



Contents lists available at ScienceDirect

Indian Pacing and Electrophysiology Journal

journal homepage: www.elsevier.com/locate/IPEJ

Safety and feasibility of atrial fibrillation ablation using Amigo[®] system versus manual approach: A pilot study



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ARTICLE INFO

Article history:

Received 7 August 2017

Accepted 24 October 2017

Available online 1 November 2017

Keywords:

Atrial fibrillation

Catheter ablation

Remote robotic ablation

ABSTRACT

Background: The Amigo[®] Remote Catheter System is a relatively new robotic system for catheter navigation. This study compared feasibility and safety using Amigo (RCM) versus manual catheter manipulation (MCM) to treat paroxysmal atrial fibrillation (PAF). Contact force (CF) and force-time integral (FTI) values obtained during pulmonary vein isolation (PVI) ablation were compared.

Methods: Forty patients were randomly selected for either RCM (20) or MCM (20). All were studied with the Thermocool[®] SmartTouch[®] force-sensing catheter (Stc). Contact Force (CF), Force Time Integral (FTI) and procedure-related data, were measured/stored in the CARTO[®]3.

Results: All cases achieved complete PVI without major complications. Mean CF was significantly higher in the RCM group (13.3 ± 7.7 g in RCM vs. 12.04 ± 7.42 g in MCM $p < 0.001$), as was overall mean FTI (425.6 gs \pm 199.6 gs with RCM and 407.5 gs \pm 288.0 gs in MCM ($p = 0.007$) and was more likely to fall into the optimal FTI range (400–1000) using RCM (66.1% versus 49.1%, $p < 0.001$). FTI was significantly more likely to fall within the optimal range in each PV, as was CF within its optimal range in the right PVs, but trended higher in the left PVs. Freedom from atrial tachyarrhythmia was 90.0% for the RCM and 70.0% for the MCM group ($p = 0.12$) at 540 days follow-up.

Conclusions: This pilot study suggests that use of the Amigo RCM system, with Stc catheter, seems to be safe and effective for PVI ablation in paroxysmal AF patients. A not statistically significant favorable trend was observed for RCM in term of AF-free survival.

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1. Introduction

Radiofrequency (RF) catheter ablation has emerged as an important part of the clinician's armamentarium for treating drug-refractory atrial fibrillation (AF) [1]. It is a potentially curative procedure, with a relatively high success rate and low complication rate [1]. Pulmonary vein isolation (PVI) has been shown to be effective in treating paroxysmal AF, while persistent AF or AF in the presence of other underlying heart disease may require more complex ablation of not only the pulmonary veins (PVs), but of other ectopic foci as well [2].

Despite many advances, drawbacks remain. Recurrence rates after AF ablation remain relatively high, often necessitating additional procedures and/or maintenance on antiarrhythmic drugs. For

the operator, many lengthy ablation procedures result in significant radiation exposure and the associated risks [3]. Moreover, the precise nature of the procedure requires a particular expertise to maneuver the catheter to the proper locations, and to maintain the catheter stability and the appropriate contact force (CF) necessary to safely create effective transmural lesions without complications [4].

Systems have been developed for remote catheter manipulation during an ablation procedure, allowing the clinicians to perform the ablation from outside the radiation field. Remote systems hold great theoretical promise for addressing many of existing clinical and procedural issues [5]. Currently available systems use either magnetic fields or electromechanical (robotic) means to accomplish the catheter manipulation [6]. In addition to the potential benefits, these systems have also raised some concerns, and the available data has not yet compellingly demonstrated clinical benefits [7].

The Amigo[®] Remote Catheter System (Catheter Precision Inc.,

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Peer review under responsibility of Indian Heart Rhythm Society.

Ledgewood, NJ, USA) is a relatively new robotic (electromechanical) system for catheter navigation that allows the use of standard catheters and sheaths. Previously published studies, using the system for a variety of electrophysiologic procedures, have reported good results in terms of efficacy and safety [8–12]. The present study is the first designed to use a force-sensing catheter to compare force-related parameters during atrial fibrillation ablation using the Amigo robotic system vs. manual catheter manipulation.

2. Methods

Study objectives. The primary objective of this study was to compare the contact force (CF) and force-time integral (FTI) values obtained during pulmonary vein isolation (PVI) ablation procedures for PAF using the Amigo RCM system versus manual catheter manipulation.

Study population. This study included patients from the general population of patients referred to our center for pulmonary vein isolation (PVI) to treat AF. Forty consecutive patients (pts) scheduled for radiofrequency PVI for paroxysmal AF were selected with one to one ratio to receive a RCM procedure (20 pts) or the same procedure using MCM (20 pts) from October 2014 to July 2015. Written consent was obtained from all patients prior to the scheduled procedures.

