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Research Article

Robotic Ablation of Atrial Fibrillation Saves Time and Irradiation Dose

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Abstract

This analysis assesses the effect of Robotic technique on the results of ablation of paroxysmal AF.

Methods: We studied 150 patients (pts) (86 males and 64 females) having a mean age of 51.3 yrs (54 > 50, 96 below 50 yrs), who suffered from symptomatic drug refractory paroxysmal AF. Work was done in IKEM hospital in Prague. Cardiac MSCT image integration to the 3D electroanatomic LA map was used in 106 pts (70.6%, however all of them underwent intracardiac echo guided imaging during the ablation procedure. 40 pts underwent manual RF ablation using CARTO, 40 pts underwent ablation using NavX system, 70 pts underwent robotic ablation using Sensui system. Pulmonary vein isolation was done to all pts using either pulmonary vein (PV) antral isolation in 116 (77.3%) or circumferential pulmonary vein ablation in 34 pts (22.7%). All pts were followed at 3, 6, 9, and 12 months.

Results: Procedural time was significantly longer in manual (202.0 ± 19.4 minutes) compared to Robot group (146.4 ± 10.8 minutes). Total fluoroscopy time was significantly shorter in Robot group (6.9 ± 1.9 minutes) compared to non-robotic group (19.9 ± 3.1 minutes). The mean fluoroscopy dose area-product was significantly lower in Robot group (552.7 ± 194.1 μ Gy.cm2) compared to manual group (2257.2± 568.1 μGy.cm2).

Conclusions: The robotic group showed evident and clear benefit of the use of robotic navigation system in the form of much shorter total procedure time, shorter total fluoroscopy time and fluoroscopy exposure dose with less number of ablation points.

Keywords: Atrial fibrillation, Ablation techniques, Pulmonary vein isolation, Robotic ablation procedures, Radiation, Administration and dosage

Introduction

The goals of AF ablation procedures are to prevent AF by either eliminating the trigger that initiates AF or by altering the arrhythmogenic substrate [1-4]. The most commonly employed ablation strategy today, which involves the electrical isolation of the pulmonary veins by creation of circumferential lesions around the right and the left PV ostia, probably impacts both the trigger and substrate of AF [5-7]. Catheter based ablation of AF places significant demands on the skill and experience of the electrophysiologist. The objectives of developing new technologies to facilitate these procedures include precise and stable catheter navigation, reduced radiation exposure, shorter procedures, and cost effectiveness. While new technologies generally increase the cost of a procedure when they are introduced, the costs may be justified if they improve outcomes.

The Hansen Sensei robotic system (Hansen Medical Inc., Mountain View, California ®) integrates robotic technology with computed movement. The key aspect is an electromechanical manipulator that is designed to provide physicians with precise catheter control and 3-D navigation within the heart from the workstation, while the operator is away from the operating table [8]. The aim of this work was to evaluate the feasibility of catheter ablation in patients with paroxysmal atrial fibrillation using different technologies and its effect on terms of procedural efficacy and success rate

Patients and Methods

We studied 150 patients (pts) (86 males and 64 females) having a mean age of 51.3 yrs (54 > 50, 96 below 50 yrs), who suffered from symptomatic drug refractory paroxysmal

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AF. Work was done IKEM institute, Prague, Czech Republic from 2008 to 2010 as part of the doctoral degree of Dr. Amr Kamal.

