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Pulmonary vein isolation using new technologies to improve ablation lesion formation: Initial results comparing enhanced catheter tip irrigation (Surround Flow®) with contact force measurement (Smarttouch®)

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ABSTRACT

Introduction: Pulmonary vein reconnection after pulmonary vein isolation (PVI) is a significant problem in the treatment of paroxysmal atrial fibrillation (AF). We report about patients who underwent contact force (CF) guided PVI using CF catheter and compared them to patients with PVI using an ablation catheter with enhanced tip irrigation.
Methods: A total of 59 patients were included in the analysis. In 30 patients circumferential PVI was performed using the Thermocool Smarttouch® ablation catheter (ST) whereas in 29 patients circumferential PVI using the Thermocool Surround Flow SF® ablation catheter (SF) was performed. Patients were compared in regard to procedure time, fluoroscopy time/dose as well as RF-application duration and completeness of PVI. Adverse events (pericardial effusion, PV stenosis, stroke, death) were evaluated. The presence of sinus rhythm off antiarrhythmic medication was assessed during 6 months follow-up using multiple 7 day Holter-ECGs.
Results: In both groups, all PVs were isolated without serious adverse events. Procedure time was 2.15 ± 0.5 h (ST) vs. 2.37 ± 1.13 h (SF) ($p = 0.19$). Duration of RF-applications was 46.6 ± 18 min (ST) and 49.8 ± 19 min (SF) ($p = 0.52$). Fluoroscopy time was 25.2 ± 13 min (ST) vs. 29 ± 18 min (SF), fluoroscopy dose 2675.6 ± 1658 versus 3038.3 ± 1997 cGym^2 ($p = 0.36$ and 0.46 respectively). Sinus rhythm off antiarrhythmic medication validated with 7 day Holter ECGs was present in both groups in 72% of patients after 6 months of follow up.
Conclusion: PVI using the new contact force catheter is safe and effective in patients with paroxysmal AF.

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Introduction

Pulmonary vein isolation (PVI) has become a widely used and accepted treatment option in patients with paroxysmal atrial fibrillation [1–3]. Although treatment expertise and technical equipment improve, about 30% of patients need a repeat ablation procedure due to arrhythmia recurrence. It has been seen that PV reconnection is the commonest cause of AF recurrence in patients undergoing a repeat ablation procedure [4–7].

Recent preclinical research showed that the contact force between the catheter tip and the target tissue is a key factor to safe and effective lesion formation [8,9]. Insufficient contact may result in an ineffective lesion, leading to arrhythmia recurrence, whereas excessive contact force may result in complications such as perforation [9].

In a first safety and efficacy study [10] using the TactiCath ablation catheter (Endosense SA, Geneva, Switzerland) feasibility and safety of a contact force system was demonstrated.

We report one of the first series of patients who underwent contact force aided PVI using the Smarttouch® contact force ablation catheter used in conjunction with the Smarttouch software for the Carto3 mapping system (Biosense-Webster, Diamond Bar, CA, USA) and compared them to patients who underwent PVI using the Surround Flow (SF)® ablation catheter with the Carto3 system (Biosense-Webster, Diamond Bar, CA, USA) which was developed to provide better lesion formation by an enhanced irrigation of the catheter tip surface [11].

Methods

Patients

Between 05/2011 and 03/2012, a total of 59 patients with drug refractory paroxysmal AF and normal left ventricular function were consecutively included in the study. Contact force guided pulmonary vein isolation (PVI) was performed in 30 patients whereas PVI using the SF enhanced irrigation ablation catheter was performed in 29 patients. Patients with persistent AF, atrial tachycardia or additional other arrhythmias than paroxysmal AF were excluded from the study.

