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PULSE-ELECTRICAL ABLATION IN ATRIAL FIBRILLATION: EFFICACY AND SAFETY ACCORDING TO CURRENT RANDOMIZED TRIALS AND META-ANALYSES 2025–2026

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Annotation: Atrial fibrillation (AF) is the most common persistent cardiac arrhythmia and is associated with an increased risk of stroke, heart failure, hospitalizations, and cardiovascular mortality. Catheter pulmonary vein isolation (PVI) is central to the current rhythm control strategy in patients with symptomatic AF, especially when antiarrhythmic therapy is ineffective or intolerant. Traditionally, thermal methods have been used to perform PVI, primarily radiofrequency (RF) and cryoballoon ablation. Despite the proven effectiveness of these technologies, their use is associated with the risk of damage to surrounding tissues, including the esophagus, phrenic nerve and coronary arteries.Pulsed field ablation (PFA) is a fundamentally new method of catheter ablation based on the use of short, high-voltage electrical pulses that cause irreversible electroporation of cell membranes. The presumed tissue selectivity of electroporation may provide preferential damage to cardiomyocytes with relative preservation of surrounding structures. This has the potential to reduce the risk of some of the complications associated with thermal ablation while reducing the duration of the procedure.

Keywords: atrial fibrillation; pulsed field ablation; irreversible electroporation; catheter ablation; pulmonary vein isolation; radiofrequency ablation; cryoballoon ablation;

Introduction. In recent years, PFA has been rapidly introduced into clinical practice, but the question of its comparative efficacy and safety in relation to traditional ablation methods remains relevant. Current studies have shown that PFA is highly effective in isolating the pulmonary veins and preventing recurrence of atrial arrhythmias, but evidence on its long-term advantage over radiofrequency and cryoballoon ablation remains mixed. At the same time, the accumulation of new data on procedural complications, damage to the esophagus, phrenic nerve, pericardial complications, and other potentially specific adverse events requires a systematic assessment of the safety profile of this technology.Studies published in 2025–2026, including randomized controlled trials and updated meta-analyses, are of particular importance. Current evidence suggests that PFA may provide efficacy comparable to thermal methods with shorter procedure duration and potentially reduced risk of some off-target injuries. However, the results of individual studies vary, and the evidence base is heterogeneous in the type of AF, PFA systems used, criteria for efficacy and duration of follow-up. An additional objective is to identify the potential benefits and limitations of PFA and to assess the extent to which current evidence allows PFA to be considered the preferred technology for performing PVI. The methodology of the study was provisionally formulated with a definition of the clinical question, criteria for inclusion and exclusion of publications, primary and secondary endpoints, and principles for assessing the quality of the evidence[8].

1. Population (P): adult patients with paroxysmal or persistent atrial fibrillation who underwent catheter ablation;
2. Intervention (I): pulse-electric ablation;
3. Comparator (C): radiofrequency ablation, cryoballoon ablation, or other thermal catheter ablation methods;

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4. Outcomes (O): Efficacy of ablation, recurrence of atrial arrhythmias, need for repeat ablation, duration of procedure, rate of acute and late complications, and overall safety of the procedure.

The main clinical question was: Does PFA provide comparable or higher efficacy in the treatment of AF compared to traditional catheter ablation methods while improving the safety profile? The primary safety endpoints were the cumulative incidence of serious procedure-related adverse events, as well as the incidence of individual complications, including cardiac tamponade, pericardial effusion, stroke or transient ischemic attack, esophageal injury, and atrioesophageal Secondary endpoints included duration of procedure, time of energy exposure, length of hospitalization, time of fluoroscopy, acute isolation of pulmonary veins, restoration of pulmonary vein conduction, need for re-ablation, and quality of life.

The current evidence base for PFA is expanding rapidly. By 2025–2026, new randomized trials, large registries and meta-analyses have been published to evaluate PFA in terms of both efficacy and procedural safety of which 653 received PFA. In the pooled analysis, there were no statistically significant differences between PFA and thermal ablation in treatment efficacy, atrial arrhythmia recurrence, re-ablation, or serious adverse events. At the same time, PFA was associated with a shorter duration of the procedure. The authors emphasize that the certainty of the evidence for most endpoints remained low or very low.[1-2] These findings are crucial for the interpretation of the current literature: the highest quality randomized evidence confirms at least comparable efficacy of PFA to thermal technologies, but does not yet conclusively assert its superiority in long-term rhythm control. This distinction between RCTs and observational data should be taken into account when formulating final conclusions.