Patients were subjected to the following

I- Full History Taking & Clinical Examination

II- Baseline 12- Lead Electrocardiogram (ECG)

III- Routine Laboratory Investigations

VI- Cardiac Imaging Modalities

- Chest X ray Examination
- Transthoracic Echocardiography (TTE)
- Transesophageal Echocardiography(TEE)
- Cardiac Multislice Computed Tomography (MSCT)
- Intracardiac Echocardiography(ICE)

V- Preprocedural Management

- Informed consent
- Preprocedural anticoagulation
- Preprocedural antiarrhythmic drugs

VI- Procedural management

- Vascular access
- Procedural sedation
- Procedural anticoagulation
- Double transseptal puncture
- Catheters positioning

VII- Three dimensional electroanatomic mapping

- The EnSite NavX® system (Endocardial Solutions, St. Jude Medical, Inc.)
- The CARTO mapping system (Biosense, Diamond Bar, CA, USA®)

VIII- Radiofrequency Catheter Ablation

- Robotic Catheter Navigation System (Sensei System, Hansen Medical, Inc. ®)
- Manual Catheter Ablation

XI- Post procedural management & follow up patients were followed up regularly at the outpatient arrhythmia Clinic at 3, 6, 9 and 12 months, as well as at any time for any possible attacks of arrhythmic recurrences.

Patients were followed up as regards

- Clinical symptoms
- Standard 12- lead Electrocardiogram (ECG)
- In hospital Telemetry
- 7- Day Holter Monitoring
- Outpatient Mobile Telemetry with Loop Recording

The patients were divided into three groups

- **Group C (Carto)**: Forty patients with paroxysmal atrial fibrillation who underwent ablation using CARTO technology and manual ablation.
- **Group N (NavX)**: Forty patients with paroxysmal atrial fibrillation who underwent ablation using NavX technology and manual ablation.

Group R (Robotic): Seventy patients with paroxysmal atrial fibrillation who underwent ablation using NavX technology with use of robotic catheter navigation system (Sensei System).

Integration of CT Image into CARTO Mapping System: CT image fusion with 3D Carto map was done to most of the patients; the CT image was imported into the EAM system using special software (Cartomerge™, Biosense Webster, Inc., Diamond Bar, CA, USA) (Figure 1).

Integration of CT Image into EnSite NavX Mapping System

The contrast enhanced CT image in standard DICOM format

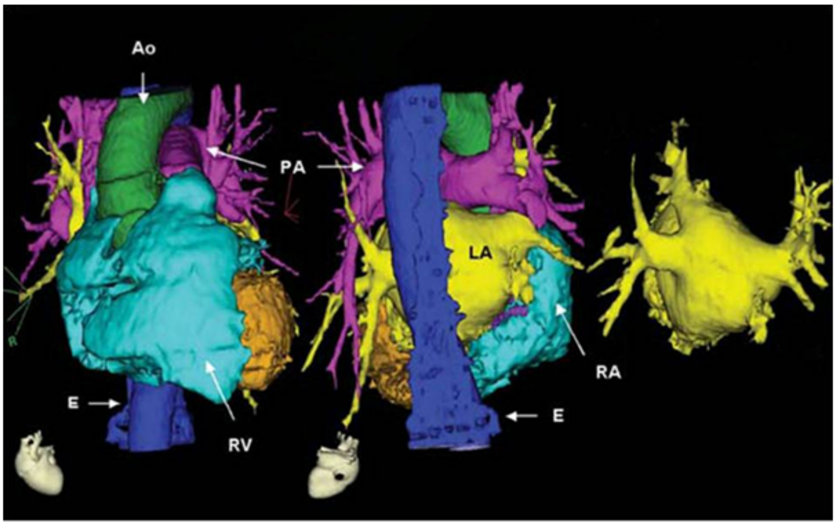


Figure 1: Segmentation process of 3D-CT image using Carto Merge Software.

was imported into the mapping system using the EnSite System software tools for digital image fusion in the same way.

Ablation Procedure: Ablation was done in all patients using the open irrigation ablation catheter in the power controlled mode either manually or after mounting on Artisan catheter for remote robotic catheter navigation system.

The end point of the ablation was the disconnection between the PV and LA, and noninducibility of AF/AFL.

