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# Acute and Long-Term Results of Catheter Ablation of Outflow Tract Arrhythmias using Remote Magnetic Navigation with Catheter-Tissue Contact Feedback Technology: Comparison with Manual Ablation

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#### **Abstract**

Background and aim: Studies evaluating the results of remote magnetic navigation (RMN) using catheter-tissue contact feedback technology are scarce. The aim of this study was to compare the results of ablation of ventricular outflow tract arrhythmias with RMN using the catheter-tissue contact feedback technology with manual ablation with and without contact-force (CF) technology.

Methods: Retrospective study of patients that underwent ablation of ventricular outflow tract arrhythmias between May 2017 and December 2021 by the same operator in two hospitals. Patients were excluded in the presence of structural heart disease or previous ablation. Procedural data, success and complication rates and recurrence were compared.

Results: Total of 81 patients, 45 underwent ablation with RMN (RMN group), 18 with manual catheters without CF technology (Manual group) and 18 with CF catheters (CF group). The three groups did not differ in relation to baseline characteristics. Patients in the CF group had a higher frequency of arrhythmias originating from the LVOT. The procedure and radiofrequency times were not significantly different, the fluoroscopy time was significantly lower in the RMN group when comparing with Manual and CF groups, 3 (2-5.5) min vs 12 (5.7-17) vs 9.5 (4.9-14.4) min, p<0.0001. There was a direct correlation between fluoroscopy time and procedure time for manual ablation (R=0.480, p=0.003), but not for RMN (R=0.200, p=0.188). p<0.0001). Global success rate was 88% and complication rate was 1% which were not significantly different between groups. Median follow-up was 910 (485-1440) days, recurrence rate was not significantly different (Log-Rank=0.455)

Conclusions: RMN ablation of ventricular outflow tract arrhythmias using the catheter–tissue contact feedback technology demonstrated high success and low recurrence rates, with a significantly lower fluoroscopy time than manual or CF guided ablation. When ablation was performed with RMN there was no correlation between the length of the procedure and the fluoroscopy time.

#### Introduction

Ablation of premature ventricular contractions (PVCs) is an effective procedure and a class I indication in symptomatic patients with a high PVC burden¹. The ventricular outflow tracts are the most frequent

sites of origin of idiopathic arrhythmias. Not only the right ventricular outflow tract (RVOT) but as shown in a recent contemporary study, also the left ventricular outflow tract (LVOT) and especially the aortic  $cusps^2$ .

#### **Kev Words**

Remote Magnetic Navigation; Premature Ventricular Contractions; Ventricular Outflow Tracts; Catheter Ablation; Catheter-Tissue Contact Feedback

Corresponding Author Leonor Parreira, Av Dr António Rodrigues Manito, 114 2900-064 Setubal Portugal. Remote magnetic navigation (RMN) presents as an excellent option when catheter manipulation should be smooth to prevent PVCs induced by the catheter, an event frequent at the level of the outflow tracts <sup>3,4</sup>. It is known for a long time that the tissue-catheter contact is important for lesion formation<sup>5</sup>. In recent years, the development of contact force (CF)-sensing catheters has promised an improvement in outcomes of manual catheter ablation of ventricular arrhythmias. One of the concerns regarding RNM is the unavailability of contact force



Figure 1: RMN workstation screen displaying simultaneously the different screens during the procedure.

Panel A: EAMshowing RF applications at the earliest activation site (red and pink dots), His tagged (yellow dots); Panel B intracardiac electrograms during ablation displaying the RF application parameters; Panel C: RMN screen showing the yellow arrow that remotely commands the direction of the ablation catheter. Good contact of the catheter tip showing an optimal starburst (red arrow) and a contact tracing displaying a solid line (blue arrow): Panel D Fluoroscopy screen with overlaid EAM. EAM: Electroanatomical map; RF: radiofrequency; RMN: remote magnetic navigation.

catheters, but this would go against the concept of RMN. This system is characterized by the high stability of the catheter tip, leading to a similar lesion size when compared to conventional ablation, although with less force applied to the tissue. Contact feedback technology became available for RMN with the development of the e-Contact Module (ECM), which allows a semi-quantitative assessment of the catheter tip-to-tissue contact. Studies comparing manual vs. RMN guided ablation after the advent of this technology are lacking. The aim of this study was to compare the results of RMN ablation of outflow tract arrhythmias using the catheter—tissue contact feedback technology against manual with and without CF catheters.

#### 2. Material and methods

#### 2.1. Patient population

This was a retrospective series of consecutive patients who underwent catheter ablation of idiopathic PVCs or ventricular tachycardia (VT) from the outflow tracts by the same operator, from May 2017 to December 2021. This study was performed in two hospitals, the procedures using RMN took place at the Luz Hospital Lisbon and the manual procedures at Setubal Hospital Center.

