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A straight or crosier-shaped catheter technique for phrenic nerve pacing during cryoballoon pulmonary veins isolation for treatment of atrial fibrillation.

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‘What’s New?’

In the study, we have compared two settings of phrenic nerve pacing catheter during cryoballoon pulmonary veins isolation for the treatment of atrial fibrillation. We have found out that the “crosier-shaped” setting maintains the catheter position better, requires fewer correction maneuvers, provides lower pacing thresholds and more often causes atrial capture during pacing. Moreover, the “crosier-shaped” technique is correlated with shorter procedure time that may be related to fewer dislocations. Both these techniques may be safely used and in case of problems with stable phrenic nerve capture switching for another technique seems reasonable.
Abstract

Background: Cryoablation is an efficient and safe method of pulmonary vein isolation (PVI) for treatment of atrial fibrillation. However, monitoring of phrenic nerve (PN) injury during PVI with cryoballoon (CB) remains an important issue.

Aims: The purpose of this study was to compare two techniques of PN pacing with decapolar deflectable catheter – “straight” vs. “crosier-shaped”.

Methods: 218 patients (87 females) age 61.8 ± 10.9 years referred for CB PVI for atrial fibrillation were recruited into the study. The patients were randomly assigned to PN pacing with ‘straight’ or ‘crosier-shaped’ catheter technique.

Results: There was no difference between groups in terms of demographics and efficiency of pulmonary vein isolation. The threshold of PN pacing was lower in ‘crosier-shaped’ catheter technique group (6.7 ± 4.9 vs. 4.8 ± 3.7 V, p<0.01). In this group procedural time was significantly shorter (72.6 ± 22.8 vs. 64.4 ± 14.8 min, p<0.01), fewer reposition maneuvers had to be done (31.8% vs. 19.4%, p<0.05) and atrial capture during PN pacing was observed more frequently (11.5% vs. 29.6%, p<0.01).

Conclusions: Both ‘straight’ and ‘crosier-shaped’ catheter technique provides equal efficiency in monitoring the phrenic nerve and avoiding its palsy. The “crosier-shaped” setting maintains its position better thus causing fewer catheter dislocations and requires fewer correction maneuvers, which might correlate with shorter procedure time. Moreover, the “crosier-shaped” technique provides lower pacing thresholds. Both these techniques may be safely used and in case of problems with stable phrenic nerve capture switching for another technique seems reasonable.
**Keywords:** atrial fibrillation, catheter ablation, catheter position, cryoballoon, phrenic nerve pacing

**Introduction**

Isolation of pulmonary veins (PVI) has become a standard approach to treat symptomatic, drug-refractory paroxysmal atrial fibrillation (AF). The experts recommend catheter ablation in class I(A) in paroxysmal and in class IIa(B) in persistent AF. Catheter ablation should be also considered prior to initiation of antiarrhythmic drugs in symptomatic paroxysmal or persistent atrial fibrillation (class IIa(B/C)) [1]. Cryoablation of pulmonary veins with a balloon catheter has become the most popular method among “single-shot” AF ablation techniques. In a large study “FIRE AND ICE” the cryoablation was proved to be non-inferior to radiofrequency (RF) ablation with respect to efficacy [2]. Moreover, the total procedure time and left atrial dwell time were significantly shorter in the cryoballoon group for the price of longer fluoroscopy time. There was also a significant difference in the occurrence of phrenic nerve injury (PNI). This complication is very uncommon in RF ablation (0 patients in “FIRE AND ICE” trial), while after cryoballoon ablation, the phrenic nerve function was impaired in 2.7% of patients at hospital discharge. The percentage of PNI following cryoablation of pulmonary veins varies from 2.7% to even 19% of patients [2–5]. Fortunately, the phrenic nerve function resolves even before discharge from the hospital in half of the cases [5]. The remaining palsies usually heal in the first months after the procedure and persistent injury is very rare. Phrenic nerve injury that does not resolve in 12 months, and thus may be treated as a permanent injury, occurs in around 0.3-0.4% cases [1,2,6]. Constant pacing and monitoring of the phrenic nerve function is a well-established technique that allows limiting PNI during cryoablation of right pulmonary veins. Methods to monitor the phrenic nerve function include palpation of diaphragm contractions, fluoroscopy to visualize its motion, electromyography by modified precordial ECG leads (CMAP) [7,8] auditory
cardiotocography, visualizing diaphragm contractions in intracardiac echocardiography (ICE) and alterations of femoral vein waveform [9–11]. Palpation is the most common method, due to its simplicity and no need for additional devices, the CMAP technique has been proven to be more efficient in the prevention of PNI [12].