Periprocedural Anticoagulation during AF Catheter Ablation: After the procedure, heparin infusion is discontinued. Warfarin therapy is restarted in all patients either the same evening of the ablation procedure or next morning. In the initial period, LMWH (e.g., Enoxaparin at a dosage of 0.5-1.0 mg/kg twice a day) is often given as bridging therapy by starting 3-4 hours after the ablation or alternatively heparin is administered intravenously until the day after the procedure, starting about 3 hours after sheath removal at a rate of 1000 IU/h. Thereafter, LMWH is administrated until the INR is ≥2. Once the therapeutic INR is achieved, LMWH is stopped, whereas warfarin is continued for at least 3 months. The anticoagulation strategy after the initial 3 months varies according to patient and procedure related factors and for most patients with a CHADS2 score of ≥2 to continue long-term warfarin treatment with a targeted INR of 2-3 is usually needed.

Cardiac MSCT image integration to the 3D electroanatomic LA map was used in 106 pts (70.6%, however all of them underwent intracardiac echo guided imaging during the ablation procedure. 40 pts underwent manual RF ablation using CARTO, 40 pts underwent ablation using NavX system, 70 pts underwent robotic ablation using Sensui system. Pulmonary vein isolation was done to all pts using either pulmonary vein (PV) antral isolation in 116 (77.3%) or circumferential pulmonary vein ablation in 34 pts (22.7%). Circumferential PV ablation was usually associated with posterior wall ablation. All pts were followed at 3, 6, 9, and 12 months.

Statistical analysis of the data

Data were fed to the computer and analyzed using IBM *SPSS software package version 20.0.* Qualitative data were described using number and percentage. Quantitative data were described using mean and standard deviation. Comparison between different groups regarding categorical variables was tested using Chi-square test. When more than 20% of the cells have expected count less than 5, correction for chi-square was conducted using Fisher's exact test. Correlations between two quantitative variables were assessed using Pearson coefficient. Significance of the obtained results was judged at the 5% level. Data was presented as Median (Min. -Max.) for abnormally distributed data or Mean ± SD. for normally distributed data.

Results

Total fluoroscopy time: Manual group vs. Robotic group 19.9 minutes vs. 6.9 minutes, P <0.000 (Table 1). 34 patients (22.6%) developed early recurrence of AF after an initial blanking period of 3 months. We had 16 patients (10.6%) with treatment failure at short term follow up, this number increased to 18 patients (12%) at midterm follow up and further small increase to 20 patients (13.3%) at long term follow up, recurrences were any episode of AF and /or AFL/AT > 30 seconds after the blanking period. The incidence of recurrence of AF in males was 13% (11/86), 14% in females (9/64), P NS.

Complications rate (Table 2): None in 92,5%, air embolism zero, cardiac tamponade zero, trivial pericardial effusion 1, groin hematoma 5%, pulmonary vein stenosis > 50% zero. No difference in complications between robotic and manual groups.

Long term success rate

The primary efficacy endpoint was complete success with no recurrences from 9 months and up to 12 months after ablation procedure without use of AAD in 77.5% of manual group and 85.7% in Robot group. Long term comprehensive success was also calculated from 9 months and up to 12 months after ablation procedure as the sum of primary and secondary efficacy endpoints, reflecting the reduction of AF burden, it was 82.5 % for manual group and 91.4 % for Robot group (Table 3).

Table 1: Comparison between manual and robotic groups as regards ablation points.

	Groups	No of Patients	Mean	P
Total no. of ablation points	Manual Gr	80	72	0.000
	Robotic Gr	70	49.9	
Total ablation time	Manual Gr	80	2094	0.000
	Robotic Gr	70	1323	
Total fluoroscopy time	Manual Gr	80	19.9	0.000
	Robotic Gr	70	6.9	
Total fluoroscopy dose	Manual Gr	80	2257	0.000
	Robotic Gr	70	552	

Table 2: Comparison between manual and robotic groups as regards complications.