All patients underwent 12-lead ECG, transthoracic echocardiography and cardiac magnetic resonance with late gadolinium enhancement to exclude the presence of structural heart disease. Arrhythmogenic right ventricular cardiomyopathy (ARVC) was ruled out according to the Task Force Criteria<sup>8</sup>. Patients with evidence of structural heart disease

and those that had undergone a previous ablation were excluded. A 24-hour Holter recording was performed before ablation and the number of PVCs per 24 hours and the presence of episodes of non-sustained ventricular tachycardia (NSVT), defined as >3 PVCs in a run were assessed.

#### 2.2. Study design

Patients were divided in three groups whether ablation was performed with RMN (RMN group), manually with catheter without CF sensor (Manual group) or manually with a CF catheter (CF group). Baseline characteristics and procedural data were evaluated and compared between groups. Correlation between the procedure time and fluoroscopy time was assessed. Patients were followed and recurrence was registered, the recurrence-free survival curves were obtained and compared in the three groups. The influence of predictive variables related to the procedure on recurrence during follow-up was evaluated.

#### 2.3. Electroanatomic Mapping and Ablation

Patients were studied in a fasting non sedate state. All beta-blockers and antiarrhythmic drugs were discontinued at least five half-lives before the electrophysiological study. In patients with VT, programmed ventricular stimulation was performed to induce VT and isoprenaline was administered when needed. During endocardial mapping of the LVOT heparin was administrated to achieve an ACT of 250-300 sec. In the RMN group the procedures were performed with the Niobe ES Magnetic Navigation System (Stereotaxis, Inc., Saint Louis, MO,

USA) and the CARTO 3 RMT (Biosense-Webster, Inc., Diamond Bar, CA, USA) system. An irrigated tip Navistar RMT Thermocool catheter (Biosense-Webster Inc., Diamond Bar, CA, USA) was used with a 3.5-mm distal tip electrode and a 2–5–2 interelectrode distance (Figure 1).

Manual procedures were all performed with the EnSite Precision (Abbott, St Paul, MN, USA) system, using an irrigated tip FlexAbility (Abbott, St Paul, MN, USA) catheter with a 4-mm distal tip electrode and 1-4-1 interelectrode spacing in the first 18 patients (Figure 2) and a TactiCath catheter (Abbott, St Paul, MN, USA) with a 3.5-mm distal tip electrode and a 2-2-2 interelectrode distance in the last 18 patients (Figure 3). Mapping of the LVOT endocardium and the aortic coronary cusps was performed using a transaortic approach in all patients. When ablation was unsuccessful at the coronary cusps or the LVOT, the coronary sinus, the great cardiac vein and anterior interventricular vein were mapped. With the CARTO 3 RMT (Biosense-Webster, Inc.) system, local activation time (LAT) was defined as the time of the maximum downslope of the unipolar distal electrogram displayed on the corresponding bipolar signal. With the EnSite Precision system LAT was defined as the time of the first peak of the bipolar electrogram9. The ablation site was selected based on the earliest endocardial activation time in relation to the onset of the surface QRS, with a QS pattern at the unipolar electrogram and confirmed by the pace mapping that provided at least 11 out of 12 pace matches between paced and spontaneous PVCs. LAT at the ablation site was measured in relation to the beginning of the QRS on the surface ECG. In patients in whom the site of the origin of the PVCs was the LVOT or aortic coronary cusps, a coronary angiography was performed before ablation. Energy was delivered from an RF generator between the distal electrode of the ablation catheter and a cutaneous patch, for up to 120 sec, to a maximum temperature of 43° C and titrated according to the location of the PVCs, to a power output limit of 50 W. When the application was ineffective, additional applications were delivered to sites adjacent to the earliest activation site. In the CF group a contact force above 30 g was avoided for all ablations. During ablation, light sedation with midazolam (bolus) or remifentanil (continuous perfusion) was administered when needed. There were no differences between ablation strategies in the Manual, CF, or RMN ablation groups. Success was defined as non-induction of VT or abolition of PVCs until 30 min after ablation. The evaluated parameters were procedure time assessed as the interval between patient's entrance and exit of the room, fluoroscopy time, total radiofrequency time, site of origin of the arrhythmia, LAT at ablation site, acute success rate, and complications related to catheter manipulation or ablation, like steam pops, thrombus formation and stroke, perforation, tamponade, pericarditis, or lesions to adjacent structures. All intracardiac electrograms were reviewed by two senior electrophysiologists.

