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in a Polish cohort of patients

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Acute safety and efficacy of pulse field ablation for atrial fibrillation in a Polish cohort of patients

Short title: Pulsed field ablation for AF ablation in Poland

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INTRODUCTION

Pulsed field ablation (PFA) is a novel tool for ablation of paroxysmal and persistent atrial fibrillation (AF) [1–4]. PFA creates irreversible nanoscale pores in myocardial cell membrane exclusively, which leads to apoptosis and death of the cell [2]. Unique features of the PFA system allow to perform the AF ablation without damaging the collateral tissue such as esophagus, phrenic nerve and blood vessels as heart tissue displays a lower threshold for injury than the collateral tissue does.

Recently published paper by Reinsch et al. [3] showed low rate of silent cerebral lesion.
What is more, in contrast to thermal damage, PFA spares the extracellular matrix so the likelihood of complication such as pulmonary vein stenosis or atrio-oesophageal fistula seems unlikely [4]. Additionally, recent studies show that PFA for electrical pulmonary vein isolation (PVI) results in excellent lesion durability and medium term follow up [3, 5].

On the other side, a recently released paper reported a 1.1% risk of pericardial tamponade in 7 high-volume centers [6].

The aim of this study was to assess acute safety, efficacy and feasibility of ablation with use of PFA in high volume Polish center.

METHODS
Our study comprised 150 consecutive patients who were referred for catheter ablation due to paroxysmal or persistent atrial fibrillation. These patients underwent PFA-based PVI at a tertiary center using the multispline Farawave ablation catheter (Farapulse Inc., Menlo Park, CA, US). The study period spanned from October 2022 to October 2023.

After ablation, patients were seen in outpatient clinic 6 months after the procedure.

Procedure
Prior to the ablation, each patient provided informed consent. Heparin boluses were administered before transseptal puncture, in doses ranging from 50 to 100 IU/kg. Additional heparin was given to achieve an activated clotting time greater than 350 seconds before introducing the Farawave catheter into the left atrium. The PFA system and the ablation procedure are detailed in prior literature. The Farawave catheter, a non-steerable, over-the-wire expandable device, is adaptable into basked and flower configurations to suit the pulmonary vein’s ostium and antrum. Biphasic waveform energy for the multispline catheter was set at 2000 V per application. A Faradrive steerable sheath (Farapulse Inc., Menlo Park, CA, US) was used in conjunction with the non-steerable catheter. The procedure aimed to achieve PVI, indicated by entrance block (the cessation or disconnection of PV potentials from the left atrium) and exit block (PV stimulation resulting in PV sleeve capture without conduction to the atrium). Beyond PVI, additional ablation, including left atrial posterior wall (LAPW) isolation with Farawave catheter in flower configuration was performed at discretion of the operator. LAPW ablation was performed under fluoroscopy and isolation was confirmed by the absence of electrograms recorded on the pentaspline PFA catheter.

Statistical analysis
Categorical data were represented as counts and percentages. The one-sample Kolmogorov–Smirnov test determined the distribution (normal or nonuniform) of continuous variables. Means and standard deviations described normally distributed variables, while medians and interquartile ranges detailed those with non-normal distributions. All statistical analyses were conducted using STATISTICA 10 (StatSoft).

RESULTS AND DISCUSSION
One hundred fifty consecutive patients, (female 36.3%) of mean (standard deviation [SD]) age 60.3 (11.7) with paroxysmal (63.0%) and persistent (37.0%) AF, were successfully treated with PFA under intravenous propofol-based deep sedation and had uneventful procedures. 37% of the patients had undergone at least one ablation for AF in the past before undergoing pulsed field ablation. Beyond PVI, additional ablation, including left atrial posterior wall isolation was performed in 66 patients (27 persistent AF, 12 long lasting persistent and 27 paroxysmal) at discretion of the operator.