Complications	Manual group (n = 80)		Robotic group (n = 70)		X2	P
	No	%	No	%		
No complications	74	92.5	66	94.4	0.432	0.692
Trivial pericardial effusion	2	2.5	0	0	1.332	0.235
Cardiac tamponade	0	0	0	0	0.000	1.000
Air embolism	0	0	1	1.4	0.647	0.622
Small groin hematoma	4	5	3	4.2	0.236	0.134
Thromboembolism	0	0	0	0	0.000	1.000

Table 3: Comparison between the three groups as regards procedural efficacy and success rate.

Efficacy	Group C (n = 40)		Group N (n = 40)		Group R (n = 70)		X2	P
	No	%	No	%	No	%		
Short term								
Good (without AAD)	32	80	30	75	54	77.1	1.646	0.801
Average (with AAD)	4	10	4	10	10	14.3		
Comprehensive success	36	90	34	85	64	91.4		
Failure	4	10	6	10	6	8.6		
Mid term								
Good (without AAD)	30	75	32	80	58	82.9	2.161	0.706
Average (with AAD)	4	10	2	5	6	8.6		
Comprehensive success	34	85	34	85	64	91.4		
Failure	6	15	6	15	6	8.6		
Long term								
Good (without AAD)	30	75	32	80	60	85.7	3.014	0.555
Average (with AAD)	2	5	2	5	4	5.7		
Comprehensive success	32	80	34	85	64	91.4		
Failure	8	20	6	15	6	8.6		

Discussion

Catheter ablation of AF is now a realistic therapeutic option for patients with paroxysmal AF. [9] In this study, one hundred and fifty patients were enrolled for catheter ablation of symptomatic paroxysmal AF who had failed at least one antiarrhythmic drug.

Multivariate analysis of predictors of success in Group C (Carto)

In our study, a multivariate analysis of predictors of success for patients with paroxysmal AF who underwent ablation using Carto 3D EAM technology and manual ablation was done and different variables were evaluated as regards their significance as predictors of success.

The significant predictors of success in Carto group were PV antral isolation as the used method of eliminating PV triggers, PV antrum as a target PV ablation site, early recurrence during blanking period, rhythm outcome, baseline ECG, duration of AF and additional ablation line (roof line) in order, while other predictors were not significant.

Zhong et al. [10] was very strict in conclusion and showed that Carto Merge system is inaccurate and they suggested that this inaccuracy may be reduced by using CT and electroanatomic images obtained at the same point in the atrial mechanical cycle. Accuracy was significantly improved when the end-atrial contraction CT image was used for registration.

Multivariate analysis of predictors of success in NavX (N) group

In our study, a multivariate analysis of predictors of success for patients with paroxysmal AF who underwent ablation using NavX 3D electroanatomic mapping (EAM) technology and manual ablation was done and different variables were evaluated as regards their significance as predictors of success.

The significant predictors of success in NavX manual group were early recurrence during blanking period, rhythm outcome, LV EF (systolic heart failure (HF), baseline ECG, test for AF inducibility, additional ablation line (roof line), diabetes mellitus, and hypertension in order, while other predictors were not significant.

Multivariate analysis of predictors of success in Group R (Robot)

In our study, a multivariate analysis of predictors of success for patients with paroxysmal AF who underwent ablation using NavX 3D EAM technology and Robotic ablation was done and different variables were evaluated as regards their significance as predictors of success.

The significant predictors of success in Robot group were early recurrence of AF during blanking period, rhythm outcome, LV EF, systolic HF, test of AF inducibility, baseline ECG, hypertension and duration of AF in order, while other predictors were not significant.