Procedure

Patients were kept on continuous oral anticoagulation with intra-procedural INR levels of 2.0–2.7 or continued taking Dabigatran. Ablation procedures were performed under conscious sedation using a three-dimensional mapping system for anatomy and catheter visualization (Carto3, Biosense-Webster, Diamond Bar, CA, USA). The individual left atrial anatomy as segmented from the previous CT scan was displayed during the procedure and fused with the reconstructed anatomy in the 3D mapping system if felt appropriate (see Fig. 1). An 8-polar catheter was placed in the coronary sinus (CS; XPT, C.R. Bard, Lowell, MA; USA) and the left atrium (LA) was accessed by single or double transseptal puncture or via an open foramen ovale. Preablation and postablation angiograms of all PVs were performed. After placement of electrode catheters within the left atrium, heparin was given to maintain an activated clotting time at $\geq$270 s.

PVI was performed using a circular steerable mapping catheter (Lasso™, Biosense-Webster, Diamond Bar, CA, USA) and an irrigated tip ablation catheter. In the contact force group the Biosense Thermocool Smarttouch® ablation catheter was used with a flow rate of 30 ml/min, a maximum temperature of 43 °C and a maximum power of 25–30 W (ST group). Smarttouch uses a force sensing system based on pressure applied to the tip, which integrates a nitinol spring and pressure sensor. The system was developed to integrate with the Biosense Carto3 mapping system. A contact force of 10–20 g as recommended by the company was aimed for. There was an online contact force reading available during mapping, as well as during RF application. In addition, color coded contact force was displayed on the anatomical map (see Fig. 1). In the conventional group all patients underwent PVI with the Biosense Thermocool Surround Flow SF® ablation catheter (SF group) with a flow rate of 17 ml/min and a maximum power of 25–30 W until electric PV isolation confirmed with the circular mapping catheter was achieved. The ThermoCool Surround Flow catheter was developed with improved irrigation provided by 56 very small holes (0.0035″) positioned around the entire electrode, holding the potential to decrease the required irrigation flow rate and allow to deliver high RF power even in areas of very low blood flow [11]. In all patients circumferential PVI circulating both ipsilateral PVs was performed (see Fig. 1). Entry and exit block (pacing anterior, inferior, superior, posterior of the PVI with 10 V and 2 ms) were documented in all patients and all PVs. To avoid too much diversity in the two groups same operators performed the ablation procedures.

Post procedural management

Patients were kept on oral anticoagulation after PVI. In all patients beta blockers were recommended. No other antiarrhythmic medications were prescribed. If patients were on antiarrhythmic drugs before the procedure, these were discontinued.

Follow-up after ablation

Patients were scheduled for visits in the arrhythmia clinic at 3 and 6 months after the ablation. At each visit, intensive questioning for arrhythmia-related symptoms was done and a 7-day Holter-ECG was performed. Success was defined as no documented symptomatic or asymptomatic AF or atrial tachycardia (AT) episode > 30 s after a blanking period of 6 weeks off antiarrhythmic medication. If no AF recurrence was detected within the first 3 months and the $CHADS_2$ score was $\leq$2, oral anticoagulation was discontinued. No antiarrhythmic medications besides beta blockers were used after the ablation procedure.

