Contents lists available at ScienceDirect

International Journal of Cardiology

ELSEVIER



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

Acute and long term outcomes of catheter ablation using remote magnetic navigation for the treatment of electrical storm in patients with severe ischemic heart failure



Qi Jin ^{a,b}, Peter Karl Jacobsen ^a, Steen Pehrson ^a, Xu Chen ^{a,*}

^a Department of Cardiology, The Heart Centre, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark

^b Department of Cardiology, Shanghai Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China

ARTICLE INFO

Article history: Received 19 October 2014 Received in revised form 3 January 2015 Accepted 25 January 2015 Available online 27 January 2015

Keywords: Electrical storm Remote magnetic navigation Ventricular tachycardia

ABSTRACT

Background: Catheter ablation with remote magnetic navigation (RMN) can offer some advantages compared to manual techniques. However, the relevant clinical evidence for how RMN-guided ablation affects electrical storm (ES) due to ventricular tachycardia (VT) in patients with severe ischemic heart failure (SIHF) is still limited. *Methods*: Forty consecutive SIHF patients (left ventricular ejection fraction, $21 \pm 6.9\%$) presenting with ES underwent ablation using RMN. All the patients received implantable cardioverter-defibrillators (ICDs) either before or after ablation. Acute ablation success was defined as noninducibility of any sustained monophasic VT at the end of the procedure. Long-term analysis addressed VT recurrence, ICD therapies and all-cause death. ES was acutely suppressed by ablation in all patients.

Results: Acute ablation success was obtained in 32 of 40 (80%) patients. The procedure time and fluoroscopy time were 105 ± 27 min and 7.5 ± 4.8 min respectively. No major complications occurred during procedures. During a mean follow-up of 17.4 months, 19 patients (47.5%) remained free of VT recurrence. The percentage of patients receiving ICD shocks after ablation was lower than before ablation (30% vs 69%, P < 0.01). The mean number of ICD shocks per individual per year was reduced from 4.3 before ablation to 1.9 after ablation (P < 0.05). Ten patients died during follow-up.

Conclusions: Acute catheter ablation with RMN is safe and effective to suppress ES in SIHF patients. RMN-guided catheter ablation can prevent VT recurrence and significantly reduce ICD shocks, suggesting that this strategy can be used as an alternative therapy for VT storm in SIHF patients with ICDs.

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1. Introduction

Electrical storm (ES) due to ventricular tachycardia (VT) in patients with ischemic heart failure (IHF) is difficult to control with medical therapy as well as with implantable cardioverter-defibrillator (ICD), and is associated with poor short- and long-term prognoses [1–3]. Previous studies have shown that manual catheter ablation targeting the tachycardia substrate may overcome electrical instability [4,5] and can effectively suppress ES and reduce VT recurrence [6–8]. However, some regions of ventricular anatomy are difficult to reach by catheter using manual navigation, and compromised catheter positioning may lead to insufficient lesion formation [9]. Manipulating a catheter in some positions has also been associated with an increase in the risk of major procedure-related complications, including pericardial effusion or tamponade [10]. Mapping and ablation using a remote magnetic navigation (RMN) may offer advantages during VT procedure compared

* Corresponding author at: Medical Department B 2014, The Heart Centre, Rigshospitalet, University of Copenhagen, Blegdamsvej 9, 2100 Copenhagen, Denmark.

E-mail address: Xu.Chen@regionh.dk (X. Chen).

to manual techniques [11–13]. Moreover, especially for severe IHF (SIHF) patients with left ventricular ejection fraction (LVEF) less than 30%, available experience on long-term outcomes of ES treated by acute catheter ablation with RMN is still limited. In the current study, we prospectively assessed the efficacy and safety of acute catheter ablation using RMN for drug-refractory ES in patients with SIHF. Furthermore, we analyzed the impact of RMN-guided catheter ablation on the long-term outcomes including VT recurrence, ICD therapies and survival rate. Therefore, the goal of this study was to provide the clinical evidence to support RMN-guided ablation as an alternative approach to manually performed ablation widely used in the treatment of ES in SIHF patients.