#### 2.4. e-Contact Module

All RMN procedures were done with the ECM that provides a semi-quantitative evaluation of the catheter tip-to-tissue contact, and optimal contact was the goal throughout the procedure (Figure 1), This technology has already been well described by Noten et al<sup>7</sup> but basically, the ECM software algorithm analyses 3 categories of data to determine whether the catheter is in contact with cardiac tissue. These categories are electrical impedance measurements, cardiac-induced

motion of the catheter tip, and the torque being applied by the magnetic field. The contact assessment is visualized to the user on the RMN screen as a starburst at the catheter tip (Figure 1 red arrow) and as a blue line on the contact tracing (Figure 1 blue arrow). When there is no contact the starburst is absent, with minimal contact the starburst is faint and has only few lines, and with optimal contact the starburst is bold and has multiple lines. Regarding the contact tracing, it shows a dotted line when the contact is suboptimal and a solid line when the contact is optimal.

#### 2.5. Follow-up

The follow-up was performed at the office on the first month, at six months, at one year and yearly after that. Clinical assessment was carried out and at least one 24-hour Holter recording was performed between one month and six months after ablation and once a year

 Table 1:
 Baseline characteristics and comparison between groups

	Overall sample (n=81)	RMN group (n=45)	Manual group (n=18)	Manual CF group (n=18)	P value
Demographic data					
Age in years, median $(Q_1-Q_3)$	50 (40-63)	50 (40-60)	48 (39-65)	60 (43-66)	0.199
Male Gender, n (%)	36 (44)	16 (36)	11 (61)	9 (50)	0.158
Risk factors, history, and medications					
Hypertension, n (%)	17 (21)	6 (13)	7 (39)	4 (22)	0.079
Diabetes, n (%)	5 (6)	1(2)	1(6)	3 (17)	0.098
Syncope or pre- syncope, n (%)	8 (10)	4 (9)	2 (11)	2 (11)	0.946
Duration of symptoms in months, median $(Q_1-Q_3)$	24 (12-30)	24 (12-25)	24 (12-36)	24 (12-42)	0.636
Family history of sudden death, n (%)	3 (4)	1 (2)	1(6)	1(6)	0.732
Betablockers, n (%)	56 (69)	31 (69)	15 (83)	10 (56)	0.196
Class I or III AA*	13 (16)	5 (11)	3 (17)	5 (28)	0.265
Standard 12 lead ECG					
PVC/VT	77/4	45/2	18/0	16/2	0.298
T wave inversion beyond V1, n (%)	5 (6)	3 (7)	1(6)	1(6)	0.979
PVC precordial transition					
V1 or V2, n (%)	11 (14)	5 (11)	1(6)	5 (27)	0.116
V3, (n%)	18 (22)	11 (24)	4 (22)	3 (17)	0.799
Beyond V3, n (%)	52 (64)	29 (64)	13 (72)	10 (56)	0.580
24-Hour Holter Monitoring					
Number of PVCs, in nx100, median $(Q_1-Q_3)$	200 (140- 272)	200 (140- 247)	214 (156- 305)	228 (133- 334)	0.667
NSVT, n (%)	26 (32)	13 (29)	7 (39)	6 (33)	0.857
Echocardiogram					
LVEF in %, median (Q <sub>1</sub> -Q <sub>3</sub> )	58 (55-60)	58 (57-60)	57 (54-60)	57 (55-60)	0.497
LAD in mm, median (Q <sub>1</sub> -Q <sub>3</sub> )	35 (33-40)	35 (33-37)	37 (33-42)	36 (35-40)	0.222

\*Except amiodarone; LAD: left atrium diameter; LVEF: left ventricular ejection fraction; NSVT: non-sustained ventricular tachycardia; PVC: premature ventricular contractions; VT: ventricular tachycardia