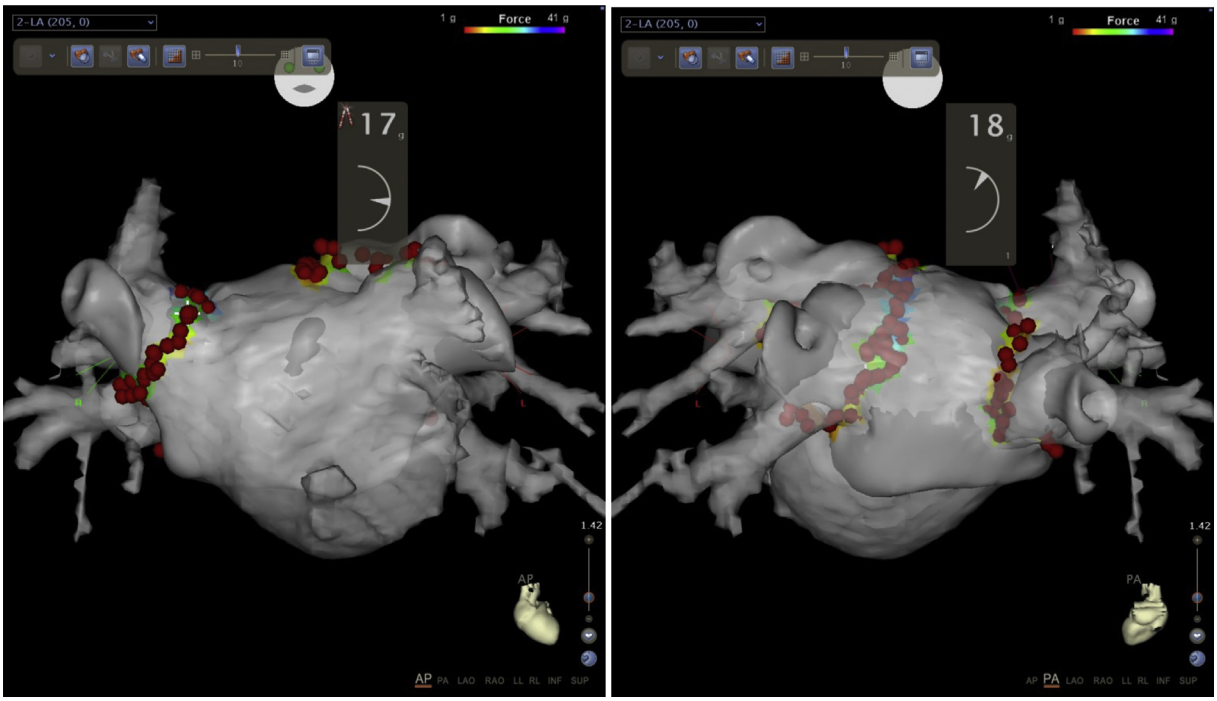

Fig. 1 – Anterior (left side) and posterior view of an anatomical map of the left atrium merged with a cardiac CT image of the same patients using the Carto3 System. Pulmonary veins were circumferentially isolated using a contact force measurement system (Thermocool Smarttouch catheter, Biosense Webster). The color-coding shows good contact (green to blue) or bad contact (red) on the map. The shown number 17 on the left and 18 on the right side shows the online contact force in grams.

Statistical analysis

Statistic Tests were performed using SPSS 20. All values are presented as mean ± SD. Student's t-test, Fisher's exact test, Wilcoxon's test and Chi-square test were applied for comparisons. A probability value of $p < 0.05$ was considered statistically significant. Test for normal distribution was done using the Kolmogorov–Smirnov Test.

Results

Patients' characteristics

Baseline characteristics did not differ between the patients included in ST group compared to patients included in the SF group (see Table 1). Patients in the ST group were 59.1 ± 10 years old, 53% were male and suffered from paroxysmal AF since 55.2 ± 53 months. Patients in the SF group were 61 ± 12 years old, 48% of them were male and suffered from paroxysmal AF since 33.1 ± 33 months.

Procedural data

PVs were successfully isolated in all patients in both groups. Procedural duration was comparable between both groups (ST 2.15 ± 0.5 h, SF 2.37 ± 1.13 h p = 0.19 respectively). In addition fluoroscopic time and dose showed a slight tendency to be lower in the ST versus the SF group (25.2 ± 13 min vs.

Table 1 – Baseline characteristics.

