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Research Article

Pulsed Field Ablation of Atrial Fibrillation: Concept, Evidence and Available Technologies Where do we stand in 2024?

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Abstract

Catheter ablation (CA) has been commonly used in treatment of symptomatic patients with Atrial Fibrillation (AF) with Pulmonary vein isolation (PVI) being considered as the cornerstone of AF ablation procedure (1). However, there are major challenges facing PVI using current CA technologies including the durability of PVI, risk of Pulmonary veins (PV) reconnection, collateral damage especially phrenic nerve injury and oesopahguial injury (2). Therefore, better technology was needed to improve efficacy and safety. Pulsed field ablation (PFA) has emerged over last few years as new ablation modality for the treatment of AF using non-thermal energy and irreversible electroporation.

This review provides an update on concept, current evidence, gap in evidence and available technology for PFA of AF.

Keywords: atrial fibrillation; catheter ablation; pulsed field ablation; pulmonary vein isolation

Abbreviations

AFL = atrial flutter

AF = atrial fibrillation

AT = atrial tachycardia

CA = Catheter ablation

CMR = Cardiac magnetic resonance

CT= computerised tomography

CTI = cavotricuspid isthmus

IRE = irreversible electroporation

LGE = late gadolinium enhancement

OGD = oesophagogastroduodenoscopy

PEF = pulsed electrical field

PFA = pulsed field ablation

PVI = Pulmonary vein isolation

PV = Pulmonary vein

RF = radiofrequency

VLCC = variable loop circular catheter

1.Introduction

PVI using radiofrequency or cryoablation technologies is currently recommended for management of symptomatic AF patients either as first line rhythm control strategy or after failed one or more antiarrhythmic drugs (3). However, catheter ablation can be associated with complications including pulmonary vein (PV) stenosis, phrenic nerve injury, cerebrovascular injury, and atrioesophageal fistula (2). Maintaining the balance between the efficacy and safety of AF ablation procedure remains a challenge. The new emerging Pulsed field ablation (PFA) technology has been proposed to offer better safety and efficacy advantages as compared to currently used catheter ablation technologies due to the minimal thermal energy imparted to target tissue and the ability to create transmural and contiguous lesions through Irreversible electroporation (IRE) (4,5).

2.Concept of PFA

PFA is an irreversible form of electroporation via applying high voltage electrical fields which induce pore formation within the lipid layer of the cell membrane resulting in homeostatic changes and cell death. This technology has been used as a treatment modality to induce targeted cell death in other medical fields such as Oncology and it is now considered as an alternate energy source for treatments of cardiac arrhythmias.

First attempt in ablation in human was described in 1982 by Melvin Scheinman and his colleagues delivering single monophasic shocks of high amplitude for atrioventricular nodal ablation to treat supraventricular arrhythmias in five patients with recurrent bouts of supraventricular tachycardia resistant to both conventional and experimental drugs. However, the extent of the ablated tissue was hardly to control, and the approach itself has put the patient at risk of barotrauma. Complete atrioventricular (AV) block was produced in all, one patient died suddenly six weeks after shock therapy, and the remainder had complete AV block with follow-up intervals ranging from four to 12 months (6).

Over years, there was growing evidence towards using of PFA as a non-thermal source of energy in ablation of cardiac arrhythmias having the following advantages:

a. Tissue Specificity:

Cardiomyocytes have lower electrical thresholds as compared to other tissues making pulsed field ablation highly specific for cardiomyocytes reducing risk of collateral damage. Moreover, direct application of pulsed field energy (PFE) to esophageal tissue resulted only in minimal damage minimizing the risk of post-ablation atrio-esophageal fistula and the same applies for phrenic nerve affection (7,8). In addition, pre-clinical studies have shown preserved structure and function of blood vessels even with direct application despite transient luminal narrowing that can be attributed to vascular spasm (9–11).

b.Time factor:

Standard ablation techniques usually require several seconds to minutes to achieve steady-state temperature gradients (12). Whereas the effect of PFA is almost instantaneous. A single PFA delivery is usually accomplished within one heartbeat, and a lesion is typically created with 3 to 4 PFA deliveries and if a circumferential electrode catheter is employed, vein isolation can be achieved within four heartbeats. Practically, it is anticipated that single vein isolation should be achievable routinely within 1 to 2 minutes and hence, a total procedure duration of 60 to 90 minutes for four PV isolation should be easily achievable in most of the cases using PFA (13,14).

c.Temperature independence:

Being a non-thermal modality, the depth of lesions is mainly affected by the pattern of energy delivery which can be adjusted by multiple parameters including voltage, frequency, polarity, number of pulses/trains, pulse cycle length, duty cycle, pulse shape, phasicity, inter-pulse delay and inter-phase delay in addition to other factors such as tissue characteristics, heterogeneity as well as fiber orientation (15–21).