#### Table 2:

#### Procedural data and follow-up data

Procedure time in min, median (Q1-Q3)         138 (120-180)         140 (118-18)         159 (114-120 (118-18))         120 (118-18)         0.680           Fluoroscopy time in min, min, min, min, median (Q1-Q3)         138 (120-180)         140 (118-180)         159 (114-120 (118-120)         165 (149-120)         0.680           Fluoroscopy time in min, median (Q1-Q3)         5 (2.5-10)         3 (2-5.5)         12 (5.7-17)         9.5 (4.9-17)         0.0001           RF duration in sec, median (Q1-Q3)         300 (120-530)         500 (120-530)         330 (120-625)         650)         0.796           Site of origin         8         8         15 (83)         10 (56)         0.085           LVOT, n (%)         15 (19)         6 (13)         2 (11)         7 (39)         0.041           LV summit, n (%)         5 (6)         3 (7)         1 (6)         1 (6)         0.979           LAT at ablation site, median (Q1-Q3)         37 (30-45)         34 (24-43)         40 (35-47)         37 (27-47)         0.148           Overall acute success in the RVOT, n (%)         40 (89)         15 (83)         16 (89)         0.819           Acute success in the LVOT, n (%)         3 (60)         2 (67)         1 (100)         0 (0)         0 (0)         0 (0)           Complications, n (%)						
median (Q1-Q3)         180)         180)         205)         165)           Fluoroscopy time in min, median (Q1-Q3)         5 (2.5-10)         3 (2-5.5)         12 (5.7-17)         9.5 (4.9-10.0001           RF duration in sec, median (Q1-Q3)         300 (120-540)         300 (120-530)         400 (120-625)         330 (120-650)           Site of origin         RVOT, n (%)         61 (75)         36 (80)         15 (83)         10 (56)         0.085           LVOT, n (%)         15 (19)         6 (13)         2 (11)         7 (39)         0.041           LV summit, n (%)         5 (6)         3 (7)         1 (6)         1 (6)         0.979           LAT at ablation site, median (Q1-Q3)         37 (30-45)         34 (24-43)         40 (35-45)         37 (27-45)         0.148           Overall acute success rate, n (%)         40 (89)         15 (83)         16 (89)         0.819           Acute success in the RVOT, n (%)         33 (80)         32 (89)         12 (80)         9 (90)         0.658           RVOT, n (%)         3 (60)         2 (67)         1 (100)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)         0 (0)		sample		group	CF group	P value
min, median (Q1-Q3)  RF duration in sec, median (Q1-Q3)  Site of origin  RVOT, n (%)  LVOT, n (%)  LS summit, n (%)  Complications, n (%)  Acute success in the LV summit, n (%)  Complications, n (%)  Complications, n (%)  Complications, n (%)  RF duration in sec, 300 (120-540)  300 (120-530)  300 (120-625)  30 (120-625)  310 (89)  310 (89)  310 (89)  310 (89)  310 (89)  310 (89)  32 (89)  32 (89)  32 (89)  32 (89)  32 (89)  32 (80)  33 (82-650)  400 (100)  400						0.680
median (Q1-Q3)         540)         530)         625)         650)           Site of origin         RVOT, n (%)         61 (75)         36 (80)         15 (83)         10 (56)         0.085           LVOT, n (%)         15 (19)         6 (13)         2 (11)         7 (39)         0.041           LV summit, n (%)         5 (6)         3 (7)         1 (6)         1 (6)         0.979           LAT at ablation site, median (Q1-Q3)         37 (30-45)         34 (24-43)         40 (35-45)         37 (27-45)         0.148           Overall acute success rate, n (%)         40 (89)         15 (83)         16 (89)         0.819           Acute success in the RVOT, n (%)         53 (87)         32 (89)         12 (80)         9 (90)         0.658           Acute success in the LV Summit, n (%)         15 (100)         6 (100)         2 (100)         7 (100)         -           Acute success in the LV Summit, n (%)         3 (60)         2 (67)         1 (100)         0 (0)         0 (329)           Complications, n (%)         1 (1)         0 (0)         0 (0)         1 (6)         0 .170           Follow-up time in days, median (Q1-Q3)         910 (485-1440)         1095 (571-1569)         1229 (896-1650)         330 (82-1650)         <0.0001 </td <td>• • •</td> <td>5 (2.5-10)</td> <td>3 (2-5.5)</td> <td>•</td> <td></td> <td>&lt;0.0001</td>	• • •	5 (2.5-10)	3 (2-5.5)	•		<0.0001