Baseline non-invasive evaluation for all patients consisted of: 12-lead electrocardiogram (ECG) and transthoracic echocardiography with assessment of cardiac chamber volume, left ventricular and valvular function. Moderate to severe left atrial dilation (anteroposterior diameters > 55 mm) was an exclusion criterion. All patients underwent transesophageal echocardiography to examine the left atrial appendage for clots that would preclude the ablation procedure.

2.1. Equipment

All manual and robotic procedures were performed using a Thermocool® SmartTouch® ablation catheter (STc) (Biosense Webster Inc., Diamond Bar, California). The Amigo system, which has been previously described in detail [8,12], consists of a robotic arm mounted on the rails at the foot of the procedure table and a remote controller connected to the robotic arm via a cable [Fig. 1]. A standard RF ablation catheter is introduced into the patient's right femoral vein through a conventional introducer (8F, 21 cm length), and is advanced into the cardiac chamber of interest. The catheter's

control handle is then inserted into the Amigo docking station, which is specially designed for that control handle. At that point, the operator can retreat to the control room, out of the fluoroscopy field, and can control catheter movements (advancement and retraction, deflection, and rotation) with the remote controller, which imitates the operation of the conventional handle. At any point during the procedure, the catheter can be removed from the robotic arm's docking station for manual manipulation, and then reattached to the robotic arm, without breaking sterility.

Mapping/ablation procedure. All procedures were performed by two experienced electrophysiologists. Before starting enrollment these physicians performed 10 AF and atrial flutter robotic ablations. Patients were studied in a state of consciousness; analgesic drugs were administered as required.

A deflectable decapolar catheter (EZ Steer™ D-F curve; Biosense Webster Inc.) was placed in the coronary sinus for all procedures. After transeptal punctures a bolus of unfractionated heparin was immediately administered, followed by a continuous heparin infusion to maintain an activated coagulation time of >300 s. Three-dimensional reconstruction of the left atrium was obtained by manual manipulation of a circular mapping catheter (Lasso 25-15; Biosense Webster Inc.). The STc force-sensing ablation catheter was manually advanced into the left atrium. For robotic procedures, the catheter was connected to the Amigo robotic arm and all further manipulation was accomplished with the use of the remote controller. The catheter was held in a non-contact position, and the force sensor was calibrated to zero. Respiration gating was achieved using the CARTO 3 system's AccuResp algorithm and the VisiTag module was used to display the contact force and to calculate and store the FTI. The STc was used to complete the ablation procedure and point by point technique was used in both groups.

Contact force and procedural endpoints. The CARTO 3 SmartTouch 3D module was used to visualize the force applied to the tissue by the catheter tip. PVs were ablated point by point in a continuous circumferential lesion set using standard setting: RF power was set at 30 W with a maximum temperature limit of 43 °C with irrigation using saline infusion at the rate of 30 ml/min. Power was reduced to 25 W if the patient complained of pain. RF energy was delivered, whenever achievable, with a contact force value within the predefined range of 10–40 g. If a contact force of 10 g was not achievable, ablations were started with minimum 5 g; in all cases, an attempt was made to limit the maximum contact force to 40 g, which, as described in our previous paper [13], has been shown to provide a clinically acceptable balance between safety

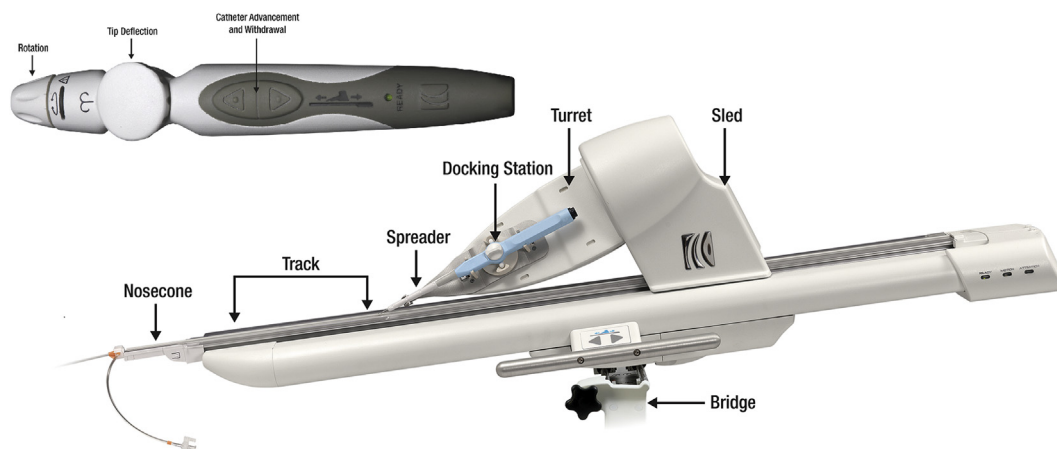


Fig. 1. Amigo Remote Catheter System robotic arm with a catheter loaded into the device and the Amigo remote controller. (From Khan 2013).

and efficacy of lesion creation. The duration of the RF energy delivery was timed to achieve an FTI (the integral of the contact force and the duration of the application of RF energy) of at least 400 gs as indicated by VISITAG with settings of 3 mm per 10 s. The procedural goal was to achieve complete electrical isolation of the pulmonary veins, as demonstrated by bidirectional conduction block and no evidence of spontaneous PV connection 30 min after ablation.