2. Methods

2.1. Study population

In this prospective observational study, forty patients with a confirmed diagnosis of ES due to VT were consecutively included at the Rigshospitalet, University of Copenhagen between January 2008 and February 2014. All patients signed an informed consent before the procedure. ES was defined as the occurrence of three or more episodes of sustained VT, separated by 5 min, during a 24 h period or the presence of incessant VT (defined as persistent sustained VT or continuous episodes of VT separated by brief bouts of normal rhythm) [14]. SIHF was defined as ischemic heart disease with severe left ventricular dysfunction (LVEF \leq 30%). Intravenous antiarrhythmic therapies, including amiodarone or other drugs, would be administrated and be adjusted if necessary in the interval before ablation. But intravenous antiarrhythmic therapy was withheld immediately before procedure. Due to the relative urgency of the ablation procedure, it was not possible to withdraw oral antiarrhythmic drugs, such as amiodarone, for 5 half-lives before the procedure. Also, blood electrolytes were measured immediately after admission and were corrected into normal range before ablation. A coronary angiogram was performed if acute ischemia was a potential cause of arrhythmia. Acute ischemic events were excluded in the present study.

In this study, all patients had evidence of monomorphic VT on a 12-lead ECG and/or stored ICD electrograms. Eight patients with ICDs before ablation had only stored ICD electrograms because ICD therapies terminated these spontaneous VTs. Patient characteristics are summarized in Table 1. The population was predominantly male (37/40, 87.5%) with a mean age of 66 ± 9.2 years. The average LVEF was 21%. Meanwhile, 65% patients had low LVEF and clinical heart failure (NYHA classification \geq III). Thirty-two patients were on amiodarone therapy before the ablation. About one third of patients had multiple monomorphic VTs recorded by ECG or ICD with a mean number of 1.35 \pm 0.52 per patient (Table 1). Average VT cycle length (VT-CL) was 393 ms. A total of 36/40 (90%) patients had an ICD implanted. The number of ICD anti-tachycardia pacing (ICD-ATP) and ICD shocks per year in individuals was 66 \pm 81 and 4.3 \pm 5.0, respectively, before ablation. 17% (6/36) of patients experienced ventricular fibrillation (VF, indicated by ICD-stored electrograms) which was terminated by ICD shocks before ablation. Others underwent ICD shocks because ATP cannot terminate sustained VTs or degenerate to VF. In the 36 patients with ICD implantation before ablation, 5 underwent inappropriate ATP therapy, and only 2 patients received inappropriate shocks.

2.2. Electrophysiological study

A 6 F steerable catheter (Inquiry, St Jude Medical, Inc.) and a 5 F quadripolar catheter (Medtronic, Inc) were positioned within the coronary sinus and at the apex of the right ventricle via the left femoral vein. A transseptal puncture was performed in the LAO radio-graphic position during pressure monitoring. Left atrial access was confirmed by an appropriate left atrial pressure waveform and fluoroscopic position. An open-irrigated magnetic ablation catheter (Navistar Thermocool-RMT, Biosense Webster Inc.) was introduced into the left ventricular (LV) cavity through a steerable sheath (Agilis, St. Jude Medical Inc.). A single bolus of 50–100 IU/kg body weight of heparin was administrated after transseptal puncture. Additional heparin was administrated to maintain an activated clotting time between 250 and 300 s as required. Surface ECG and endocardial electrograms were continuously monitored and recorded. ICD therapies were turned off and the device programmed to a VVI mode. The whole procedure on each patient was recorded by Odyssey system (Stereotaxis Inc).

2.3. Remote magnetic navigation system

The ablation catheter was navigated with the CARTO RMT system (Biosense Webster) and the RMN Niobe II system or Niobe ES (Stereotaxis Inc., St. Louis, Missouri) to perform 3D LV electroanatomic mapping and ablation. The CARTO RMT system transmitted real-time catheter tip location and orientation to the magnetic navigation system. This information was displayed on the Navigant fluoroscopic reference screen, which enabled continuous real-time monitoring of catheter tip position without refreshing the fluoroscopic images.

2.4. Mapping and ablation strategy

Substrate mapping followed by activation mapping was performed in patients with initial sinus rhythm and well tolerated VT. A programmed stimulation protocol was

Table 1

Baseline characteristic of patients.