A catheter for pacing the phrenic nerve is commonly placed in the superior vena cava above the level of cryoballoon [10,11] or in the right subclavian vein [13]. The optimal place for pacing should include a constant capture of phrenic nerve with reasonable pacing threshold and stable catheter position. Usually, a decapolar, deflectable catheter is used due to its versatility in positioning in the caval vein and multiple pacing electrodes at a different level. The deflectable catheter may be placed in the superior vena cava in a straight position (with distal electrodes oriented cranially) or in a retroflexed, curved position (with distal electrodes oriented caudally) thus taking on a shape of a crosier. In the crosier-shape setting, the catheter has a larger area of contact with the vein walls what may improve its stability. To our best knowledge, no previous studies comparing these two settings were ever published.

**Methods**

We performed a dual center, open-label, prospective experimental study to evaluate differences between “straight” and “crosier-shaped” setting of phrenic nerve pacing catheter during cryoballoon pulmonary vein isolation. The study enrolled consecutive patients scheduled for pulmonary vein isolation with cryoablation technique due to symptomatic, paroxysmal or persistent atrial fibrillation. As all patients who have cryoballoon ablation performed in our centers routinely undergo phrenic nerve pacing, the unique exclusion criterion was lack of informed consent. Patients were assigned in a 1:1 fashion to the study and control groups. The primary endpoint was defined as the need for performing any
correction maneuvers to maintain phrenic nerve capture. The maneuvers used for maintaining phrenic nerve pacing were defined as follows:

1. correction of catheter position without termination of cryoapplication;
2. correction of catheter position with concomitant termination of cryoapplication and
3. correction of catheter position that included switching to another pacing technique.

Additionally, we analyzed the following parameters: threshold of phrenic nerve capture, the time required to position the phrenic nerve pacing catheter, occurrence of phrenic nerve palsy and procedural time. The time required to position the catheter was defined as a period needed to achieve a position of the catheter that provided phrenic nerve capture with an output of 20mA and impulse duration 2ms. This parameter was then dichotomized as lasting below or above 30 seconds. According to our everyday routine approach, the phrenic nerve was paced at 60 beats per minute with an output of 20mA and 2ms impulse duration, independently of the value of phrenic nerve threshold.

All procedures were performed by the same operator to limit operator-dependent errors. The main goal of the procedure was the electrical isolation of pulmonary veins. For this purpose, following our standard of care, a cryoballoon catheter (Arctic Front Advance Cryoballoon Catheter, Medtronic, MN, USA) was positioned in ostium of each pulmonary vein and cryoapplications were delivered. Electrical isolation was confirmed with a circular mapping catheter (Achieve Mapping Catheter, Medtronic, MN, USA). Optimal initial positioning of the cryoballoon catheter in the ostium of pulmonary vein, repositioning or particular catheter maneuvers, as well as additional cryoapplication in case of lack or late pulmonary vein isolation, were on the discretion of the physician performing the procedure. All procedures were performed in conscious sedation. During cryoballoon applications in the ostia of right pulmonary veins, in all cases, a decapolar, steerable catheter was introduced through either
right or left femoral vein to the right atrium for phrenic nerve pacing. Three different catheters, all with 5mm spacing between pacing poles, were used - Dynamic XT (Boston Scientific, Marlborough, Massachusetts, USA) in 108 patients (49.5%), Coronary Sinus Decapolar (Hagmed, Rawa Mazowiecka, Poland) in 61 patients (27.9%) and Triguy Decapolar (APT Medical, Shenzhen, PRC) in 49 patients (22.4%). During transseptal puncture and isolation of left pulmonary veins, the catheter was positioned in the coronary sinus and before the cryoablation of right pulmonary veins, it was relocated to superior vena cava. In the group of “straight” shape, the catheter was advanced until proximal pacing electrodes reached the level of the right atrium and superior vena cava junction and it was minimally bent to get in contact with the vein wall [Figure 1]. Then the optimal pacing site around the anterolateral wall of the vein was searched by rotation and minor vertical movements of the catheter. In the “crosier-shaped” group the catheter was fully bent in the right atrium and advanced to the superior vena cava until distal pacing electrodes reached around 1 cm over the level of the atrium-vein junction. Then the curvature was released to achieve contact of multiple poles with the vein anterolateral wall [Figure 2]. The optimal pacing site was searched by rotation and switching of pacing poles. In both groups, the pacing was bipolar, from adjacent poles. If phrenic nerve palsy was observed the cryoapplication was stopped by double pressing of the stop button. In such a case continuation or abandoning further cryoballoon application in the ostium of the vein was left for the physician decision.