The force-time integral is a measure of delivery of RF energy transfer that takes into account the stability of the catheter-tissue interface throughout the RF application (i.e., the CF), as well as the duration of the energy delivery. For the purposes of this study, a range of 400 gs (the established procedural target value) to 1000 gs was considered the optimal FTI range. Values that fell outside of the optimal range were categorized as very low (<100 gs), low (100–399 gs), high (1001–2000 gs), or very high (>2000 gs).

Follow-up. After the blanking period (90 days), patients were followed up at 3, 6, 9, 12, 15 and 18 months. At all clinical visits a standard 12 lead ECG was obtained, and 24 h Holter monitoring was performed at 6, 12 and 18 months. Arrhythmia recurrence was defined as observation of an atrial arrhythmia (AF/atrial flutter (AFL)/atrial tachycardia (AT) of at least 30 s documented by ECG or Holter monitoring [1]. All patients received a IC antiarrhythmic drug (flecainide or propafenone) during the blanking period; after the blanking period, antiarrhythmic agents were discontinued. Anticoagulant therapy was administered to all patients for at least 3 months, starting the day after the procedure and continued after the 3 months blanking period only in those patients with CHA₂DS₂VASc score ≥ 2 .

Statistical analysis. Statistical analysis of force data for each ablation lesion was performed using Wizard for Macintosh version 1.8.16. Student's t-test was used to compare RF time, mean contact force and force-time integral between the Amigo-controlled and manually-controlled catheter cohorts. Categorical assessment of lesion creation was done using chi square analysis. Force-time integral data for each lesion were classified according to an arbitrary schema, which comprised five categories: "very low" (<100 gs), "low" (100–399 gs), "good" (400–1000 gs), "high" (1001–2000 gs), and "very high" (>2000 gs). The contact force assessment comprised three categories: "low" (<10 g), "good" (10–40 g), and "high" (>40 g). All analyses were performed for all lesions within each cohort, as well as by individual pulmonary vein. Kaplan-Meier atrial arrhythmia-free survival post-blanking for the RCM and MCM patients was calculated.

3. Results

Population. Forty patients (mean age 54.2 ± 9.22 years; 77.5% male) were enrolled in the study, 20 in the remote catheter manipulation (RCM) group and 20 in the manual catheter manipulation (MCM) group, with the selection of patients as described above. Baseline clinical characteristics are summarized in Table 1. The patients in the RCM and MCM groups were similar in terms of demographics, medical history, cardiac status, and medical therapy at the time of the ablation procedure; no statistically significant differences were noted.

Procedural data. Operator fluoroscopy (fluoro) exposure was respectively 373.1 ± 160.9 s for RCM procedures while 776.2 ± 477.4 s for the MCM procedures ($p = 0.003$). Patient fluoroscopy exposure was also reduced (RCM 439.8 ± 134.70 vs. MCM 776.2 ± 477.4 ; $p = 0.008$). Total procedure time, defined as the time from the first puncture to the removal of the introducers, was similar for both groups (RCM 148.8 ± 22.1 min vs. MCM 161.2 ± 31.8 min; $p = \text{NS}$). No complications occurred in any patient during the procedure.

Ablation data. All ablation procedures in the RCM and MCM groups were successful, with complete isolation of all pulmonary veins, and no major procedure-related complications were reported; one patient in the MCM group had a mild pericardial effusion resolved with the administration of medical therapy. No patients in the RCM group had to transition to manual catheter manipulation during the procedure to successfully complete the procedure.

Contact force and FTI data were analyzed for the RCM and MCM groups overall, and for RF applications in each PV.

The average contact force (ACF) was respectively 13.23 ± 7.86 for the RCM-S group and 12.04 ± 7.42 for the MCM group ($p < 0.01$). Contact force in target range (10–40 g) was 56.4% with RCM and 51.5% with MCM ($p < 0.01$) [Fig. 2]. The ACF generated was significantly higher for lesion creation in the right inferior pulmonary vein (RIPV) and right superior pulmonary vein (RSPV), and equivalent in the left inferior and left superior veins (LIPV and LSPV). ACF data are shown in Fig. 3.

