13, 14} and rapidity of electrogram signal attenuation.¹¹ There are no detailed accounts of the feasibility of its use in the LV, although a single case has been reported.¹⁵ *A priori* doubts on its ability to reach and navigate the LV existed. The length of the steerable inner guide of 11.5 cm is sufficient to allow navigation in the atria. To reach the LV, particularly its apex, it required advancement of the outer guide across the interatrial septum and close to the mitral valve, sometimes across it as well. This, however, did not impair effective manipulation of the robotic catheter, and allowed detailed mapping of VT substrates in a variety of locations, and in challenging situations such as the presence of an LVAD or near cavity obliteration in the setting of LV hypertrophy. Perhaps as relevant as effective catheter navigation was catheter stability. Being a rigid catheter when not manipulated, the catheter retains its position in any anatomical location, mostly unaffected by blood flow or cardiac motion. This is in contrast with magnetic navigation systems, in which the catheter shaft is necessarily soft by design (in order to allow its pulling by magnetic fields), and that softness makes it subject to motion by blood flow, particularly at the LV outflow tract. The catheter remained consistently stable when not actively manipulated, and allowed effective delivery of radiofrequency ablation lesions that could be visualized real-time on ICE. Catheter manipulation using the Stereotaxis remote magnetic navigation system (Stereotaxis Inc, St. Louis, MO, USA) has been used for ablation of VT.^{16–18} These studies have demonstrated feasibility of remote navigation with similar acute success rates. However, the frequent requirement of a concomitant manual ablation (with the necessary additional cost of a second catheter) has been an important limitation.¹⁶ Further improvements in the magnetically-guided ablation catheter are undergoing investigation in VT in the STOP-VT trial (NCT00851279). There are no data to ascertain comparative advantages of different remote navigation systems, but all remote navigation systems share the advantages of reduced procedure and fluoroscopy times and operator convenience.

Potential disadvantages of the system include the need for a 14-French venous and trans-septal access, which could lead to a persistent interatrial communication. Additionally, these cases were performed by experienced operators. There is a learning curve required to become proficient with the system.⁶ In our center, our previous experience with this system exceeding 300 procedures (atrial fibrillation ablations) was an important determinant of its successful use in VT; the learning curve showed that about 35 cases were required to maximize benefits of the HRS.

A complication of retroperitoneal hematoma was noted in our series, but since it originated in the femoral artery opposite to the HRS system insertion site, it was felt to be unrelated to the Hansen system, but causation remains uncertain. Also, a complication of pericardial effusion did develop in one of our patients. This is unlikely to have resulted from catheter manipulation in the left ventricle, as accumulation of the effusion was slow and did not result in tamponade. However, this could certainly be a greater consideration with the robotic system compared to manual catheter manipulation, given the enhanced tissue contact. Contact sensing using Intellisense® was used in all cases but commonly disregarded due to consistently high force measurements when navigating in the LV. This may be related to high friction between the ablation catheter and the HRS sheath due to the

pronounced curvature imposed on the system when positioned in the LV via a trans-septal and trans-mitral approach. Thus, monitoring contact required maximal use of ICE and 3D mapping systems. Further improvements in contact sensing will be required to adequately monitor tissue contact in the LV.

Limitations

Our series was relatively small and included only 23 patients. All the procedures were performed at a single institution. We believe however, that the series includes a wide range of clinical situations and substrate locations to support general utility of the system in LVVT. Generalization of these findings to other centers and operators will require a larger study. The study was meant to demonstrate feasibility only. - A larger, randomized study would be needed to compare the efficacy of robotic VT ablation with a conventional manual approach.

Conclusions

Our data supports the utility of the HRS in mapping and ablation of LVVT via a trans-septal, trans-mitral approach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Figure 1.

Mapping and ablation of anteroapical scar-related VT. A and B show right anterior oblique and left anterior oblique fluoroscopic views of the robotic catheter system reaching the LV apex (in particular, the lateral aspect of the apex) where the LV VT substrate was found. An epicardial sheath is also present. C and D show corresponding 3D maps of bipolar endocardial voltage amplitudes, demonstrating a large scar. Sites 1 and 2 correspond to the exit site of the VT circuit and its middiastolic location, respectively. E on the left shows pacing from site 1, with concealed entrainment and post-pacing interval (PPI) identical to the VT cycle length (TCL), and stimulus-to-QRS delay identical to signal-to-QRS (S-QRS). E, on the right, shows a middiastolic potential at site 2 during VT.

Figure 2.

