Research Square

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Patient comfort of Pulsed Field Ablation Using a Circular Catheter for Paroxysmal Atrial Fibrillation Under Conscious Sedation: A comparison with radiofrequency ablation

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Research Article

Keywords: Atrial Fibrillation, Pulsed Field Ablation, Radiofrequency Ablation, Conscious Sedation, Intraoperative Pain

Posted Date: October 14th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10876943/v1

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Additional Declarations: No competing interests reported.

Abstract

Objective

To compare the patient comfort of Pulsed Field Ablation (PFA) and Radiofrequency Catheter Ablation (RFCA) in patients with paroxysmal atrial fibrillation (PAF) under conscious sedation.

Methods

62 patients with PAF were randomly assigned to either the PFA group (n = 31) or the RFCA group (n = 31). All procedures were done with conscious sedation using dexmedetomidine and fentanyl together. Patient comfort was assessed using an intraoperative pain score. Additionally, the acute procedural success rate, procedural efficiency, and safety events were recorded.

Results

Acute procedural success was achieved in all patients with no major complications in either cohort. Compared to the RFCA group, patients undergoing PFA reported significantly less intraoperative pain (mean VAS score: 5.81 ± 1.72 vs. 6.87 ± 1.75, P = 0.0148) and required markedly shorter operation times (median: 94.0 vs. 120.0 min, P < 0.001).

Conclusion

Under conscious sedation, PFA reduces intraoperative pain and shortens procedure time compared with RFCA, while maintaining similar efficacy and safety.

Trial registration:

This study was registered with the China Clinical Trial Registry on August 27,2024, under registration number: ChiCTR2400088774.

What's New?

1. This prospective randomized controlled trial reveals that patients undergoing PFA experience significantly less intraoperative pain and require lower doses of sedative medications, compared with RFCA.

2. PFA demonstrates superior procedural efficiency by markedly shortening both ablation and total operation times, while maintaining a 100% success rate and safety profile to RFCA.

1 Introduction

Atrial fibrillation (AF) is the most common clinical arrhythmia, for which catheter ablation is the primary therapy[1,2]. Traditional RFCA causes tissue necrosis via heat, which can damage nearby tissues (e.g., the esophagus, nerves) due to heat spread. The significant procedural pain associated with this technique makes general anesthesia the most commonly used approac[3,4].

Pulsed field ablation (PFA) is a novel non-thermal modality that utilizes high-voltage pulses to induce irreversible electroporation of cell membranes[5]. Recent studies demonstrate that PFA is as effective as RFCA for pulmonary vein isolation[6–8]. However, the optimal sedation protocol for PFA remains unestablished[9,10], and direct comparisons evaluating intraoperative pain and procedural efficiency under conscious sedation are limited. This study aims to compare PFA and RFCA with respect to intraoperative pain, procedure duration, and overall safety in patients with atrial fibrillation (AF) undergoing conscious sedation.

2 Methods

2.1 Study Design

Between October 2024 and May 2025, 104 patients with paroxysmal atrial fibrillation scheduled for catheter ablation at the Affiliated Hospital of Xuzhou Medical University were prospectively screened. After applying the predefined exclusion criteria, 42 patients were excluded, and 62 patients were enrolled and randomized in a 1:1 ratio to undergo either PFA or RFCA (Fig. 1). The random allocation sequence was generated by an investigator who was not involved in participant enrollment using the RAND() function in Microsoft Excel, with participants allocated to the PFA and RFCA groups in a 1:1 ratio. The allocation sequence was concealed from the enrolling investigators until eligibility was confirmed and written informed consent was obtained. The group assignment was then released to the enrolling investigators. This was an open-label trial; participants, operators, outcome assessors, and data analysts were not blinded to treatment allocation.

As this was an exploratory pilot randomized trial and insufficient prior data were available to support a reliable sample size estimation, no formal sample size calculation was performed. No interim analyses or formal stopping guidelines were planned. The study protocol was approved by the institutional Ethics Committee (XYFY2024-KL351-01) and registered with the Chinese Clinical Trial Registry (ChiCTR2400088774). No changes were made to the prespecified primary or secondary outcomes after trial commencement. A post-hoc exploratory analysis was performed to assess potential learning-curve effects of PFA on procedural efficiency and sedative requirements.