FTI for all lesions was $425.62 \text{ gs} \pm 199.6$ in the RCM-S group and 407.49 ± 288.0 the MCM group ($p = 0.007$); the mean data is graphically depicted in Fig. 4. FTI values for each PV are shown in Fig. 4: 1) LSPV: RCM 420.14 ± 165 gs vs MCM 445.85 ± 338 gs, $p = \text{NS}$ 2) LIPV: RCM 398.7 ± 267.72 gs vs MCM 338.27 ± 201.69 gs $p = 0.007$ 3) RSPV: RCM 442.8 ± 173.45 gs vs MCM 438.69 ± 270.70 gs, $p = \text{NS}$ 4) RIPV: RCM 435.95 ± 199.99 gs vs

Table 1

Baseline patient characteristics. The remote catheter manipulation group (RCM) and manual catheter manipulation group (MCM) were well matched for demographics, medical history, cardiac medications, and hemodynamics.

	RCM Group (n = 20)	MCM Group (n = 20)	p value
Age (years; mean \pm SD, range)	54.2 ± 9.22 , 41–79	53.4 ± 8.58 , 38–70	P=NS for all parameters
Male (n/%)	15/75	16/80.0	
Patient history			
CHA ₂ DS ₂ -VASc (mean \pm SD)	1.12 ± 1.37	0.9 ± 1.18	
Hypertension (n/%)	9/45.0	10/50.0	
Diabetes-Type II (n/%)	3/15.0	2/10.0	
Dyslipidemia (n/%)	5/25.0	6/30.0	
Baseline medications (n/%)			
Class IC antiarrhythmics	12/60.0	13/65.0	
Amiodarone	1/5.0	1/5.0	
Oral anticoagulants	20/100.0	20/100.0	
ACE inhibitors/ARBs	7/35.0	8/40.0	
Beta blockers	8/45.0	8/45.0	
LVEF (%; mean \pm SD)	61.0 ± 3.41	59.8 ± 2.64	
LA diameter (mm; mean \pm SD)	39.76 ± 2.16	39.45 ± 1.83	

Key: SD = standard deviation; RCM = robotic catheter manipulation; MCM = manual catheter manipulation; LVEF = left ventricular ejection fraction; LA = left atrium.

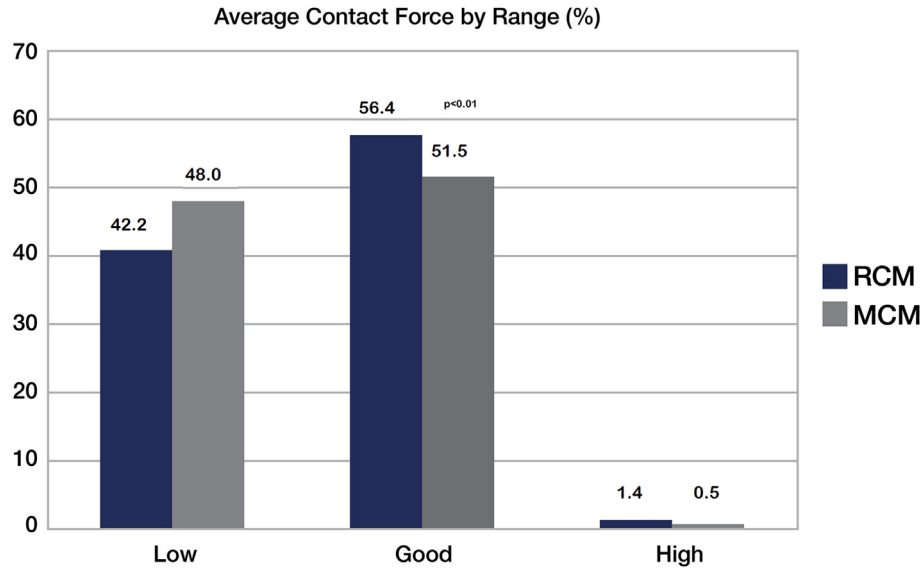


Fig. 2. Average contact force ranges generated by remote catheter manipulation (RCM) vs. manual catheter manipulation (MCM) for all pulmonary veins. Low <10 g; Good 10–40 g; High >40 g. Significantly more patients in the RCM-S group achieved an average contact force within the target range ($p = 0.001$).