3.Questions to be answered

a) Head-to-head comparison and randomised controlled studies

Although multiple observational studies have been conducted on different PFA systems, only few head-to-head comparison studies have been conducted showing similar procedure efficacy and shorter procedure time (22,23).

ADVENT trial was the first randomized, single-blind, noninferiority head-to-head study published in 2023 showing the noninferiority of PFA versus conventional RF ablation in patients with paroxysmal AF as regards freedom from a composite of initial procedural failure, documented atrial tachyarrhythmia after a 3-month blanking period, antiarrhythmic drug use, cardioversion, or repeat ablation and device- and procedure-related serious adverse events at 1 year (24). The SINGLE SHOT CHAMPION trial is another ongoing randomised controlled non-inferiority trial comparing the FARAPULSE PFA versus the Arctic Front Cryoballoon (Medtronic) in patients with paroxysmal AF undergoing PVI (25).

b) Durability of lesions

Moving beyond the “honeymoon phase” of PFA, an important question has arisen regarding the durability of lesions despite the very high perfect acute procedural success with an excellent safety profile reported at the early trials. Beyond the border created by PFA where there is permanent damage, there is a penumbra of tissue with reversible electroporation which demonstrates loss of electrical activity in the acute stage despite retaining residual viability. Upon recovery of membrane function, this tissue can regain electrophysiological function; thus, hampering lesion durability and hence acute disappearance of local electrograms immediately after pulse delivery may not guarantee lesion durability highlighting the need for setting reliable metrics for defining successful durable lesion delivery (26).

Tancredi Magni and his colleagues reported recurrence rate of 3.1% within one-year in a cohort of 447 patients underwent AF PFA, 50% of the recurrences were AF, 14.3% had AFL and the remaining had both (27).

In the recent multinational retrospective registry, MANIFEST-PF which included 1568 patients underwent PFA for paroxysmal or persistent AF, the 1-year Kaplan-Meier estimate for freedom from atrial arrhythmia was 78.1% with a more common clinical effectiveness in patients with paroxysmal AF versus persistent AF (81.6% versus 71.5%; P=0.001) (28). Furthermore, redo procedures confirmed a durable isolation in 71% of PVs in the recurrent cases in EU-PORIA registry (European Real-world Outcomes with Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation) (29). Prior operator experience with cryoballoon ablation was associated with a higher PVI durability compared to operators with only point-by-point radiofrequency experience (76% vs 60%; $P < 0.001$). However, the operators’ cumulative experience in atrial fibrillation ablation (≤5 vs >5 years) and the size of the PFA device used (31 mm vs 35 mm) had no impact on PV lesion durability (29).

The question whether the recurrence rate is directly related to the operator experience with this new technology, contact force applied or frequency of energy delivered needs to be studied in a large-scale randomized study.

c)Different technologies

Another important point that should be considered is that the results of one trial using a certain PFA system are not generalizable and do not necessarily apply to other systems. Unlike thermal energy delivered by RF generators where the effect of lesions is to a far extent predictable, PFE delivery greatly differs between different systems with a lot of parameters that can be

modulated by the manufacturer including pulse amplitude, pulse duration, unipolar/bipolar, monophasic/biphasic, interpulse delay, interphase delay, pulse train number and pulse train duration (30). Moreover, the optimal waveform (monophasic or biphasic) regarding safety and efficacy is another point that deserves further studies (26).

4.Available technologies, current evidence, and ongoing trials

a.Farapulse PFA system (Boston Scientific)

Among the currently available systems, the Farapulse PFA system has arguably received the most attention (31) The FDA recently approved ablation system in patients with paroxysmal and persistent atrial fibrillation (AF) after demonstrating favourable safety and efficacy in four controlled prospective trials (IMPULSE, PEFCAT, PEFCAT-2, and PersAFone) (31–33).