The study was performed in accordance with the Declaration of Helsinki. Local bioethical committee of the Medical University of Łódź, Poland, approved the trial and all patients gave informed consent.

**Statistical analysis**

Statistical analysis was performed using Statistica software (ver. 12, StatSoft Inc., OK, USA). Continuous variables are expressed as a mean±standard deviation. The t-Student test and
Wilcoxon-Mann-Whitney test were applied for between-group comparison, accordingly to data distribution. Categorical variables are presented as frequency. The chi-square test and its modification were used to compare categorical data. Values of p<0.05 were considered statistically significant.

Results

Our studied population included 218 consecutive patients (87 females), mean age 61.8 ± 10.9 years assigned in 1:1 ratio into “straight” group, and “crosier-shaped” groups. Detailed characteristics of studied groups are shown in Table 1. The study groups did not differ significantly in terms of age, heart function nor comorbidities.

During procedures, almost 99% (98.8%) of pulmonary veins were successfully isolated, which required approximately 1.5 (1.4 ± 0.4) cryoballoon application per vein with a mean single freezing duration of approximately 243 seconds (242.6 ± 36.7). Patients from “straight” group required significantly more application per vein (1.49 ± 0.45 vs. 1.25 ± 0.30; p < 0.05), however the total time of cryoballoon applications was similar in both groups (1263.9 ± 394.8 vs. 1251.0 ± 307.8; Table 2).

The “straight” position favored pacing from distal 1-2 poles in all 110 patients (100%). In the “crosier-shaped” group the electrodes used for pacing varied: 3-4 – 19 patients (17.6%), 5-6 – 64 patients (59.3%); 7-8 – 22 patients (20.3%), 9-10 – 3 patients (2.8%).

The position of the phrenic nerve pacing catheter did not significantly affect the total time of cryoballoon applications nor the frequency of phrenic nerve palsy. Positioning time was similar for both groups. The positioning took less than 30 seconds in 85.5 % of patients from the “straight” setting and in 81.5% of patients in the “crosier-shaped” setting (not significant). There was also no significant difference in the number of patients in whom the lack of phrenic nerve capture due to catheter dislocation caused termination of cryoablation.
We have found significant differences in terms of the need for correction of catheter position between study groups. The “straight” setting needed to be corrected in 31.8%, while the “crosier-shaped” only in 19.4% of patients (p = 0.036). Switching to a different setting due to recurrent catheter dislocations occurred in 7.2% of patients in the “straight group” and in 1.9% of patients from the “crosier-shaped” group. These differences showed a trend toward being statistically significant (p = 0.06).

A statistically significant difference between the two catheter setting was observed in the pacing threshold. The “crosier-shaped” setting mean pacing threshold (4.8 ± 3.7 mA) was significantly lower than the threshold for “straight” setting (6.7 ± 4.9 mA; p = 0.001). Moreover, the “crosier-shaped” setting more often caused atrial capture during phrenic nerve pacing (29.6% vs. 11.5%; p = 0.004).

Importantly, two groups differed in the total procedure time. The procedures where “crosier-shaped” setting was applied were significantly shorter (64 ± 14.8 min. vs. 72.6 ± 22.8 min; p = 0.006) than these with “straight” setting. Interestingly, this parameter was similar in both groups (66.0 ± 14.1 min. vs. 69.3 ± 25.1 min.; p = 0.3), if only patients without any need for correction of phrenic nerve pacing catheter were analyzed. The results are summarized in Table 2.

**Discussion**

We proved that the “straight” and “crosier-shaped” settings of phrenic nerve pacing catheter are equal in terms of efficiency in the prevention of phrenic nerve injury and positioning time. At the same time, they do not affect the time of cryoballoon application or efficiency of PVI. This suggests that these two techniques may be used interchangeably, according to operators’
preference and switching the technique is reasonable when the chosen one does not provide adequate pacing stability.