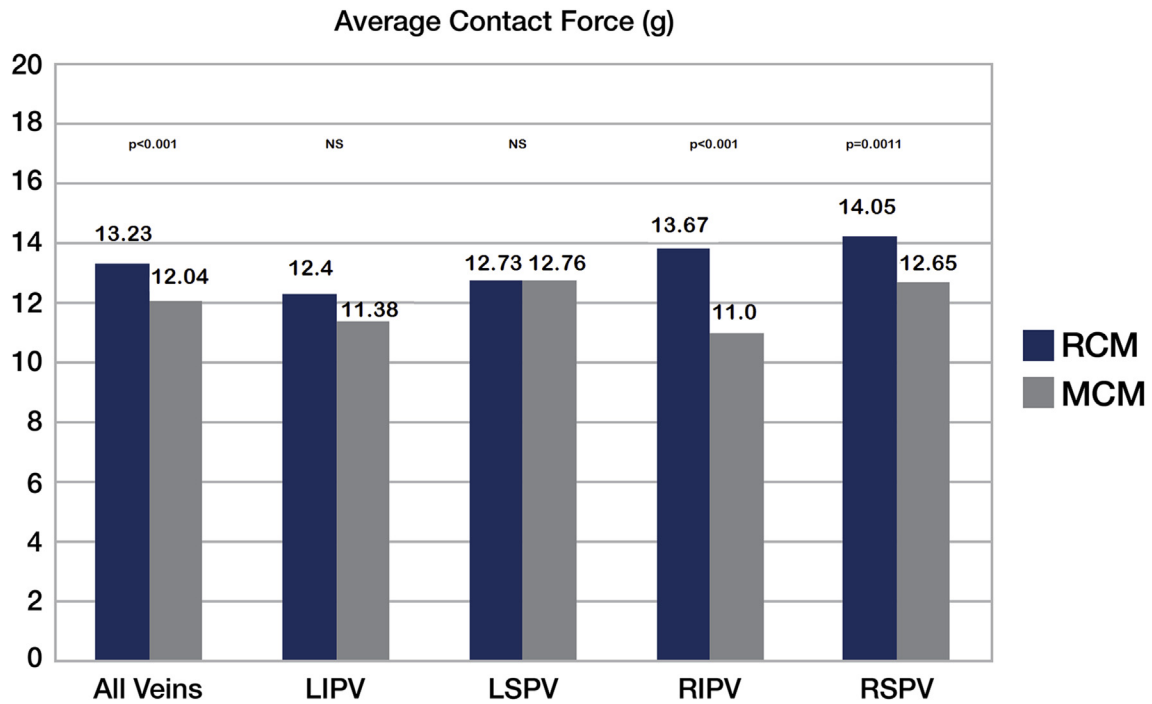


Fig. 3. Average contact force for the overall study populations and by pulmonary vein. Remote catheter manipulation (RCM) generated significantly greater contact force in the two right-sided pulmonary veins and overall as compared to manual catheter manipulation (MCM); contact force was statistically equivalent in the two left-sided pulmonary veins.

MCM 383.82 ± 291.40 gs, $p = 0.016$. The likelihood to achieve the optimal FTI (400–1000 gs) versus range was 66.1% for the RCM-S group while 49.1% for the MCM group ($p < 0.001$) as shown in Fig. 5.

Follow-Up. Patients were followed according to the schedule and procedures previously described. Kaplan-Meier atrial arrhythmia-free survival post-blanking for the RCM and MCM patients is compared in Fig. 6.

At 540 days of follow up a favorable, but not significant outcome (AF free survival) in RCM group was observed.

In the RCM study group, successful clinical outcomes were noted in 18 of the 20 patients (90%). One RCM patient required an

additional ablation procedure at approximately 13.5 months after the initial procedure, with small areas of reconnection found in the LSPV, LIPV and RSPV. There were no late procedure-related complications in the RCM group. Among MCM patients, 14 of 20 patients (70.0%) had successful clinical outcomes. One patient had an arrhythmia recurrence at the end of the blanking period, which was managed by pharmacological cardioversion to sinus rhythm and further reinstating antiarrhythmic drug therapy. The four remaining clinical failures had recurrences of their atrial tachyarrhythmias, and required repeat ablation procedures at times ranging from approximately 3.5–9.5 months after their original