The FARAPULSE PFA System is composed of three main components: FARADRIVE™ Steerable Sheath designed for access and navigation, FARAWAVE™ PFA Catheter designed to treat a range of PV anatomies using a 12-F over-the-wire catheter with 5 splines that each contain 4 electrodes, which can be deployed in either a flower or basket configuration (Figure 1) and FARASTAR™ PFA Generator designed for an easy three-button click to PREPARE, CONFIRM and DELIVER therapy using bipolar & biphasic waveforms with proprietary pulses

While the commercially available 12F multispline-electrode catheter FARAWAVE™ PFA Catheter is designed to be used for PVI, the trial design in PEFCAT II and PersAFone also allowed for the use of the 12F deflectable focal PFA catheter (Faraflex, Farapulse Inc.) for CTI, posterior wall of the left atrium (LA), and mitral isthmus ablation.

The first in-human experience with pulsed field AF ablation using Farapulse PFA system was in 2018 by Reddy and his colleagues including 22 patients with symptomatic paroxysmal AF who underwent their first ablation procedure with either endocardial approach (15 patients) or epicardial approach (7 patients). The acute success rate was 100%, where all patients in whom energy was successfully delivered to the tissues had complete electrical isolation and no adverse events were reported neither intraoperative nor after 1 month of follow up (34).

The IMPULSE (A Safety and Feasibility Study of the IOWA Approach Endocardial Ablation System to Treat Atrial Fibrillation] and PEFCAT (A Safety and Feasibility Study of the FARAPULSE Endocardial Ablation System to Treat Paroxysmal Atrial Fibrillation) trials were feasibility studies primarily designed to assess the safety and effectiveness of catheter-based PFA in paroxysmal atrial fibrillation using the over-the- wire, single shot–type multielectrode PFA catheter (Farawave, Farapulse) to achieve PVI. In 81 patients with symptomatic paroxysmal AF, acute success of PV isolation was 100%, with only one adverse event (pericardial tamponade) after 120 days of follow up (1.2%). The durability of lesions was assessed after 3 months by invasive remapping and improved from 18 to 100% with waveform refinement. In addition, the 12-month Kaplan-Meier estimate of freedom from arrhythmia was 87.4 ± 5.6% (35). The PEFCAT II trial also investigated the first-in-human treatment of cavotricuspid isthmus (CTI) dependent flutter with the novel, deflectable focal PFA catheter (Faraflex, Farapulse) in addition to treatment of the PVs (36).

Invasive remapping for patients recruited in these 3 nearly identical trials (IMPULSE, PEFCAT, and PEFCAT II) revealed that durable PVI was achieved in 84.8% of PVs (64.5% of patients) in the entire cohort, and 96.0% of PVs (84.1% of patients) treated with the optimized biphasic energy PFA waveform. Primary adverse events occurred only in 2.5% of patients (2 pericardial effusions or tamponade, 1 hematoma); in addition, there was 1 transient ischemic attack. Furthermore, the 1-year Kaplan-Meier estimates for freedom from any atrial arrhythmia for the entire cohort and for the optimized biphasic energy PFA waveform cohort were 78.5 ± 3.8% and 84.5 ± 5.4%, respectively. This data confirmed that PVI with the flower or basket PFA catheter in paroxysmal AF patients, is safe, efficient, durable, and results in a high rate of freedom from recurrent atrial arrhythmias (36).

Neven and his colleagues reported also six-month follow-up of PVI using PFA for paroxysmal AF confirming that PVI using PFA for paroxysmal AF in a “real-world” setting is safe and feasible with favourable post-ablation clinical course and 6-month follow-up. Only a single participant developed cardiac tamponade, 27 patients (90%) were in normal sinus rhythm on day 90, 3 patients had AF/AT recurrence requiring redo procedure and all 30 patients were free of anti-arrhythmic drugs and in normal sinus rhythm on day 180 (37).