Mapping and ablation of inferior scar-related VT. A and B show the robotic catheter position in left and right anterior oblique fluoroscopic views, respectively. The septal aspect of the mid-inferior wall is being mapped. C, shows the 3D map of the inferior scar, with sites 1 and 2 at the border zone and in the center of the scar, respectively. D shows, on the left, the 12 lead surface electrogram of the VT. On D, mid panel, pacing from the edge of the scar (site 1) shows near-identical pace-map (numbers refer to percent QRS matching) with short stimulus-to-QRS delay (86 ms) that matched the delay from signal-to-QRS during VT at that site (right panel). These data were consistent with site 1 being the exit site of the scar in the VT circuit. E shows pacing from the center of the scar (site 2), with near-identical pace-maps, but long (162 ms) stimulus-to-QRS delay, that matched the delay from signal-to-QRS during VT at that site (mid panel). During paced rhythm, a post-systolic signal was present (right panel).

Figure 3.

Mapping and ablation of a septal scar. Stable catheter positioning allowed real-time monitoring of lesion creation on ICE. A and B show the robotic catheter position in left and right anterior oblique fluoroscopic views, respectively. The septal aspect of the apex was being mapped. C and D show ICE images before and 15 seconds after application of radiofrequency. The catheter tip is in the distal septum, where increased echogenicity is seen at the ablation site. E and F show 3D maps of the large septal and apical scar and the ablation lesions, respectively.

Figure 4. Mapping and ablation of a basal lateral scar. A and B show the robotic catheter position in left and right anterior oblique fluoroscopic views, respectively. The mid lateral wall is being mapped. C shows an ICE image showing catheter contact and lesion formation in the LV lateral wall. D shows the 3D map of the lateral scar and the ablation lesions created.

Figure 5. Mapping and ablation of an inferior wall scar in the presence of an LVAD. A, B, and C show the robotic catheter position in the right (A) and left (B and C) anterior oblique fluoroscopic views, with the catheter tip around the LVAD inflow cannula. D shows an ICE image of the LVAD cannula and the ablation catheter. E shows the 3D scar maps and ablation lesions.

Figure 6.

Mapping and ablation of an apical scar in the setting of end-stage apical hypertrophy. A, B and C show the robotic catheter position in the right anterior oblique fluoroscopic view, with the catheter tip manipulated around the apical aneurysm. C shows the robotic sheath retracted to allow additional manual catheter manipulation. D through G show ICE images of the apical aneurysm, the catheter tip in different positions, and real-time monitoring of an ablation lesion just proximal to the apical aneurysm. H and I show the 3D scar maps and ablation lesions.

Figure 7.

Mapping and ablation of subaortic PVCs. A shows the robotic catheter at the earliest mapped site in the right ventricular outflow tract in a right anterior oblique projection. B and C show the robotic catheter at the earliest mapped site of the LVOT in right and left anterior oblique fluoroscopic views, respectively. D, E, and F show ICE images with the robotic catheter in the right (D) and left (E and F) outflow tract. E and F show frames in diastole (E) and systole (F), to highlight the subaortic location of the catheter tip. The right and left earliest sites were identical in timing, and ablation was delivered from both sites. G shows the 3-dimensional map and the ablation lesions.

Table**Clinical and procedural variables**

Age (years)	64±13
Male sex (n,%)	19 (83%)
Ejection Fraction (%)	33±14
Ischemic Cardiomyopathy (n,%)	18 (78%)
Previous ICD (n,%)	19 (83%)
Indication for ablation	
ICD shocks (n,%)	11 (48%)
Symptomatic VT with ATP (n,%)	4 (17%)
Symptomatic VT (n, %)	5 (22%)
Symptomatic PVCs (n,%)	3 (13%)
Ablation strategy *	
Substrate-based (n,%)	20 (87%)
Activation mapping (n,%)	6 (26%)
Pace mapping (n,%)	15 (65%)
Entrainment mapping (n,%)	7 (30%)
Substrate location/focal origin location *	
Subaortic (n,%)	2 (9%)
Left ventricular outflow tract (n,%)	4 (17%)
Septal (n,%)	5 (22%)
Apical (n,%)	5 (22%)
Anterior (n,%)	5 (22%)
Inferior (n,%)	2 (9%)
Lateral (n,%)	5 (22%)
Posterior (n,%)	5 (22%)
Procedure time (hr)	3.8±1.2
Fluoroscopy time (min)	22±11
Ablation time (min)	33±21
Follow-up time (months)	13.4± 6.7

* Some patients had more than one