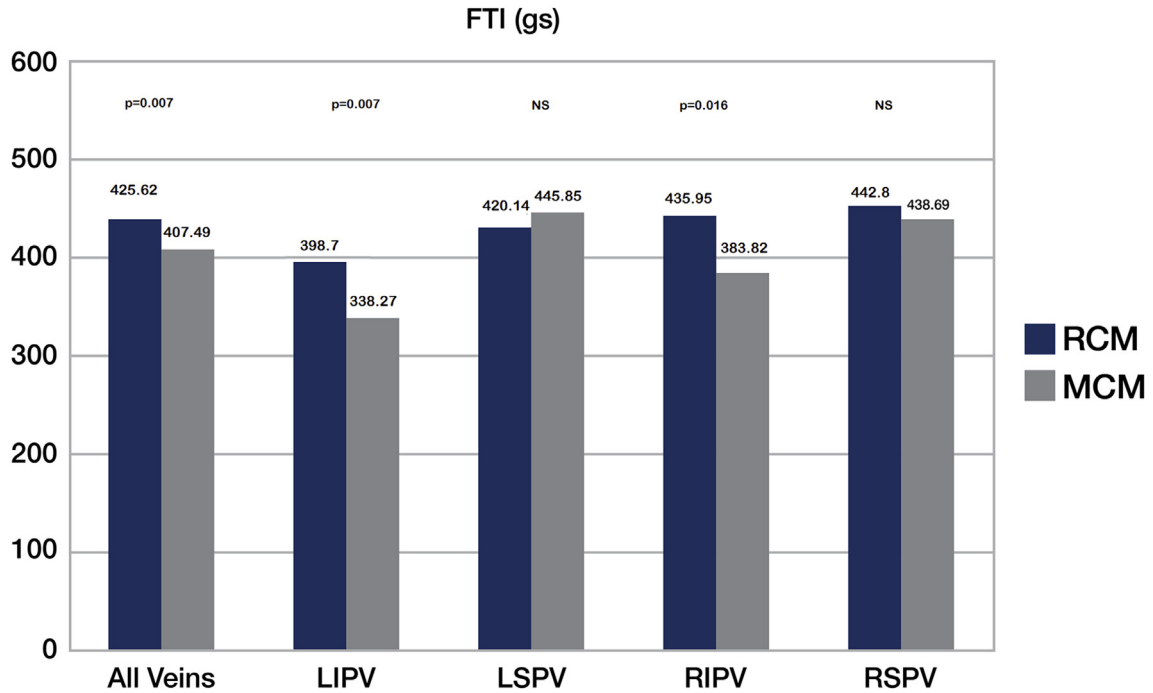


Fig. 4. Force-time integral (FTI) for the overall study populations and by pulmonary vein. Remote catheter manipulation (RCM) generated statistically higher FTI values vs. manual catheter manipulation (MCM) for the overall population, as well as in the left and right posterior pulmonary veins.

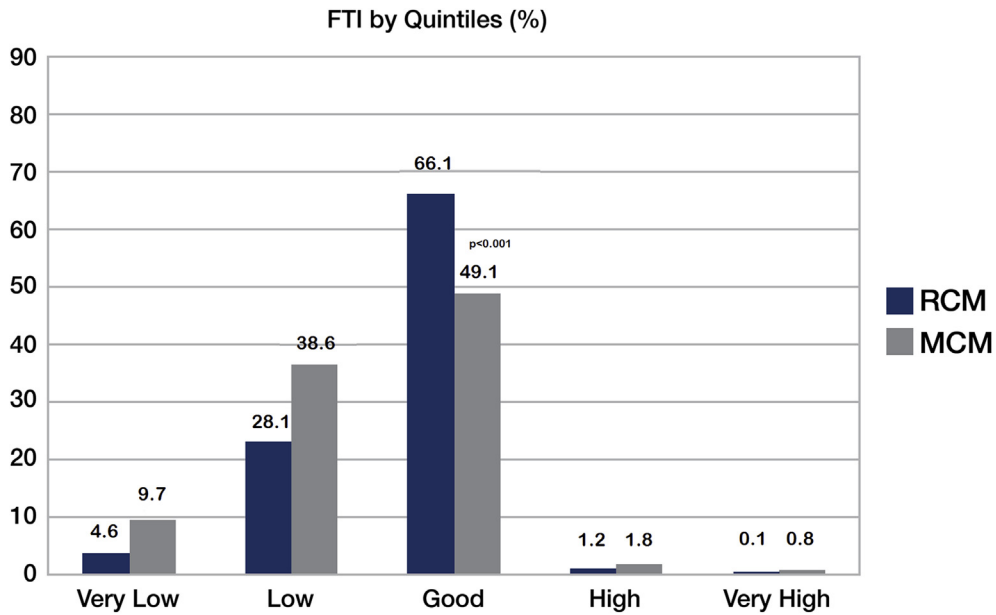


Fig. 5. Force-time integral (FTI) ranges generated by remote catheter manipulation (RCM) vs. manual catheter manipulation (MCM) for all pulmonary veins. Very Low <100 gs; Low 100–400 gs; Good 400–1000 gs; High 1000–2000 gs; Very High >2000 gs. Remote catheter manipulation was 47% more likely to produce an FTI in the target range than manual manipulation.

procedures; three of those were found to have reconnection at sites in all four pulmonary veins; one had reconnections in the LIPV, RSPV, and RIPV.

4. Discussion

Main finding. To our knowledge, the present study is the first comparing procedural acute data of contact force-guided pulmonary vein isolation for paroxysmal AF ablation performed using the Amigo Robotic Catheter System versus standard manual catheter

manipulation; additionally it provided follow up outcomes.