RVOT, n (%)         61 (75)         36 (80)         15 (83)         10 (56)         0.085           LVOT, n (%)         15 (19)         6 (13)         2 (11)         7 (39)         0.041           LV summit, n (%)         5 (6)         3 (7)         1 (6)         1 (6)         0.979           LAT at ablation site, median (Q1-Q3)         37 (30-45)         34 (24-43)         40 (35-45)         37 (27-45)         0.148           Overall acute success rate, n (%)         40 (89)         15 (83)         16 (89)         0.819           Acute success in the RVOT, n (%)         53 (87)         32 (89)         12 (80)         9 (90)         0.658           Acute success in the LV summit, n (%)         15 (100)         6 (100)         2 (100)         7 (100)         -           Acute success in the LV summit, n (%)         3 (60)         2 (67)         1 (100)         0 (0)         0.329           Complications, n (%)         1 (1)         0 (0)         0 (0)         1 (6)         0.170           Follow-up time in days, median (Q1-Q3)         910 (485-1440)         1095 (571-1569)         1229 (896-1650)         330 (82-1650)         <0.0001		•	,	•	•	0.796
LVOT, n (%) 15 (19) 6 (13) 2 (11) 7 (39) 0.041  LV summit, n (%) 5 (6) 3 (7) 1 (6) 1 (6) 0.979  LAT at ablation site, median (Q1-Q3) 37 (30-45) 34 (24-43) 40 (35-45) 47 0.148  Overall acute success 71 (88) 40 (89) 15 (83) 16 (89) 0.819  Acute success in the RVOT, n (%) 32 (89) 12 (80) 9 (90) 0.658  Acute success in the LV 3 (60) 2 (67) 1 (100) 7 (100) -  LVOT, n (%) 30 (0) 2 (67) 1 (100) 0 (0) 0.329  Complications, n (%) 1 (1) 0 (0) 0 (0) 1 (6) 0.170  Follow-up time in days, median (Q1-Q3) 15 (99) 15 (99) (896-650) 1669)	Site of origin					
LV summit, n (%) 5 (6) 3 (7) 1 (6) 1 (6) 0.979  LAT at ablation site, median (Q1-Q3) 37 (30-45) 34 (24-43) 40 (35- 37 (27- 0.148 45) 47)  Overall acute success 71 (88) 40 (89) 15 (83) 16 (89) 0.819  Acute success in the FVOT, n (%) 32 (89) 12 (80) 9 (90) 0.658  Acute success in the LV 3 (60) 2 (67) 1 (100) 0 (0) 0.329  Summit, n (%) 1 (1) 0 (0) 0 (0) 1 (6) 0.170  Follow-up time in days, median (Q1-Q3) 15 (89) 15 (89- 650) 16 (896- 650)	RVOT, n (%)	61 (75)	36 (80)	15 (83)	10 (56)	0.085
LAT at ablation site, median (Q1-Q3) 37 (30-45) 34 (24-43) 40 (35-47) 0.148   Median (Q1-Q3) 45 37 (27-45) 47 0.148    Overall acute success 71 (88) 40 (89) 15 (83) 16 (89) 0.819    rate, n (%)	LVOT, n (%)	15 (19)	6 (13)	2 (11)	7 (39)	0.041
median (Q1-Q3)       45)       47)         Overall acute success rate, n (%)       71 (88)       40 (89)       15 (83)       16 (89)       0.819         Acute success in the RVOT, n (%)       53 (87)       32 (89)       12 (80)       9 (90)       0.658         Acute success in the LVOT, n (%)       15 (100)       6 (100)       2 (100)       7 (100)       -         Acute success in the LV summit, n (%)       3 (60)       2 (67)       1 (100)       0 (0)       0.329         Complications, n (%)       1 (1)       0 (0)       0 (0)       1 (6)       0.170         Follow-up time in days, median (Q1-Q3)       910 (485- 1095 (571- 1229 330 (82- 650) (896- 650) (896- 650) (1669)       30 (82- 650) (896- 650) (896- 650) (896- 650)       40 (89)	LV summit, n (%)	5 (6)	3 (7)	1(6)	1(6)	0.979
rate, n (%)  Acute success in the RVOT, n (%)  Acute success in the LV 3 (60) 2 (67) 1 (100) 0 (0) 0.329  Summit, n (%)  Complications, n (%) 1 (1) 0 (0) 0 (0) 1 (6) 0.170  Follow-up time in days, median (Q1-Q3) 1 (140) 1569) (896 650) 1669)	,	37 (30-45)	34 (24-43)		- (	0.148
RVOT, n (%)  Acute success in the LV 3 (60) 2 (67) 1 (100) 0 (0) 0.329  summit, n (%)  Complications, n (%) 1 (1) 0 (0) 0 (0) 1 (6) 0.170  Follow-up time in days, 910 (485- 1095 (571- 1229 330 (82- <0.0001 nedian (Q1-Q3) 1569) (896- 650) 1669)		71 (88)	40 (89)	15 (83)	16 (89)	0.819
LVOT, n (%)  Acute success in the LV 3 (60) 2 (67) 1 (100) 0 (0) 0.329 summit, n (%)  Complications, n (%) 1 (1) 0 (0) 0 (0) 1 (6) 0.170  Follow-up time in days, 910 (485- 1095 (571- 1229 330 (82- <0.0001 median (Q1-Q3) 1569) (896- 650) 1669)		53 (87)	32 (89)	12 (80)	9 (90)	0.658
summit, n (%)       1 (1)       0 (0)       0 (0)       1 (6)       0.170         Follow-up time in days, median (Q1-Q3)       910 (485-1095 (571-1229)       330 (82-30001)       <0.0001		15 (100)	6 (100)	2 (100)	7 (100)	-
Follow-up time in days, 910 (485- 1095 (571- 1229 330 (82- <0.0001 median (Q1-Q3) 1440) 1569) (896- 650) 1669)		3 (60)	2 (67)	1 (100)	0 (0)	0.329
median (Q1-Q3) 1440) 1569) (896- 650) 1669)	Complications, n (%)	1(1)	0 (0)	0 (0)	1(6)	0.170
Recurrence*, n (%) 11 (16) 5 (13) 4 (27) 2 (13) 0.404	• • • •		(	(896-	(-	<0.0001
	Recurrence*, n (%)	11 (16)	5 (13)	4 (27)	2 (13)	0.404