Inclusion criteria: Age 18-75 years old; meet the diagnostic criteria for paroxysmal atrial fibrillation; have undergone catheter ablation for the first time; left ventricular ejection fraction (LVEF) greater than 50%.

Exclusion criteria:1) Presence of thrombus in the left atrium or left atrial appendage; 2) Contraindication to brain magnetic resonance imaging (MRI); 3) History of stroke or transient ischemic attack (TIA) in the last 3 months or clear neurological deficit consistent with stroke; 4) Fresh cerebral infarction detected on preoperative MRI; 5) History of catheter ablation for AF; 6) Severe comorbidities, such as liver/kidney failure or severe respiratory dysfunction; 7) Refusal to give informed consent.

2.2 Anesthesia and Procedure

All patients received a standardized conscious sedation protocol consisting of intravenous dexmedetomidine (maintenance: 0.2 μg/kg/h) combined with fentanyl (maintenance: 2 μg/kg/h). Dosages of both medications were increased if patients experienced significant intraoperative pain or were unable to tolerate discomfort. The same operators performed all procedures, and the ablation strategy consisted of circumferential pulmonary vein isolation (PVI).

2.3 PFA Procedure

After anesthesia, a steerable decapolar catheter was inserted into the coronary sinus through the left femoral vein, and a quadripolar catheter was placed in the right ventricle through the left femoral vein. At the same time, an 8.5 Fr Swartz SL1 sheath and dilator were introduced via the right femoral vein. An ICE catheter (SoundStar 10F, Biosense Webster) was inserted into the right atrium through an 11F sheath via the right femoral vein.

After transseptal puncture guided by fluoroscopy and ICE, a circular PFA catheter equipped with a magnetic sensor (Jinjiang Electronic) was introduced into the left atrium and utilized for pulmonary vein isolation (PVI). The voltage used for PVI was 1800 V. Successful PVI was confirmed by the following evidence:(I) disappearance or dissociation of pulmonary vein potentials; (II) inability to capture the adjacent atrium by pacing from several sites along the ablation line within the isolated veins with a PFA catheter.

After PVI, left atrial voltage mapping was done during sinus rhythm with the same catheter. If atrial fibrillation persisted after PVI, electrical cardioversion was performed. After a 20-minute observation period, PVI was verified again[11]. If there was recovery of pulmonary vein-atrial conduction, more ablation was performed to achieve PVI again. Patients with left atrial low-voltage zones underwent substrate modification.

2.4 Radiofrequency Procedure

After anesthesia, a steerable decapolar catheter was inserted into the coronary sinus through the left femoral vein. At the same time, an 8.5 Fr Swartz SL1 sheath and dilator were introduced via the right femoral vein. An ICE catheter (SoundStar 10F, Biosense Webster) was inserted into the right atrium via the right femoral vein using an 11F sheath.

Under fluoroscopy and ICE guidance, an open-irrigated tip ablation catheter (STSF, Biosense Webster) was advanced into the left atrium. Point-by-point ablation via the electroanatomic mapping system (Carto 3, Biosense Webster) was used for PVI, with a maximum power of 50W and an irrigation rate of 15 ml/min to keep the tip temperature < 45 ℃. The endpoint of the ablation procedure is complete bidirectional pulmonary vein electrical isolation.

Left atrial voltage mapping was then performed during sinus rhythm. If atrial fibrillation persisted after PVI, electrical cardioversion was carried out. For those with left atrial voltage problems, substrate modification was conducted[11].

2.5 Anticoagulation Management

All patients were given oral anticoagulant therapy before the operation. Oral anticoagulation was maintained throughout the ablation without interruption. Before performing the transseptal puncture, we checked the ACT (activated clotting time) with the Medtronic ACT Plus, and a loading dose of heparin was administered based on the patient's body weight and preoperative ACT value. While moving around in the left atrium, the ACT was monitored every 30 minutes, and additional heparin was given as needed based on the ACT level. The whole process, the target ACT range was 300-350 seconds[12].

2.3 Endpoints

Primary Endpoint: Intraoperative pain: Patients' subjective pain was assessed using the Visual Analogue Scale (VAS) [13]. A score of ≥8 was defined as pain intolerant.

Secondary Endpoints:

Procedural efficiency: This included the acute procedural success rate, as well as the recorded left atrial operation time (LAOT), ablation time (AT), and total operation time (TOT).