A significant observation from our study is that the lower pacing threshold and more frequent atrial capture occur during pacing with “crosier-shaped” catheter. The phrenic nerve is separated from the superior vena cava at its junction with right atrium by pericardium. Nerve capture in this region may require higher amplitude than in the brachiocephalic vein and superior vena cava where the nerve descends along their border covered with mediastinal pleura [14]. The lower pacing threshold and more frequent atrial capture for the “crosier-shape” setting may be due to improved contact with the vein wall and possible distending of the vein caused by opening the curvature of the retroflexed catheter [Figure 3]. Differences in pacing threshold or the atrial capture do not seem to affect the patients’ experience during phrenic nerve pacing. Due to anatomical variants of the phrenic nerve course, either of these techniques may work better in different patients.

Another significant difference between the two techniques observed in our study is the need for switching the catheter setting due to dislocations, instable capture or high pacing threshold. More correction maneuvers and changes to another technique occurred in the “straight” catheter setting. We suspect that this may be explained by the fact that the pressure applied to the vein by the retroflexed catheter with opened curvature is probably higher. Moreover, the surface of the catheter that is in contact with the vein wall is larger thus improving friction forces and causing better wedging of the catheter in the vein lumen. Due to that the “crosier-shaped” catheter maintains its position better and is less prone to dislocate spontaneously or e.g. during cough or breathing movements. This may be particularly important in procedures performed by a single operator when the ability to correct the position of phrenic nerve pacing catheter is limited during the first minutes of cryoablation. In this time the operator may need to apply constant pressure, with both hands, on the balloon
catheter and sheath to provide adequate adhesion of the balloon to the vein ostium. The stable position of phrenic nerve pacing catheter allows the operator to focus on the proper cryoenergy application rather than on achieving stable phrenic nerve capture. The stable pacing could be achieved with pacing from more separated rather than adjacent dipoles, however, no scientific evidence regarding such an approach is available yet.

The total procedure time was significantly lower in the “crosier-shaped” setting group. Patients from “straight” group required significantly more applications per vein, what may be related to the increased need for early stopping of cryoapplications due to loss of phrenic nerve capture. However the total time of cryoballoon application did not differ significantly between groups, so this total procedure time differences cannot be only explained by the need for additional freezes. No significant differences were also found in the time of catheter positioning. Shorter procedure time in the “crosier-shaped” setting group may be a result of more position corrections in the “straight” setting. These maneuvers, as well as doubled positioning time in case of technique switching, prolongs the procedure. Shortening the procedure is particularly important in terms of limiting the thromboembolic risk due to catheters dwelling in the left atrium. These features of different catheter positions should be taken into consideration when pacing is used for monitoring of phrenic nerve function.

Currently, there is no reliable method of predicting PNI prior to the procedure [11], however, the Ichichara at al. proved that preprocedural computed tomography and evaluation of distance between the right superior pulmonary vein ostium and the right peri-cardiophrenic bundle may predict PNI [15]. The second generation of cryoballoon significantly improved the success rate of AF ablation and significantly reduced the procedure time [16] at the cost of a trend to cause more phrenic nerve injuries and transient oesophageal lesions [5]. The higher potential for this complication requires operators to pay more attention to the effective prevention of PNI, in which results of our work may be helpful.
There were a few important limitations of our study. First, the open-label fashion that is due to need for manual positioning of the catheter done by the operator. Secondly, the fact that all the procedures were performed by the same electrophysiologist strongly limits the generalizability of our findings, but on the other hand, omits an issue of the difference in technique and experience between operators. Thirdly, the results were obtained using three types of deflectable catheters, which can be un reproducible with other types of diagnostic steerable catheters.

**Conclusion**

Both “straight” and retroflexed, “crosier-shaped” catheter settings provide equal efficiency in monitoring the phrenic nerve and avoiding its palsy. These two techniques do not differ significantly in terms of positioning time. The “crosier-shaped” setting maintains its position better thus causing fewer catheter dislocations and requires fewer correction maneuvers. Due to that, it is correlated with a shorter procedure time. Moreover, the “crosier-shaped” technique provides lower pacing thresholds. It also caused atrial capture during pacing more frequently. Both these techniques may be safely used and in case of problems with stable phrenic nerve capture switching for another technique seems reasonable.
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TABLES