<sup>\*</sup> After a successful procedure. CF: contact-force; LAT: local activation time; LVOT: left ventricular outflow tract; LV: left ventricle; RF: radiofrequency: RMN: remote magnetic navigation: RVOT: right ventricular outflow tract.

thereafter. For patients that were followed at another institution data were retrieved from the national patient registry and from medical records or discharge letters and were validated by reviewing patients' files. Patients who failed to have recent clinical records were contacted by phone. Recurrence was defined as reappearance of symptoms or a 24-hour Holter with a PVC number higher than 1000 PVCs per 24 hours.

#### 2.6. Statistical analysis

All analyses were performed using SPSS statistical software, version 25.0 (SPSS, Inc, Chicago, Illinois). Data is presented as median and lower and upper quartile (Q1-Q3) for continuous variables and as absolute numbers and percentages for categorical variables. Continuous variables were compared with the use of Kruskal Wallis test for multiple samples. Categorical variables were compared with the use of the chi-squared test for independent samples. The correlation between the procedure time and the fluoroscopy time was performed with a Pearson correlation coefficient, R. Kaplan-Meier survival function was used to compare the recurrence-free survival in the three groups and the Log- rank test for comparison between groups. The influence of predictive variables on recurrence during follow-up was evaluated by Cox regression analysis. Univariate analysis was performed to select the variables to be included in the multivariate analysis. We included in the multivariate analysis those variables with a p-value ≤ 0.05 in the univariate analysis. Hazard ratios and their 95% confidence intervals were calculated. For all tests a p value <0.05 was considered as statistically significant.



Panel A: EAM showing the tip of the ablation catheter at the S00; Panel B: PVCs disappear in the first seconds of RF application; Panel C: PVC morphology and intracardiac signals at ablation site. CF: contact force; EAM: electroanatomical map; LCC: left coronary cusp; LMCA: left main coronary artery; PVC: premature ventricular contractions: RF: radiofrequency; S00: site of origin



Figure 3: Example of a case of PVCs from the LVOT performed manually with a CF-catheter.

Panel A: EAM showing the tip of the ablation catheter at the SOO; Panel B: PVCs disappear during RF application; Panel C: PVC morphology and intracardiac signals at ablation site. CF: contact force; DA: descending thoracic aorta; EAM: electroanatomical map; LCC: left coronary cusp; LMCA: left main coronary artery; PVC: premature ventricular contractions: RF: radiofrequency; SOO: site of origin

#### 2.7. Ethics

All patients signed the informed consent form, and the study was approved by the Ethical Committee of both hospitals. The study is in compliance with the Helsinki Declaration.

#### 3. Results

#### 3.1. Patient population

We included 81 patients, median age 50 (40-63) years, 44% males. Baseline characteristics of the study patients as well as comparison between the groups are displayed in Table 1. All patients were symptomatic mostly with palpitations, the median duration of symptoms was 24 (12-30) months and 10% had a history of syncope or pre-syncope. Only four patients presented with sustained VT, the other seventy-seven had frequent PVCs with a median of 20,000 (14,000-27,200) of PVCs/24 hours prior to ablation. Five patients had T wave inversion beyond V1 but none with diagnostic criteria for ARVC, the transition of the PVC was at V3 or after V3 in 86% of patients. The median LVEF was 58% (55-60) and only four patients had LVEF below 45% that recovered after successful ablation. Patients in the three groups did not differ in relation to the analyzed parameters (Table 1).

### 3.2. Electroanatomical Mapping and ablation 3.2.1. Procedure Data

Procedure data is displayed in Table 2. The procedure time, RF duration, or precocity of the electrogram at the ablation site were not significantly different between groups. Regarding the site of origin of the PVCs, the LVOT was more frequently the site of origin of the arrhythmia in the CF group (39% vs 13% vs 11%, p=0.041), than in the RMN and Manual groups respectively, the RVOT and the LV

summit were equally represented in the three groups. All patients with sustained VT had the origin of the arrhythmia in the RVOT. Fluoroscopy time was significantly lower in the RMN vs Manual and CF groups, respectively 3 (2-5.5) min, 12 (5.7-17) min and 9.5 (4.9-14.4) min, p<0.0001. The overall acute success rate of 88% was not significantly different among groups. The site of origin of the PVCs was not associated with differences in the success of the procedure. One patient in the CF group developed a pericardial effusion that prolonged the hospital stay for another 48 hours and responded to pharmacological management.