Safety indicators: Perioperative complications were noted, such as cardiac tamponade, stroke, phrenic nerve damage, pulmonary vein stenosis, and vascular complications. Additionally, complications related to conscious sedation and anesthesia were noted, such as hypoxemia, respiratory depression, hypotension, aspiration, paradoxical agitation, and the necessity for conversion to general anesthesia.

2.4 Statistical Analysis

The Shapiro-Wilk test was conducted to determine whether the data followed a normal distribution. Levene’s test was used to determine the equality of variances. Continuous data that had a normal or nearly normal distribution were given as mean ± SD and contrasted using the independent samples t-test. Non-normally distributed data were given as median (IQR) and analyzed by the Mann-Whitney U test. Categorical data were presented as n (%), and comparisons among groups were performed using the Chi-square ($\chi 2$) test. If the chi-square test assumptions were violated, Fisher's exact test was used. Spearman's correlation analysis was performed to evaluate the correlations.

3 Results

3.1 Baseline Characteristics

Baseline characteristics of the patients are shown in Table 1. 62 patients with paroxysmal atrial fibrillation were randomized 1:1 to receive either PFA or RFCA. No significant differences were observed in baseline characteristics between the two groups.

Table 1
Baseline characteristics

Age, years	**All**	**RFCA**	**PFA**	**P-value**
	(n = 62)	**(n = 31)**	**(n = 31)**	
	62.50 (59.00, 70.00)	**64.00 (58.00, 71.00)**	**62.00(59.50, 70.00)**	**0.838**
BMI, kg/m^2	25.39 ± 3.45	25.09 ± 3.21	25.69 ± 3.71	0.503
Woman, n (%)	25 (40.32%)	11 (35.48%)	14 (45.16%)	0.605
CHA_2DS_2-VASc Score	1.00 (1.00, 2.00)	1.00 (1.00, 2.00)	2.00 (1.00, 2.50)	0.481
LVEF(%)	62.56 ± 3.80	61.94 ± 3.42	63.19 ± 4.10	0.195
LAD, mm	38.03 ± 4.19	38.06 ± 4.80	38.00 ± 3.57	0.952
LVEDD, mm	48.53 ± 3.03	48.10 ± 3.02	48.97 ± 3.04	0.262
Drinking, n (%)	1(1.61%)	0 (0.00%)	1 (3.23%)	1.000
Smoking, n (%)	5(8.06%)	3 (9.68%)	2 (6.45%)	1.000
Comorbidities, n (%)				
Hypertension	21 (33.87%)	11 (35.48%)	10 (32.26%)	1.000
Coronary artery disease	7 (11.29%)	5 (16.13%)	2 (6.45%)	0.425
Diabetes	6 (9.68%)	4 (12.90%)	2 (6.45%)	0.671
Dyslipidemia	3 (4.84%)	2 (6.45%)	1 (3.23%)	1.000
Previous stroke	5 (16.13%)	0 (0.00%)	5 (16.13%)	0.053
Medication use pre ablation, n (%)				
Rivaroxaban	60 (96.77%)	30 (96.77%)	30 (96.77%)	1.000
Dabigatran etexilate	2 (3.23%)	1 (3.22%)	1 (3.23%)	1.000
ß-Blocker	29 (46.77%)	15 (48.39%)	14 (45.16%)	1.000
Amiodarone	5 (8.07%)	1 (3.23%)	4 (12.90%)	0.354
Propafenone	6 (9.68%)	4 (12.90%)	2 (6.45%)	0.671

BMI: Body Mass Index, LAD: Left Atrium Dimension, LVEF: Left Ventricular Ejection Fraction, LVEDD: Left Ventricular End-Diastolic Dimension

3.2 Procedural Details

Successful PVI was achieved in all patients under conscious sedation. One patient remained in atrial fibrillation after PVI and then had electrical cardioversion. Left atrial voltage mapping was done during sinus rhythm with the ablation catheter. The low-voltage area (LVA) was identified when ≥ 3 consecutive points had a bipolar voltage < 0.5 mV. LVAs were found in 10 out of 62 patients. In the PFA group, 2 of 31 patients had LVAs, one of whom had substrate modification. In the RFCA group, 8 of 31 patients had detectable LVAs; 3 underwent substrate modification.