Although retrospective, the MANIFEST-PF survey is the largest multinational survey including cohort of 1758 patients with paroxysmal/persistent AF (58/35%) undergoing PFA at 24 clinical centres by 90 operators using the FARAPULSE system confirming that PFA is efficacious for PVI with favourable safety profile consistent with preferential tissue ablation. The acute success of PVI was as high as 99.9%, with no recorded PFA-related complications; namely persistent phrenic nerve paralysis, symptomatic PV stenosis or oesophageal injuries. Among non PFA-related complications, vascular complications were the most common (3.17%), most of which were minor complications and didn’t require surgical intervention. Cardiac tamponade occurred in 0.97% of cases while the incidence of stroke was 0.39%. Coronary vasospasm with associated ST segment elevation during mitral isthmus ablation was reported in only one patient and subsequently relieved with intracoronary nitroglycerine (38).

The relatively small percentage of patients with persistent AF included in all of the above studies obviated the need for dedicated trials for such population. The PersAFOne trial was a single-arm study aiming to evaluate bipolar biphasic PEF ablation for 25 patients with persistent AF in terms of safety and efficacy (lesion durability for both PVI and left atrial posterior wall ablation) using the Farawave for PVI and the focal PFA catheter; Faraflex for extra PV ablation. Acute success was achieved in 100% (both PVI and left atrial posterior wall ablation) and invasive remapping 2-3 months later revealed durable isolation in 96% of PVs and 100% of left atrial posterior walls. As for the safety outcome, oesophagogastroduodenoscopy (OGD) revealed no oesophageal mucosal lesions and cardiac computerised tomography (CT) scan revealed no PV stenosis (39).

The PersAFOne III t rial is an ongoing prospective multi-center single arm trial which will be studying the safety and feasibility for PFA of persistent AF and associated AFL. The study has a composite primary safety endpoint that is defined as the incidence of early-onset and late-onset device- or procedure-related pre-specified adverse events (40).

Comparing the different thermal ablation approaches, Nakatani and his colleagues prospectively enrolled eighteen of the patients involved in the IMPULSE and PEFCAT trials and compared them to 23 patients undergoing AF ablation by RF (n=16) or cryoablation (n=7) in terms of safety. Cardiac magnetic resonance (CMR) was performed in all patients pre-operatively, <

3 hours post-procedure and after 3 months to assess the short- and long-term effects of the different ablation techniques on the oesophagus and aorta. Although oesophageal contact with left atrial ablation sites was similar in both groups (P=0.41), the incidence of oesophageal lesions was 0% in the PFA group as compared to 43% in the thermal ablation group (P<0.001). On the other hand, the incidence of aortic injuries was not significantly different between the 2 groups, no phrenic nerve affection occurred in both groups and all aortic and oesophageal lesions resolved on the follow up CMR after 3 months (41). Moreover, CMR with LGE has also shown that PFA-induced LGE is larger, yet transient suggesting a potential for preserving LA anatomy and function (42).

b.PulseSelect PFA System (Medtronic)

The PulseSelect PFA System is a new promising investigational PFA system which transmits a controlled biphasic, bipolar waveform to user-selectable electrodes via an over-the-wire, a circular array of 9 gold electrodes (electrode length, 3 mm; 20° forward tilted array with a diameter of 25 mm; 9F shaft) (Figure 1). The circular catheter can also record PV and atrial potentials and perform pacing. The system can deliver a variety of power profiles with voltages applied to the electrodes ranging from 500 to 1500 volts (43).

The PULSED AF pilot trial (Pulsed Field Ablation to Irreversibly Electroporate Tissue and Treat AF) was the first in-human multi-center study evaluating the safety and efficacy of this new system. In this first-in-human pilot trial, 35 patients with paroxysmal AF along with 3 patients with persistent AF had their PVs successfully isolated (152/152) with no major adverse events after a 1-month follow up period (44).

The recently published PULSED AF pivotal trial was a prospective, global, multicentre, nonrandomized, paired single-arm study in which patients with paroxysmal (n=150) or persistent (n=150) symptomatic AF refractory to class I or III antiarrhythmic drugs were treated with PFA. All patients were monitored for 1 year using weekly and symptomatic trans-telephonic monitoring. PFA was shown to be effective at 1 year in 66.2% of patients with paroxysmal AF and 55.1% of patients with persistent AF. The primary safety end point occurred in 1 patient in both the paroxysmal and persistent AF cohorts (one cerebrovascular accident in paroxysmal AF cohort and one cardiac tamponade in persistent AF cohort). This pivotal trial demonstrated a low rate of primary safety adverse events (0.7%) and consistent effectiveness using the PulseSelect PFA System (45).

c.Sphere-9 Catheter and Affera Mapping and Ablation System (Medtronic)

The Affera lattice-tip Sphere-9 catheter (Figure 1) is another unique catheter technology which is capable of delivering both RF and PF energies for ablation using same catheter. This catheter can be used within an electroanatomical mapping system (Prism-1, Affera Inc., Newton, MA, USA) and PFA is delivered via the PFA generator (HexaPULSE, Affera, Inc.).