Historical perspective. Although many advances have been made over the years, including three-dimensional electro-anatomical mapping systems, improvements in catheter design and techniques, and the use of intracardiac echocardiography to visualize sensitive anatomic structures [7,14] significant issues in AF ablation procedures remain. The nature of the procedure requires the expertise to maneuver the catheter to the requisite positions, and to maintain the steady and continuous contact with endocardial tissue required to ensure the creation of transmural lesions

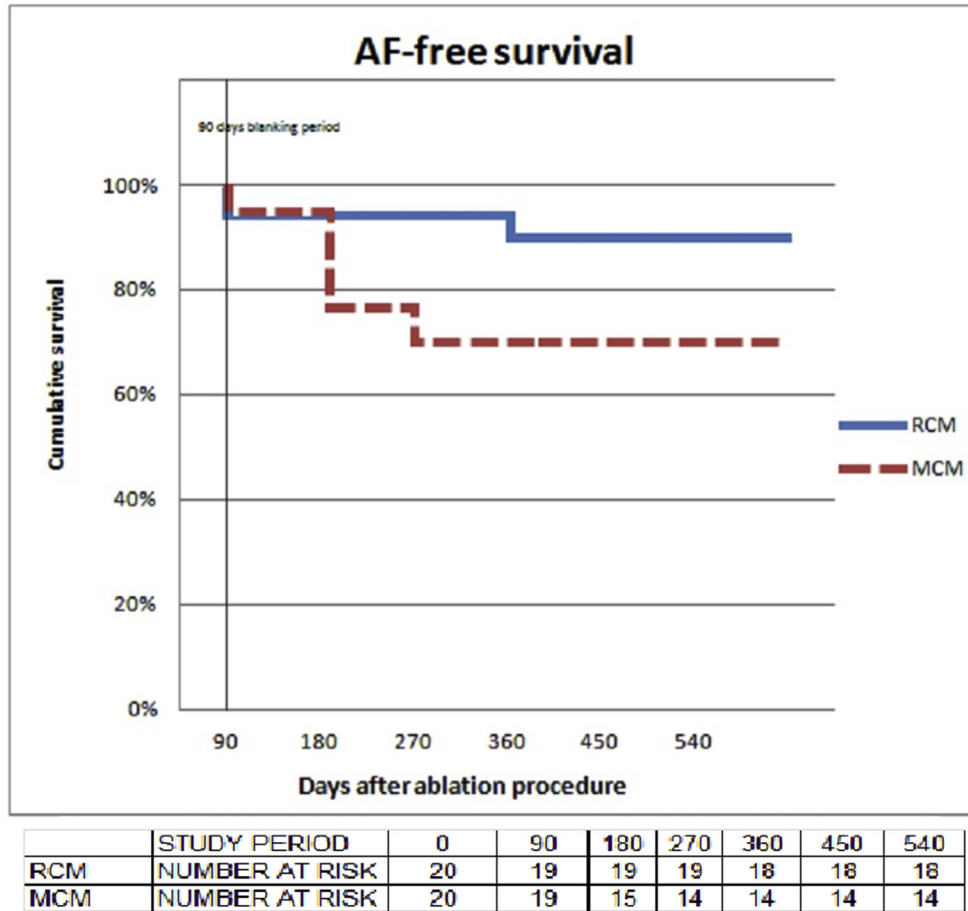


Fig. 6. Kaplan-Meier freedom from AF during post-blanking follow-up.

without adverse events. Arrhythmia recurrence rates after AF ablation remain relatively high and often require additional ablation procedures, continued administration of antiarrhythmic drugs, and more frequent emergency room visits [15]. The procedure can be extremely lengthy, exposing the operator to radiation. The exposure to X-ray radiation is higher among interventional cardiologists than any other medical specialty, and may be responsible for a greater incidence of brain and neck tumors in that group [3]. The Amigo system is a relatively new robotic tool for remote catheter navigation, which was designed to mitigate some of the shortcomings of previous RCM systems. The robotic system is portable, and can be mounted on the rails at the foot of the procedure table. It does not interfere with the mapping system, and uses standard ablation catheters and introducer sheaths. Because no part of the robotic system enters the patient, the operator can switch back and forth between RCM and MCM without compromising sterility. The remote controller closely mimics the standard catheter control handle, allowing the operator to intuitively maneuver a familiar catheter, which moves in a manner familiar to the operator, thus requiring a relatively short learning curve [11]. In a first multicenter non-randomized mapping trial, the authors demonstrated that this system was safe and effective for positioning the catheter at pre-specified target sites within the right atrium and ventricle [10]. In a sub-analysis, the same authors reported a short learning curve in the use of Amigo system as demonstrated by the reduction of manipulation time and total fluoroscopy time over the first 3-4 cases [11]. Gil et al. [8] recently used the Amigo system to perform a series of 60 typical atrial flutter

ablations, achieving a successful procedure in 98% of the patients without any complication related to the remote catheter manipulation system. Additionally Datino et al. [9] evaluated the use of this remote catheter manipulation system in a cohort of 50 consecutive patients referred to ablation procedure for different types of arrhythmias in comparison to 50 matched manual ablation procedures during the same time period. They observed no differences between the two groups in term of efficacy, safety, procedural time, or patient fluoro time, while operator fluoroscopy exposure time was significantly reduced in Amigo group [9]. However, none of these previous studies provided a quantitative evaluation of the contact force applied to the cardiac tissue during the ablation procedures.

