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

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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 only in myocardial cell membranes, which leads to apoptosis and death of the cells [2]. Unique features of the PFA system allow for performing the AF ablation without damaging adjacent tissue such as the esophagus, phrenic nerve, and blood vessels, as heart tissue displays a lower threshold for injury than collateral tissue.

A recently published article by Reinsch et al. [3] showed a low rate of silent cerebral lesions. What is more, in contrast to thermal damage, PFA spares the extracellular matrix so the likelihood of complications, 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 on medium-term follow-up [3, 5].

On the other hand, another recently published article reported a 1.1% risk of pericardial tamponade in 7 high-volume centers [6].

This study aimed to assess acute safety, efficacy, and feasibility of ablation with the use of PFA in a high-volume Polish center.

METHODS

Our study involved 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 an outpatient center 6 months after the procedure.

Procedure

Before 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 have been described in the literature. The Farawave catheter, a non-steerable, over-the-wire expandable device, is adaptable into basket 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 the entrance block (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 the operator's discretion. 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 presented 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 were used for 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%), at the 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. Thirty-seven percent 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 the operator's discretion.

LAPW lesions (mean 24.9 SD 9.9) were created with the catheter in the flower configuration. 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, and 4% had a stroke or transient ischemic attack. Mean ejection fraction was (SD) 57.5% (11.2), and the mean LA area was 26.2 (6.3) cm^2 (standard deviation [SD]).

Periprocedural data are 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 the mean activated clotting time value was 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 time of 25.1 min (9.6) [SD] between the first and last ablations. There were no complications such as 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 the safety, feasibility, and efficacy of PFA ablation with the use of pulsed field ablation in a Polish cohort of patients. The procedure is safe and does not entail any serious complications (excluding vascular access common to all ablation procedures); it is feasible and effective. The median follow-up of 6.0 months (Q1–Q3: 4–7 months) was too short to draw conclusions concerning efficacy. However, the duration of the procedure, safety, and the possibility of performing the application on the posterior wall of the LA offer great potential to ablate 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 results of 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.

Table 1. Periprocedural data

	Mean (SD)
Time of the procedure in minutes (n = 150)	65.9 (23.6)
LA dwell time in minutes (n = 150)	42.2 (14.0)
Time from first to last PFA delivery in minutes (n = 150)	24.9 (10.7)
Number of applications (n = 150)	46.4 (14.3)
Time of the procedure in minutes (Group PVs + PWA, n = 66)	73.1 (30.12)
LA dwell time in minutes (Group PVs + PWA, n = 66)	49.9 (17.7)
Time from first to last PFA delivery in minutes (Group PVs + PWA, n = 66)	30.2 (12.4)
Number of applications (Group PVs + PWA, n = 66)	56.6 (8.9)
Time of the procedure in minutes (PV-only group , n = 84)	61.9 (18.9)
LA dwell time in minutes (PV-only group, n = 84)	37.2 (10.7)
Time from first to last PFA delivery in minutes (PV-only group, n = 84)	21.7 (8.3)
Number of applications (PV-only group, n = 84)	38.0 (8.6)

Abbreviations: LA, left atrium; PFA, pulse field ablation; PV, pulmonary vein; PWA, posterior wall ablation; SD, standard deviation

Article information

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