In a 2026 meta-analysis of four RCTs, the relative risk of treatment success in PFA was 1.11 (95% CI 0.87–1.42), with no statistically significant advantage over thermic methods. The risk of atrial arrhythmias recurrence also did not differ significantly between groups. A similar situation was observed with regard to repeated ablation[3]. Thus, based on modern RCTs, PFA should be considered as an equally effective alternative to traditional thermal ablation, but there is not yet enough evidence of its unequivocal superiority. The long-term results of the ADVENT study are important. In the four-year follow-up of ADVENT-LTO, the effectiveness of PFA was maintained: freedom from the primary endpoint was 72.8% after PFA and 64.3% after thermal ablation, but the difference did not reach statistical significance. At the same time, fewer repeated ablations were observed in the PFA group — 10.4% versus 17.7%. These results indicate continued clinical efficacy of PFA over the long term, although the primary endpoint did not demonstrate statistically significant superiority[3]. A 2025 meta-analysis by Prajapati et al., which included 28 comparative studies and 7944 patients, demonstrated a lower recurrence rate after PFA compared to radiofrequency and cryoballoon ablation. However, a significant proportion of the included studies were observational, which increases the risk of bias. Therefore, the benefit obtained should be interpreted as a signal in favor of potentially higher efficacy of PFA, requiring confirmation by large Russian as a foreign language[4].

In a 2026 meta-analysis by Kamel et al., including 18 studies and 5638 patients, both technologies provided a high incidence of acute PVI of about 95–100%. PFA was associated with a reduction in the duration of the procedure by approximately 14 minutes and a lower overall complication rate. At the same time, after 12 months, there was a lower rate of recurrence of arrhythmias after PFA. However, only two studies were randomized, so the results may be due to differences in patient and site characteristics[5]. Another 2026 meta-analysis that included 23 comparative studies also demonstrated a reduction in procedure time for PFA and a lower incidence of

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phrenic nerve damage. However, no differences were found in stroke, bleeding, and cardiac tamponade[6]. Thus, the most compelling advantage of PFA over cryoballoon technology may be less in improving rhythm control and in procedural efficiency and reducing the risk of individual off-target injuries**.**

In a 2026 meta-analysis by Li et al., including six studies and 1610 patients, PFA was associated with a lower rate of atrial tachyarrhythmias recurrence compared to thermal ablation, as well as a reduction in procedure duration and left atrial time. At the same time, no differences in the overall incidence of complications were revealed[6]. However, the need for additional substrate modification in persistent AF remains debatable. A recent meta-analysis of PFA in persistent AF found no significant benefit of adding posterior left atrial wall isolation to PVI compared to PVI alone, with the combined strategy increasing the duration of the procedure[7]. This underscores an important feature of the current PFA strategy: the high efficiency and safety of the technology itself does not mean that expanding the ablation volume automatically improves long-term rhythm control. The safety profile is one of the key arguments in favor of PFA.The supposed tissue selectivity of irreversible electroporation minimizes thermal damage to surrounding structures. Unlike RF and cryoablation, PFA potentially reduces the risk of damage to the esophagus and phrenic nerve.At the same time, modern RCTs have not yet demonstrated a convincing statistical reduction in the cumulative incidence of serious complications. In a 2026 meta-analysis by Mojica et al., no differences in serious adverse events between PFA and thermal ablation were found[8].At the same time, observational studies and meta-analyses show a potential reduction in the incidence of phrenic nerve injury and some other complications in PFA.

1. coronary vasospasm;
2. hemolysis;
3. acute kidney injury;
4. pericardial tamponade;
5. vascular complications;
6. possible dysfunction of the autonomic nervous system.

The rarity of individual events means that even large RCTs may not be powerful enough to reliably assess them. Therefore, the final safety characterization of PFA requires a combination of RCT data, large registries and post-marketing surveillance.

One of the main problems with the current evidence base is the relatively short follow-up period of most studies.ADVENT-LTO data are an important exception because they provide four-year results. They demonstrate that PFA remains effective and that there is no signal of a significant deterioration in results over the long term[9].2026 meta-analysis by Antoun et al., including six studies and 800 patients, found that heart rate variability may be better maintained after PFA than after thermal ablation. Frequency recurrences of arrhythmias did not differ significantly. These results suggest potentially less impact of PFA on autonomic regulation of the heart[10].The clinical significance of maintaining autonomic function has not yet been determined. Therefore, this result should be considered as a promising research avenue rather than an established clinical benefit of PFA. PFA represents a significant technological advance in the treatment of atrial fibrillation.

Conclusion

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Modern randomized trials confirm its efficacy comparable to thermal methods, and large registries demonstrate high acute efficacy and a low incidence of serious complications.The most convincing advantages of PFA are the reduction in the duration of the procedure and a significant reduction in the risk of some traditional complications, primarily esophageal damage, persistent damage to the phrenic nerve and pulmonary vein stenosis completely safe technology. As its use expands, specific complications are identified, including coronary spasm, hemolysis with potential acute kidney injury, and a continuing risk of pericardial tamponade.Therefore, the current concept of PFA should not be based on the idea of complete superiority of the new technology over traditional methods, but on an understanding of its unique balance of efficacy, procedural speed, and specific safety profile to be considered as a preferable or at least a viable alternative to thermal ablation for performing pulmonary vein isolation in suitable patients with AF. However, its role in extended substrate ablation, especially in persistent AF, requires further study

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