TABLE 1. Clinical characteristics of studied groups.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Straight (n = 110)</th>
<th>Crosier-shaped (n = 108)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>61.5 ± 13.6</td>
<td>62.2 ± 7.2</td>
<td>NS</td>
</tr>
<tr>
<td>Body mass index</td>
<td>29.0 ± 4.3</td>
<td>29.8 ± 4.6</td>
<td>NS</td>
</tr>
<tr>
<td>Paroxysmal/Persistent atrial fibrillation</td>
<td>87 / 23</td>
<td>81 / 27</td>
<td>NS</td>
</tr>
<tr>
<td>EHRA score</td>
<td>2.7 ± 0.5</td>
<td>2.6 ± 0.6</td>
<td>NS</td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td>54.8 ± 8.4</td>
<td>57.4 ± 7.3</td>
<td>NS</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>34 (30.9%)</td>
<td>30 (27.8%)</td>
<td>NS</td>
</tr>
<tr>
<td>Chronic heart failure</td>
<td>6 (5.5%)</td>
<td>6 (5.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>51 (46%)</td>
<td>45 (42%)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension</td>
<td>71 (64%)</td>
<td>69 (63.8%)</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes mellitus type 2</td>
<td>9 (8.2%)</td>
<td>14 (12.9%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Quantitative data are presented as mean ± standard deviation. Categorical data are presented as number (frequency). EHRA = European Heart Rhythm Association; NS = not significant.
### TABLE 2. Comparison of “straight” and “crosier-shaped” techniques

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Straight</th>
<th>Crosier-shaped</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of acute PVI</td>
<td>98.1 ± 0.08</td>
<td>99.3 ± 0.04</td>
<td>NS</td>
</tr>
<tr>
<td>Total time of cryoballoon application (s)</td>
<td>1263.9 ± 394.8</td>
<td>1251 ± 307</td>
<td>NS</td>
</tr>
<tr>
<td>Cryoapplications per vein</td>
<td>1.49 ± 0.45</td>
<td>1.25 ± 0.30</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Pacing threshold with 2ms impulse (mA)</td>
<td>6.7 ± 4.9</td>
<td>4.8 ± 3.7</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Total procedural time (min)</td>
<td>72.6 ± 22.8</td>
<td>64.4 ± 14.8</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Min. temperature in LSPV (°C)</td>
<td>-48.3 ± 5.4</td>
<td>-49.1 ± 8.1</td>
<td>NS</td>
</tr>
<tr>
<td>Min. temperature in LIPV (°C)</td>
<td>-45.1 ± 7.5</td>
<td>-43.9 ± 6.6</td>
<td>NS</td>
</tr>
<tr>
<td>Min. temperature in RSPV (°C)</td>
<td>-49.1 ± 7.4</td>
<td>-48.7 ± 6.7</td>
<td>NS</td>
</tr>
<tr>
<td>Min. temperature in RIPV (°C)</td>
<td>-45.6 ± 14.1</td>
<td>-45.8 ± 14.6</td>
<td>NS</td>
</tr>
<tr>
<td>Time for positioning of PNP catheter: less than 30s. / more than 30s.</td>
<td>94 / 16 (85.5% / 14.5%)</td>
<td>88 / 20 (81.5% / 18.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Atrial capture during PNP (in sinus rhythm)</td>
<td>10 (11.5%)</td>
<td>24 (29.6%)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Any maneuver to correct PNP</td>
<td>35 (31.8%)</td>
<td>21 (19.4%)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Cryoballoon application termination due to PNP catheter dislocation</td>
<td>12 (10.9%)</td>
<td>6 (5.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Switch for another PNP technique</td>
<td>8 (7.2%)</td>
<td>2 (1.9%)</td>
<td>NS (0.06)</td>
</tr>
<tr>
<td>Phrenic Nerve Palsy</td>
<td>5 (4.5%)</td>
<td>8 (7.4%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Quantitative data are presented as mean ± standard deviation. Categorical data are presented as number (frequency). LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; Min. = Minimal; NS = not significant; PVI = pulmonary vein isolation; PNP = phrenic nerve pacing; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein, s. = seconds
FIGURE LEGENDS

Figure 1. “Straight” position of phrenic nerve pacing catheter in projections: A – AP, B – LAO, C – RAO; AP = anterior-posterior; LAO = left anterior oblique; RAO = right anterior oblique

Figure 2. “Crosier-shaped” position of phrenic nerve pacing catheter in projections: A – AP, B – LAO, C – RAO

Figure 3. (Representative Figure) Comparison of catheter settings in RAO projection: A - “Straight”, B - “Crosier-shaped”