The 7.5 F catheter has an expandable 9-mm lattice nitinol tip, a central indifferent electrode and 9 mini-electrodes, 0.7-mm each, on the spherical surface with temperature sensing capability. In addition, it has an expandable spheroid-shaped lattice tip with a 10-fold larger effective area compared to the conventional 3.5 mm electrode and can deliver higher energy with a lower risk of tissue overheating including linear lesions to mitral isthmus, left atrial roof and cavotricuspid isthmus (46).

The efficacy and safety of such system was studied on a cohort of 76 patients with paroxysmal (n=55) or persistent AF (n=21). The primary feasibility endpoint of acute PV isolation was achieved in 100% of the patients and the primary safety endpoint, defined as a composite of major adverse events within seven days, was achieved in 98.7% of patients with only one patient developed an access-site hematoma that required surgical intervention (47).

The multicentre, prospective, randomised; Treatment of Persistent Atrial Fibrillation with Sphere-9 Catheter and Affera Mapping and Ablation System (SPHERE Per-AF) is an ongoing trial that will test the effectiveness and safety of the Sphere-9 catheter together with the Affera cardiac mapping system in the treatment of persistent AF patients (48).

d.VARIPULSE (Biosense Webster)

Another system which is currently under trial is the VARIPULSE ablation system (Biosense Webster, Inc. Irvine, California) which has recently achieved the CE mark approval for the treatment of symptomatic drug refractory recurrent paroxysmal AF using PFA. This system consists of a novel, mapping-integrated, variable-loop, pulsed field ablation VARIPULSE™ Catheter and TRUPULSE™ PFA generator.

The variable loop circular catheter (VLCC) (figure 1) is a steerable, multielectrode, irrigated catheter. A bidirectional circular tip is attached to the distal end of the 8.5 Fr shaft is which can be expanded and contracted, as necessary, to fit PVs of different sizes. The 10 platinum/iridium electrode rings are used for visualization, stimulation, recording, and bipolar pulsed field ablation. All 10 poles of the VLCC are used for ablation, except in the case of electrode overlap which require the most distal and most proximal electrodes to be turned off (49).