The mean (SD) 24.9 LAPW (9.9) lesions were administered with the catheter in flower pose.

Out of 604 pulmonary veins, 601 were successfully isolated (99.3%). Twenty two percent of patients had heart failure, 73% hypertension, 19% diabetes, 20% coronary artery disease, 3% obstructive sleep apnea, 4% had stroke or transient ischemic attack. The mean ejection fraction was (SD) 57.5% (11.2), the mean LA area was 26.2 (6.3) cm$^2$ (standard deviation [SD]).

Periprocedural data is shown in Table 1. The mean fluoroscopy time was 17.2 (6.8) minutes (SD), median exposure was 8.51 (Q1–Q3) 5.46–13.5 Gy cm$^2$ and mean activated clotting time value 412.4 (130.3) seconds (SD).

In 145 patients (96.6%), first-pass PVI was achieved by using the multispline PFA catheter, with a mean of 25.1 min (9.6) [SD] elapsing between the first and last ablations.

There was no cardiac tamponade, stroke, transient ischemic attack, phrenic nerve palsy or atrial-oesophageal fistula. Three patients had a vascular arteriovenous femoral fistula, with one requiring surgery. This study shows initial experience concerning safety, feasibility and efficacy of PFA ablation with use of pulsed field ablation in Polish cohort of patients. The procedure is safe with no serious complication (excluding vascular access common to all ablation procedures), feasible and effective. The median follow-up of 6.0 months (Q1–Q3: 4–7 months) is too short to draw conclusions concerning efficacy. However, the duration of the procedure, safety, and the possibility to perform the application on the posterior wall of the
LA suggest great potential for the new method in ablating both paroxysmal and persistent AF. Although the risk of silent cerebral ischemia during PFA is still under investigation with reported occurrence from 3 to 19% [3, 6] and while large scale clinical trials are lacking, clinical evidence has demonstrated very good efficacy in achieving durable PVI without ablation related serious adverse events. These findings need to be confirmed in ongoing prospective randomized, multicenter trials.

Article information
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REFERENCES


**Table 1. Periprocedural data**

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of the procedure in minutes (n = 150)</td>
<td>65.9 (23.6)</td>
</tr>
<tr>
<td>LA dwell time in minutes (n = 150)</td>
<td>42.2 (14.0)</td>
</tr>
<tr>
<td>Time from first to the last PFA delivery in minutes (n = 150)</td>
<td>24.9 (10.7)</td>
</tr>
<tr>
<td>Number of applications (n = 150)</td>
<td>46.4 (14.3)</td>
</tr>
<tr>
<td>Time of the procedure in minutes (Group PVs + PWA, n = 66)</td>
<td>73.1 (30.12)</td>
</tr>
<tr>
<td>LA dwell time in minutes (Group PVs + PWA, n = 66)</td>
<td>49.9 (17.7)</td>
</tr>
<tr>
<td>Time from first to last PFA delivery in minutes (Group PVs + PWA, n = 66)</td>
<td>30.2 (12.4)</td>
</tr>
<tr>
<td>Number of applications (Group PVs + PWA, n = 66)</td>
<td>56.6 (8.9)</td>
</tr>
<tr>
<td>Time of the procedure in minutes (Group „only” PVs, n = 84)</td>
<td>61.9 (18.9)</td>
</tr>
<tr>
<td>LA dwell time in minutes (Group „only” PVs, n = 84)</td>
<td>37.2 (10.7)</td>
</tr>
<tr>
<td>Time from first to the last PFA delivery in minutes (Group „only” PVs, n = 84)</td>
<td>21.7 (8.3)</td>
</tr>
<tr>
<td>Number of applications (Group „only” PVs, n = 84)</td>
<td>38.0 (8.6)</td>
</tr>
</tbody>
</table>

Abbreviations: LA, left atrium; PFA, pulse field ablation; PVs, pulmonary veins; PWA, posterior wall ablation; SD, standard deviation.