Table 3:	Cox regression analysis with crude and adjusted hazard ratios (HR) of recurrence for the evaluated procedure variables
	of recurrence for the evaluated procedure variables

Variables	Unadjusted		Adjusted <sup>†</sup>		
	HR (95% CI)	P value	HR (95% CI)	P value	
Procedure with RMN	0.552 (0.168-1.804)	0.327			
Procedure with CF	0.972 (0.208-4.54)	0.971			
Procedure time	1.015 (1.004-1.026)	0.007	1.013 (1.00-1.025)	0.049	
Radiofrequency time	1.001 (0.999-1.003)	0.251	-		
Fluoroscopy time	1.057 (0.985-1.135)	0.122	-		
LAT at SOO	1.019 (0.971-1.068)	0.452	-		
RVOT site	0.768 (0.203-2.902)	0.697			
LVOT site	0.414 (0.053-3.236)	0.401			
LV summit site	7.604 (1.599-36.17)	0.011	2.283 (0.356- 14.64)	0.384	

† HR adjusted to procedure time and summit site . CF: contact-force; LAT: local activation time; LVOT: left ventricular outflow tract; LV: left ventricle; RMN: remote magnetic navigation: SOO: site of origin.

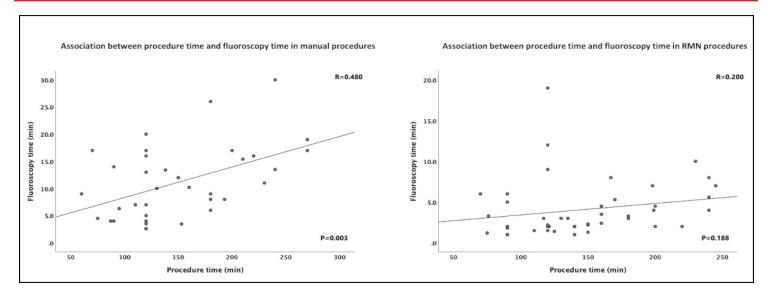


Figure 4:

Correlation between procedure time and fluoroscopy time during manual and RMN procedures

## **3.2.2. Correlation between procedure time and fluoroscopy time**

The fluoroscopy time was positively correlated with the procedure time in the overall sample increasing with the latter (R=318; p=0.004). However, although this was also true for the manual group in whom the correlation was stronger (R =0.480; p=0.003) in the RMN group there was no correlation (Figure 4).

#### 3.3. Follow-up

The median follow-up time in the overall study population was 910 (485-1440) days, minimal 31 days, and maximal 1775 days. No patients were lost to follow-up. The follow-up was significantly shorter for the CF group. During this time eleven patients (16%) had recurrence of the PVCs, four within the first 24 hours, two in the RMN group and one patient in the other two groups. The survival free from recurrence Kaplan-Meier curves for the three groups are displayed in Figure 5. The recurrence rate was not significantly different (log-rank =0.455). The first Holter performed after ablation in patients that underwent a successful procedure and did not present recurrence of symptoms, showed a median of 10 (0-100) PVCs /24 hours.

#### 3.4. Predictors of recurrence

The influence of the analyzed variables on recurrence during follow-up were tested with Cox regression analysis. The HR (95% CI) are displayed in Table 3. The use of RMN or the use of CF was not associated with recurrence when compared to manual non-contact catheters. Both the length of the procedure and the location at the LV summit were associated with a higher recurrence rate, but only the former was independently associated, with an adjusted HR (95% CI) of 1.013 (1.000-1.025), p=0.049.

#### 4. Discussion

The stability of the magnetic catheters used in RMN enables lesion formation with less dependency on CF than with conventional

catheters<sup>6</sup>. However, there were some concerns regarding the lack of a contact indicator for RMN, especially after the development of CF technology for manual ablation.

Theoretically CF technology by continuously monitoring the contact force between the catheter tip and the tissues, aims at improving efficacy by an increase of the lesion size which is proportional to the force applied<sup>10,11</sup>, and at the same time decreasing complications resultant from excessive force applied to the heart. Nonetheless, studies comparing manual ablation with and without CF have shown contradictory results<sup>12-14</sup>.

Many previous studies have demonstrated the efficacy of RMN in the ablation of all types of arrhythmias with a better safety profile than conventional ablation <sup>15-19</sup>. Since ECM is now available for RMN it is important to assess its efficacy. This new feature has proved to increase the performance of RMN for ablation of atrial fibrillation leading to a significant reduction in the duration of the RF application that resulted in a shorter duration of the procedure <sup>20</sup>. Also, in the ablation of ischemic ventricular tachycardia has demonstrated higher long-term efficacy and lower fluoroscopy use <sup>18</sup>. However, to the best of our knowledge this is the first study comparing the acute and long-term results of manual versus RMN ablation of PVCs from the outflow tracts, using the novel catheter–tissue contact feedback technology.