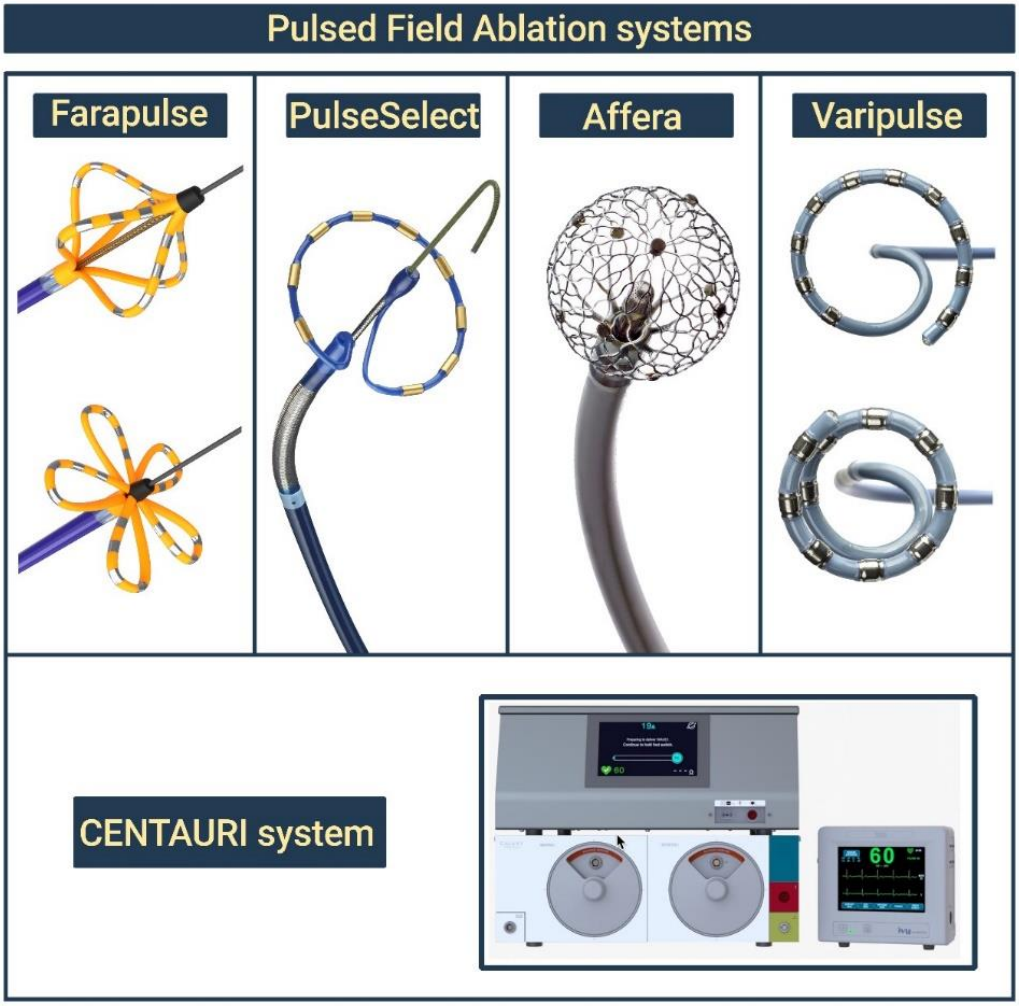

Figure 1: Available PFA systems

The ablation system is designed to be used with the CARTO™ 3 System, enabling mapping integration to the application of PF energy and incorporates proprietary technology to deliver short-duration, high-voltage bipolar biphasic pulses to a multielectrode ablation catheter. Each pulse is delivered as a square wave with positive and negative phases. PFA is applied in a bipolar configuration with an energy of 1800V. Each pulsed field application includes trains of microsecond-long biphasic pulses in between, for a total application duration of approximately 250 microseconds. The generator can also be configured to deliver energy to specific electrode pairs and to adjust energy delivery based on clinical need.

The inspIRE prospective multi-center clinical trial (Study for Treatment of Paroxysmal Atrial Fibrillation [PAF] by PFA System with Irreversible Electroporation [IRE]) was the first clinical study for the PFA system with full electroanatomical mapping system integration. It assessed the safety and efficacy of the new fully integrated biphasic pulsed field ablation (PFA) VARIPULSE system, which is comprised of a multi-channel generator, variable decapolar irrigated loop circular VARIPULSE™ Catheter and TRUPULSE™ Generator (Biosense Webster, Inc.) for the treatment of paroxysmal atrial fibrillation (PAF). Across 13 centers, 226 patients were enrolled (wave I-40, wave II-186). No primary adverse events were reported in either cohort and PVI without acute reconnection was achieved in 97.1% of targeted veins. Primary efficacy was achieved in 70.9%, 12-month freedom from symptomatic AF /AFL /AT recurrence and repeat ablation was 78.9% and 92.3%, respectively (50).

Recently, Twelve-month outcomes data from the pilot phase of the admIRE study (Assessment of Safety and Effectiveness in Treatment Management of Atrial Fibrillation with the Biosense Webster IRE Ablation System) showed that among 20 patients who completed the 12-month follow-up visit, 100% achieved acute success from ablation procedures and 80% remained free from atrial arrhythmia recurrence at one year. Additionally, no procedure or device-related primary adverse events were reported at this phase (51).