Robotic Catheter Navigation System

In the present study it was evident that the major advantage of robotic navigation as compared to manual navigation is catheter stability (Figures 2 and 3). It is obvious from our observations

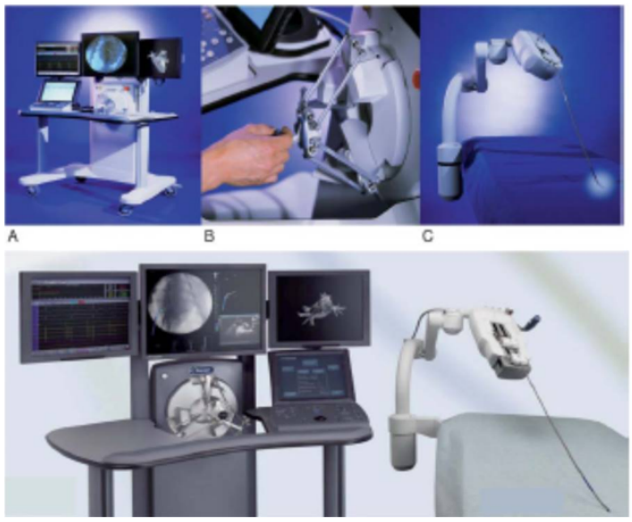
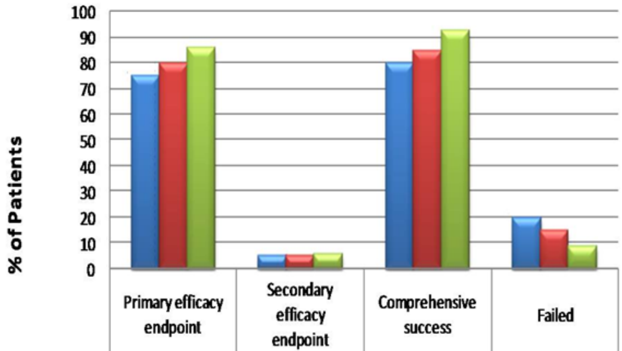


Figure 2: Hansen Robotic System.



	Primary efficacy endpoint	Secondary efficacy endpoint	Comprehensive success	Failed
Carto group	75	5	80	20
NavX group	80	5	85	15
Robot group	85.7	5.7	92.4	8.6

Figure 3: Comparison of efficacy between the three groups.

that robotic navigation system is proved to be safe and feasible with same has been proved on experimental studies [11,12] and on early human experience reported in literature [8,13-17].

Owing to the precise catheter navigation in conjunction with better catheter stability of the robotic navigation system, patients in the robotic arm of this study needed less RF applications as well as much less RF time, when compared to the other two groups of manual ablation, and these findings was independent on the type of the three dimensional LA map.

In our pooled data analysis, the total number of ablation points was significantly higher in manual group (Carto and NavX) (72.2 ± 29.4) compared to Robot group (49.9 ± 12.6). Moreover, the total ablation time was significantly higher in manual group (Carto and NavX) (2094.8 ± 911.7 seconds) compared to Robot group (1323.1 ± 355.6 seconds).

Conclusions

The ideal ablation strategy for Atrial Fibrillation (AF) uses the least amount of ablation needed to achieve the highest possible success rate. Comparison of the manual groups (group C and group N) showed that use of Carto technology was associated with greater number of ablation points and longer total ablation time for a comparable set of lesions, however this was not translated into either a significant difference in procedural time or procedural outcome and complications rate was comparable between the 2 groups with no significant difference. Robotic navigation system could perform ablation procedures in a substantially equivalent manner to conventional manually controlled catheters; however, the remote robotic navigation system would be able to overcome the limitations of manual control by combining the ease of navigation with a readily available wide navigational field. In addition, it will reduce the physician's radiation exposure during long procedures of electrophysiologic study and catheter ablation.

Remote robotic catheter navigation system can add precise catheter control, stability and maneuverability to electrophysiology mapping and ablation procedures. These features, coupled with the added safety of IntelliSense and the potential of lesion and map optimization using catheter tissue interface pressure, make robotic catheter control an attractive option for the modern EP lab.

Robotic ablation was associated with significantly lower fluoroscopy exposure well as significantly shorter overall procedure time.

Robotic ablation is as effective and safe as manual ablation with very low procedural and post procedural complication rates.

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