Contact force (CF) and force-time integral (FTI) findings. A target contact force range of 10-40 g was used by the operators in both arms of the study to determine when an adequate, but not excessively aggressive, catheter-tissue interface was achieved. This range is consistent with other studies that have sought to define a CF that is safe, yet ensures the creation of transmural lesions [16]. A post-hoc analysis of the data, using the same values to define the optimal CF range, was used to evaluate the ability to maintain CF in the optimal range during the delivery of RF energy. Similarly, the in-procedure force-time integral (FTI) goal of 400 gs and the post-hoc analysis optimal range of 400-1000 gs are consistent with previous findings [4]. It has previously been postulated that the routine use of CF-sensing catheters with MCM might improve the operator's ability to obtain and maintain better catheter-tissue contact, thus improving the ability to create transmural lesions [17]. Findings of

the present study lend credence to the argument that RCM using the Amigo system may enhance catheter stability/contact quality and force application during the application of RF energy; a recently published subanalysis of the SMART-AF Trial data and its accompanying editorial [18,19] postulated that, “contact quality, not just the absolute quantity of CF is likely a significant contributor to procedural success.” The statistically higher contact force and FTI values with RCM, the lower FTI standard deviation with RCM, and the ability to more consistently achieve values in the optimal target ranges (RCM 56.4% vs. 51.5% for ACF; 66.1% vs. 49.1% for FTI), could allow to speculate that catheter stability achieved with RCM could be increased when compared to manual. Additionally the ability to avoid very high FTI values could translate into fewer instances of perforation or damage to adjacent anatomic structures, although this study was not sufficiently powered to provide evidence of fewer complications.

Procedural times findings. Similar overall procedure times were observed for both RCM and MCM ablations confirming that RCM procedure is not to be considered as longer and time-consuming than manual. Although being outside the radiation field also obviates the need for wearing lead garments, which should reduce operator fatigue and the physical strain for operator. Significant reduction of more than 50% in the mean time for both operator and patient radiation exposure was observed. These two findings are somewhat better than those previously reported by Datino and colleagues [9] with the Amigo system.

Follow-up findings. While the results of the follow-up of the patients in this study are not sufficient to significantly conclude that the quality of CF and FTI values obtained with the Amigo system translate into improved long-term clinical outcomes, the initial data are encouraging, with fewer arrhythmia recurrences and fewer additional ablations in the RCM group. Larger studies will be necessary to definitively demonstrate clinically and statistically superior outcomes for contact-force-guided PVI procedures using the Amigo robotic system vs. manual catheter manipulation.

Limitations. While this study provides encouraging data on the ability of the Amigo RCM system used in combination with the STc CF-sensing catheter to deliver more consistent RF energy when creating transmural lesions during PVI procedures, it does not provide definitive answers to the many questions that surround the benefit/risk ratio associated with RCM vs. MCM. Our study was relatively small and involved early single-center experience with the Amigo system.

To date, a novel tool to evaluate ablation efficacy is used in some centers, the so called Ablation index, a novel ablation quality marker, that incorporates contact force (CF), time and power in a weighted formula. Our promising should be confirmed while using this novel tool in order to optimize lesions set [20].

Our fluoroscopy time might be influenced by some difficult transseptal accesses, so the reduction of fluoroscopy time is it to be confirmed by larger experiences. Further, RCM patients number in follow up was so limited to fully assess improvements in long-term efficacy using the RCM/CF-sensing system. Future randomized multicenter trials, providing greater long-term follow-up, and powered appropriately to assess safety and efficacy, will be required to verify the very promising results of this study.

5. Conclusions

The present study suggests that combination of the Amigo RCM system the force-sensing STc catheter, in the setting of paroxysmal AF ablation, seems to be safe and feasible when compared to standard manual approach. More extensive data are needed to support preliminary findings of this pilot-study.

Compliance with ethical standards

- a) Disclosure of potential conflicts of interest: No conflicts of interests that are directly or indirectly related to the research to declare for all authors.
- b) No funding received.
- c) Research involving Human Participants and/or Animals: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this study we collect ethical approval from our internal review board.
- d) Informed consent: “Informed consent was obtained from all individual participants included in the study.” All data have been anonymized before data collection.

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