Trial Name	Year	Design	Number of patients	System used	Primary endpoints	Outcomes
IMPULSE	2020	Single-arm prospective clinical study.	40	IOWA Approach Endocardial Ablation System	Safety endpoints up to 7 days. Acute success.	Acute success 100% Adverse events: 17.5%
PEFCAT	2022	Single-arm prospective clinical study.	71	FARAPULSE Endocardial Ablation System	Safety endpoints up to 30 days. Acute success.	Acute success: 100% Adverse events: 15.49%
PEFCAT II	2022	Prospective, multicentre, observational study.	10	FARAPULSE Endocardial Multi Ablation System	Safety endpoints, Acute PV isolation.	Acute success: 100% Adverse events: 60%
PersAFOne	2020	Single-arm prospective clinical study.	25	FARAPULSE Endocardial Ablation System	Primary feasibility endpoint. Primary safety endpoints up to 30 days	Acute PV isolation 100% Adverse events: only one pericardial effusion/tamponade was recorded.
MANIFEST PF	2022	Retrospective observational study.	1758	Farawave, Farapulse-Boston Scientific Inc.	Successful PVI. safety endpoints.	Acute PVI Success Rate: 99.9% Adverse events: 5.5%
Pulsed-field ablation-based pulmonary vein isolation: acute safety, efficacy and short-term follow-up in a multi-centre real-world scenario	2022	Prospective observational study.	138	Farawave, Farapulse Inc, Menlo Park, CA, USA	Acute PVI success. Secondary safety endpoints up to 12 months including complications.	Acute PVI: 100% Adverse events: 0.7%
PULSED - AF	2022	Non-randomized, prospective, multicentre, clinical study.	38	Medtronic Pulse Select Pulsed Field Ablation (PFA) System	Successful PVI. safety endpoints up to 30 days.	Acute PVI: 100% Adverse events: Only one access site haematoma.
PULSED AF Pivotal Trial	2023	prospective, multi-centre, non-randomized, unblinded clinical study.	150 with paroxysmal AF 150 with persistent AF	CARTO, EnSite, Rhythmia, Others	Acute procedural success and freedom of arrhythmias for 12 months. Safety endpoints in 12 months.	Primary effectiveness: 66.2% in paroxysmal AF and 55.1% in persistent AF.Safety adverse events: 0.7% PFA effective in paroxysmal AF 66.2 % and 55.1% in persistent AF.

Table 1: summarizes the current body of evidence for PFA of AF

e.E-CENTAURI™ System (Galvanize Therapeutics)

The CE Marked CENTAURI™ system is new promising open system compatible with the commercially available catheters and was recently acquired by CardioFocus company.

The CENTAURI System has three components: the CENTAURI Generator that delivers biphasic, monopolar PFE at three selectable energy settings through the tip electrode of the ablation catheter; the CENTAURI Connect device that permits connectivity of compatible focal ablation catheters and their mapping systems; and a Cardiac Monitor (Ivy Biomedical Systems) that synchronizes PFA delivery to the R-wave.

This promising system was investigated for safety and PVI durability in ECLIPSE AF trial. , a prospective, single-arm, multi-center study including 82 patients undergoing PVI for paroxysmal or persistent AF. At this study, the CENTAURI System was used sequentially with three commercial ablation catheters and their associated mapping systems: TactiCath™ SE and EnSite™ Precision ('EnSite'); INTELLANAV STABLEPOINT™ ('StablePoint') and RHYTHMIA HDx™ ('RHYTHMIA'); THERMOCOOL SMARTTOUCH™ ('ThermoCool ST') and CARTO®3 ('CARTO'). PVI was achieved in 100% of pulmonary veins with first-pass isolation in 92.2%. invasive remapping was performed 90 days after the index procedure with overall 89% per-PV chronic durability rate within the

Optimized PFA Cohorts, Regarding the safety, four serious adverse events of interest (three vascular access complications and one lacunar stroke) had happened, and all considered related to the standard PVI procedure only (52).

Furthermore, a new focal, Pulsed Electric Field (PEF) ablation catheter called QuickShot™ is being investigated in QuickShot PEF-AF clinical study, first human investigational study which will be using this new focal, PFA ablation catheter which is compatible with the CE Marked CENTAURI™ system. QuickShot, paired with CENTAURI, would carry several unique features: proprietary waveform that allows PEF ablation without microbubble formation and muscle contraction so that procedures may be performed under conscious sedation according to physician preference, large ablation zone, allowing for 10 mm lesion tags, deep lesion creation negating the need for radiofrequency energy, a contact sensing algorithm and compatibility with standard 8.5 French, commercially available sheaths (53).

5.Conclusion

Pulsed field ablation is a new promising technology with a highly selective and tissue-specific mechanism of action that seems to be effective and safe in treating AF patients. Although published studies are so far reassuring confirming safety and efficacy. However, multicentre, randomized controlled studies comparing PFA with other ablation energy sources would be very important to assess the long-term outcomes and recurrence rate.

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