Data	Surround Flow catheter group N = 29	Smarttouch catheter group N = 30	P value
Age	61 ± 12	59.1 ± 10	**0.53**
Gender male	48%	53%	**0.7**
Art. Hypertension	52%	55%	**0.8**
Coronary artery disease	10%	17%	**0.7**
Diabetes mellitus	10%	7%	**1.0**
Previous stroke	7%	0	**0.5**
Body mass index	22.5 ± 3	23.6 ± 3	**0.22**
Duration of AF in months	33.1 ± 33	55.2 ± 53	**0.13**
Episodes per year	157 ± 160	123.8 ± 138	**0.59**
Size of left atrium mmode/ planimetric mm^2	40.4 ± 4/22 ± 5	43.6 ± 8/22.0 ± 6	**0.08/0.96**
Anticoagulation with warfarin	90%	72%	**0.014**
With new anticoagulants	0%	24%	
Previous beta blocker	72%	71%	**0.93**
Previous class Ic or III antiarrhythmic drug	77%	65%	**0.33**

29 ± 18 min, p = 0.36 and 2675.6 ± 1658 cGym^2 vs. 3038.3 ± 1997 cGym^2, p = 0.46 respectively). Likewise, the RF time required was slightly lower in the ST vs. the SF group (46.6 ± 18 min vs. 49.8 ± 19 min, p = 0.52) (See Table 2).

Adverse events

Overall, adverse events were low. No patient suffered from a cardiac tamponade, stroke, significant PV stenosis >50% or esophageal fistula. No catheter charring was observed. Minor complications were seen in two patients from the SF group: one with a small AV fistula and one with a pseudoaneurysm. Both patients were managed without surgical intervention.

Freedom from atrial arrhythmia 6 months after PVI

Follow up after 6 months was available for 29/29 patients in the SF and 29/30 patients in the ST group. In both groups, 72% of patients showed stable sinus rhythm clinically and on 7-day-Holter ECGs off antiarrhythmic medication.

Discussion

Main findings

To our knowledge this is the first study comparing two new strategies to improve lesion formation during RF ablation: The new contact force measurement with the enhanced irrigation of the ablation catheter tip. Moreover, it is the first report with a midterm follow up after PVI using the contact force guided system showing that the new system was very safe and equally effective acutely and during a 6 months follow-up compared to the enhanced irrigated tip ablation catheter approach. A tendency towards a shorter procedure time, lower fluoroscopic time and dose and a reduced RF time was noted with the new system but did not reach statistical significance.

Usefulness of contact force measurement

In the first study using the TactiCath ablation catheter (Endosense SA, Geneva, Switzerland) feasibility and safety of a contact force system was demonstrated [10]. In this study a total of 43 patients underwent right sided SVT ablation and 34 patients underwent ablation for AF. Operators were blinded during mapping phase regarding the contact force used. Variability of contact force between operators and different areas of the atriums differed highly. In one patient a cardiac tamponade occurred; directly before this event a very high contact force with 137 g was recorded.

In another small study [12] using the TactiCath catheter 22 patients underwent circumferential PVI. Operators were blinded to the used contact force. In this study no adverse events occurred. In this study again the contact force varied widely showing best contact force on the left side at the superior and inferior side and worst contact at the anterior side; on the right side best contact was achieved anterior and inferior and worst contact at the carina. Acute PV reconnection after adenosine application occurred only in areas with previous low contact force (for the left sided PVs 8.3 ± 6.7 g vs. 18 ± 12.7 g, and for the right sided PVs 10.8 ± 6.8 g vs. 24.5 ± 14.8 g respectively).

In the data of the Efficas I trial [13] 40 patients underwent PVI with the operator blinded to the applied contact force. After 3 months the majority of patients underwent repeat ablation procedure regardless of arrhythmia recurrence. In 26 patients 52 gaps out of 318 segments were recorded. In the segments with the recorded gaps contact force was lower compared to segments without recorded gaps. In the Efficas trial likewise the TactiCath system was used. These first data of the TactiCath catheter showed very promising results, however larger studies proving the concept are still missing.