Characteristic		Total
No. of patients		40
Age (year)		66 ± 9.2
Sex: male/female, n (%)		37/3 (92.5%/7.5%)
LVEF (%)		21 ± 6.9
NYHA II/III + IV, n (%)		14/26 (35%/65%)
PCI/CABG, n		15/22
Amiodarone therapy before ablation (yes/no)		32/8
Clinical multiple VTs, n (%)		13 (32.5%)
Clinical VTs per patient (#)		1.35 ± 0.52
Clinical VT-CL, ms		393 ± 86
ICD recipients: ICD-VVI/ICD-DDD/CRT-D, n	Before ablation	14/7/15
	After ablation	16/9/15
ICD ATP per patient per year		66 ± 81
ICD shock per patient per year		4.3 ± 5.0

PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; ATP, anti-tachycardiac pacing.

applied to induce VT at multiple RV/LV sites with the 500-, and 400-ms drive cycle with up to 3 extrastimuli decrementally to 200 ms or ventricular refractoriness. If incessant VT was still present after catheter placement, activation and substrate mapping were performed simultaneously. In patients with poorly tolerated VT in the clinical setting, restrict activation mapping was performed after substrate mapping in sinus rhythm.

Bipolar isovoltage maps of LV were constructed to delineate the scar and border zone areas. Areas with potential amplitudes \geq 1.5 mV were defined as normal and those with amplitudes between 0.5 mV and 1.5 mV as border zone [14]. The scar area was defined during sinus rhythm by electrograms with an amplitude \leq 0.5 mV. Regions with fragmented, abnormal electrograms and late potentials were annotated using color tags. Points with QRS morphology during pace-mapping identical to those seen during documented VT were also annotated. Entrainment-mapping techniques were applied trying to characterize the arrhythmic circuit in patients with well tolerated VTs.

Radiofrequency energy was delivered in the temperature control mode with target tissue temperature of less than 45–48 °C. Power was set at 30–40 W with a flush rate of 10–25 mL/min. Radiofrequency lesions were delivered either during VT or during sinus rhythm in the regions identified or judged to be critical for the sustenance of clinical or inducible VTs. After VT, whether induced or incessant, was terminated by ablation, further ablation targeting local late potential during sinus rhythm was performed. After the catheter ablation, the same stimulation protocol mentioned above was applied to induce the tachycardia. Any induced sustained monomorphic VT was targeted with further ablation, and the inducible protocol of VT was repeated subsequently until no further VT was inducible.

2.5. Complications

Complications were divided into two categories: major and minor. Major complications included cardiac tamponade, acute myocardial infarction, stroke, major bleeding and exacerbation of heart failure. Minor complications were defined as pericarditis and inguinal haematoma.

2.6. Study endpoints

The procedural endpoint was ablation of any clinical and non-clinical inducible VTs. VT morphology was defined as "clinical" if it had been documented previously by a 12-lead electrocardiogram [7]. Nonclinical VTs were defined as those presenting different morphology and/or cycle length from any spontaneous episode documented in 12-lead ECG and/or stored ICD electrograms. Therefore, complete successful ablation was defined as the inability to reinduce any VT except polymorphic VT or ventricular fibrillation (VF). The primary study endpoint was the time to first recurrence of any sustained VT after ablation. The secondary endpoints were ICD shocks and all-cause death after ablation.

2.7. Follow-up

All patients without a previous ICD implant were implanted before discharge. After ablation, ICD therapies were reprogrammed with active VT and VF zones. The first VT detection zone was programmed to include the slowest documented VT to prevent VT below detection. Patients were monitored at least 48 h in-hospital before discharge. After VT ablation, patients are typically seen at 1 month, and every 3 months afterwards to assess VT recurrences or were followed using remote monitoring systems. VT recurrence after hospital discharge was evaluated by careful ICD interrogation at each visit or by remote monitoring. Any sustained VT during follow-up, whether symptomatic, treated by ICD or not, was considered a recurrence of VT.

2.8. Statistical analysis

Continuous variables were expressed with mean \pm SD, and categorical variables as a percentage. An unpaired Student's *t*-test was used to compare the continuous variables from two groups. Categorical data were analyzed using chi-square test analysis or Fisher exact test where appropriate. For the long-term outcomes, survival functions were estimated by Kaplan–Meier analysis. A value of P < 0.05 was considered statistically significant. SPSS v19.0 statistical package was used for analysis.

3. Results

3.1. Acute outcomes of catheter ablation with RMN

LV endocardial mapping was performed via transseptal approach in all patients. All the monomorphic sustained VTs were targeted for ablation. Fig. 1 shows an example of substrate mapping and ablation in a patient with anterior wall myocardial infarction. A total of 84 VTs were induced in this studied population with a mean number of 2.1 ± 1.0 induced VTs per patient. In this patient group, at least one type of VT, whether clinical or non-clinical, could be induced in each of the patients during the procedure. The frequency of multiple induced VTs during the procedure was higher than that documented in clinical settings (26/40 vs 13/40, P < 0.01) (Tables 1 and 2). The average CL of

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