Previous studies comparing RMN with manual ablation with and without CF catheters, have already reported no differences in the success rate or the procedure time<sup>21,22</sup>. Our results are similar although with longer procedure times than the ones reported by Shauer et al<sup>22</sup> respectively, 140 (118-180) min for RMN group, 159 (114-205) min for Manual group and 120 (118-165) min for CF group versus 113+53 min for RMN and 115 + 69 min for manual ablation which is probably due to the different definitions of procedure duration in that study. As previously reported our study also showed a significant shorter fluoroscopy duration in the RMN group. What is remarkable is the magnitude of the difference in our study in comparison with the studies

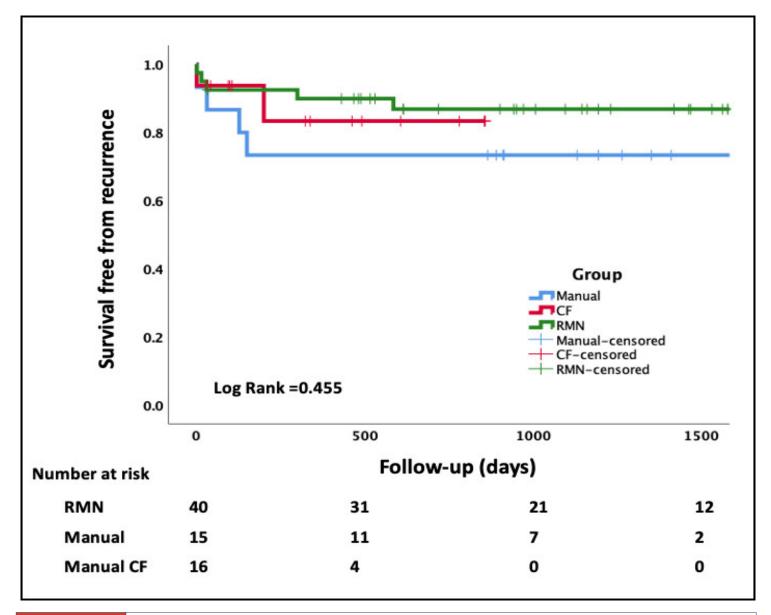


Figure 5: Kaplan-Meier survival estimate of recurrence after a successful ablation in the three groups

CF: contact-force; RMN: remote magnetic navigation

by Vries et al<sup>21</sup>, Shauer et al<sup>22</sup>, and with our own previous data<sup>4</sup>, which is probably due to the use of ECM technology. A major finding not reported previously, is the absence of correlation between the duration of the procedure and the fluoroscopy time in the RMN group as opposed to the manual procedures where we found a direct correlation. The fact that the dose of radiation remains low independently of the length of the procedure, is particularly important for very long procedures where the use of RMN may lead to an even lower amount of radiation exposure to the patient.

The success rate was not significantly different between groups as previously reported<sup>21,22</sup>. Nevertheless, the success rate with RMN reported in this study was higher than previously reported by our group (89% versus 81%) <sup>4</sup>, or the 80% success rate reported by Shauer et al<sup>22</sup>, using a previous version of the system without ECM. RMN

is associated with a better safety profile than conventional ablation<sup>23</sup> and the development of CF technology has not been able to revert this trend<sup>19</sup>.

The recurrence rate with RMN using ECM technology is low, half the recurrence rate of manual ablation although not reaching statistical significance and lower than previously reported with a similar follow-up time<sup>21</sup>, which may be due to more durable lesions obtained with this technology. The only independent predictor of recurrence was the procedure time. Long procedures usually mean difficult cases, mostly related to one of the following, difficulty on finding the site of origin of the arrhythmia due to infrequent PVCs, inaccessible sites, inability to achieve durable lesions due to intramural focus or a combination of all. So, it is not surprising that the longer the procedure the higher the possibility of recurrence.

#### 5. Limitations

There are some potential limitations of the present study. Firstly, there was no randomization, resulting in unbalanced numbers of PVCs from the LVOT in the different groups, however the success of the procedure for PVCs from this location was not different between groups, nor was it associated to recurrence. The follow-up time was significantly shorter for the CF group, but looking at survival curves, had the follow-up time been the same the results would have been at most similar but never better. Secondly, it was a retrospective study with a relatively small number of patients making it insufficient to interpret similar results as non-significant. However, taking into consideration that the success rates for RMN and CF were the same, it is difficult to accept that a bigger sample would show different results. As for the recurrence rate, we may speculate that with a bigger sample and a longer follow-up the recurrence rate might have been lower for the RMN group.

#### 6. Conclusions

In this group of patients RMN ablation of outflow tract ventricular arrhythmias using the ECM technology demonstrated a high success and low recurrence rate with significantly lower fluoroscopy times than manual or CF guided ablation. The fluoroscopy time was not correlated with the length of the procedure when performed with RMN, which is particularly important for prolonged procedures.

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