The TactiCath Force-Sensing Irrigated Ablation Catheter (Endosense), which received regulatory approval in Europe in May 2009, has three optical fibers that emit wavelengths. When the catheter tip touches tissue, the optical fibers bend. TactiCath's software calculates the changes in the wavelengths between the optical fibers and translates this information into a measurement of how much pressure is being applied to the heart tissue the Smarttouch catheter however uses a force sensing system based on pressure applied to the tip, which integrates a nitinol spring and pressure sensor. The system was developed to integrate with the Biosense Carto3 mapping system. Up until now no study exist which compares the differences between the two systems therefore only the force sensing itself can be compared.

Enhanced lesion formation: strategies and results

In both groups all PVs were successfully isolated and no catheter related complications occurred. In patients treated with the contact force guided catheter there was no statistical significance difference regarding a reduced procedure time, reduced fluoroscopic time or lower RF time required to completely isolate all PVs. Up to now, only very limited data is available regarding contact force guided PVI, especially concerning the Smarttouch ablation catheter used in this study.

In one small study using the ST system [14] 40 patients were assigned to circumferential PVI either with contact force guidance available or with the operator blinded to the used contact force. Complete PVI could be achieved in all patients. The endpoint was acute reconnection after a waiting period of 1 h and use of adenosine. In the group with the known contact

Table 2 – Procedural data.

Data	Surround Flow catheter group N = 29	Smarttouch catheter group N = 30	P value
Procedure time (hours)	2.37 ± 1.13	2.15 ± 0.5	**0.19**
Fluoroscopic time (minutes)	29 ± 18	25.2 ± 13	**0.36**
Fluoroscopic dose (cGym2)	3038.3 ± 1997	2675.6 ± 1658	**0.46**
RF time (minutes)	49.8 ± 19	46.6 ± 18	**0.52**

force acute reconnection was significantly lower with 4% vs. 21%. In this study procedure time was comparable in both groups and fluoroscopic time showed a slight tendency to be lower in the group with the known contact force. As in our study, adverse events were rare.

In another study [15] using the ST catheter in one group and the standard Navistar Thermocool (Biosense Webstar) catheter in the other group a significant reduction in RF time and procedure time required was observed. However, in the current study the Surround Flow catheter was used for comparison. In a study by Bertaglia et al. [11]. were the Thermocool Navistar catheter was compared to the Thermocool Surround Flow catheter showing a higher acute PVI success after a waiting period of 30 min in the group with the SF catheter; the fact that we compared two ablation catheters that are both supposed to be more effective than conventional catheters could explain that—in contrast to the study by Martinek et al. [15] – we could not detect any significant difference between both approaches.

Freedom from atrial arrhythmias

After a follow up of 6 months 72% of patients in both groups were free from atrial arrhythmias of >30 s off antiarrhythmic medication. Up to now no study published follow up data regarding the ST catheter. In a sub-study of the Toccata trial using patients who underwent PVI a small number of patients (5/5) treated with a contact force <10 g showed arrhythmia recurrence, whereas patients treated with an average contact force >20 g experienced stable sinus rhythms after a follow up of 12 months [16]. These results were obtained from a very small patient group using a different contact force system. Nevertheless, the effective contact force still has to be investigated.

Limitations

This study was not a randomized study although patients were consecutively included. Because of small patient numbers and follow up of 6 months results could be misinterpreted. If PVI reconnection occurred at the end of the procedure, these PVs were reisolated; however, no analysis of occurring gaps and areas of low contact force was performed.

Conclusion

PVI using the new contact force catheter is safe and effective in patients with paroxysmal AF. Procedural characteristics as procedure duration, RF time and fluoroscopy time were not different using contact force measurement as compared to an ablation approach using enhanced ablation catheter tip irrigation. Contact force guided PVI reached the same success rate as PVI using enhanced tip irrigation after 6 months of follow-up. It has to be shown in larger studies if there is a definite advantage using the contact force catheter. A prospective multicenter trial testing for efficacy and safety is on its way and results are expected in 2014 [17].

Conflict of interest

No conflict of interest for all authors.

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