3.2 Intraoperative pain and procedural efficiency

Full procedural details are summarized in Table 2. Intraoperative VAS pain scores were significantly lower in the PFA group compared to the RFCA group (5.81 ± 1.72 vs. 6.87 ± 1.75, P = 0.0148). Patients in the PFA cohort required significantly lower doses of fentanyl (140.84 ± 43.83 μg vs. 183.84 ± 52.85 μg, P = 0.0018) and dexmedetomidine (21.48 ± 11.10 μg vs. 38.18 ± 43.35 μg, P = 0.0063).

Table 2
RFCA VS PFA Procedural data

LAOT, min	**RFCA (n = 31)**	**PFA (n = 31)**	**P-value**
	54.00 (47.00, 67.50)	**53.00 (45.50, 64.50)**	**0.652**
AT, min	21.00 (20.50, 26.00)	2.86 (2.36, 3.35)	**< .001**
TOT, min	120.00 (100.00, 130.00)	94.00 (78.50, 103.00)	**< .001**
Mean ACT, s	289.00 (269.50, 311.50)	275.00 (266.00, 289.00)	0.123
Total heparin dose, IU	9265.48 ± 2373.76	9480.65 ± 2711.63	0.741
SCL, n (%)	2(6.45%)	4(12.90%)	0.671
Cardiac tamponade, n (%)	0(0%)	0(0%)	N/A
Muscle Tremors, n (%)	0(0%)	9(29.03%)	0.002
VAS	6.87 ± 1.75	5.81 ± 1.72	0.0148
Fentanyl(ug)	183.84 ± 52.85	140.84 ± 43.83	0.0018
TOT-adjusted fentanyl dose(ug/min)	1.512 ± 0.354	1.492 ± 0.420	0.7354
dexmedetomidine(ug)	38.18 ± 43.35	21.48 ± 11.10	0.0063
TOT-adjusted dexmedetomidine dose (ug/min)	0.313 ± 0.333	0.224 ± 0.104	0.1
Significant intraoperative pain, n (%)	11(35.48%)	6(19.35%)	0.255
Additional sedation requirement, n (%)	7(22.58%)	2(6.45%)	0.147
LAOT = Left Atrial Operation Time, AT = Ablation Time, TOT = Total Operation Time, ACT = Activated Clotting Time.			

While left atrial operation time (LAOT) was comparable between the two cohorts (P = 0.652), ablation time (AT) was significantly shorter in the PFA group compared to the RFCA group (median: 2.86 vs. 21.00 min, P < 0.001). Consequently, total operation time (TOT) was also significantly reduced in the PFA group (median: 94.00 vs. 120.00 min, P < 0.001).

3.3 Post-hoc Exploratory Analysis of the PFA Learning Curve

In this post-hoc exploratory analysis, Spearman's rank correlation analysis showed that, with increasing procedural experience, total operation time (ρ = −0.595, P < 0.001), fentanyl consumption (ρ = −0.522, P

= 0.003), and dexmedetomidine consumption (ρ = −0.410, P = 0.022) decreased significantly. (Refer to Fig. 2).

3.3 Safety Evaluation

No major adverse events (such as cardiac tamponade or stroke) or anesthesia-related complications were observed in either group. Additionally, the absence of phrenic nerve and esophageal injuries in the PFA group supports the safety advantages of its tissue selectivity. Intraoperative muscle twitching was significantly more common in the PFA group (9 vs. 0 cases, P = 0.002). These episodes occurred only as diaphragmatic twitching and did not interfere with procedures performed under conscious sedation.

4 Discussion

This study directly compared patient comfort during paroxysmal atrial fibrillation (PAF) ablation using a specialized circular pulsed-field ablation (PFA) catheter versus conventional radiofrequency catheter ablation (RFCA) under conscious sedation. Both approaches achieved 100% acute pulmonary vein isolation, with comparable safety profiles. Notably, the PFA cohort experienced significantly less intraoperative pain and required lower doses of sedative medications. PFA also markedly reduced both ablation and total operation times.

Recent randomized controlled trials have demonstrated that PFA is both safe and effective for treating paroxysmal atrial fibrillation[14–16]. PFA catheters vary significantly in geometric design, pulse waveforms, 3D mapping integration, and multimodal capabilities (such as dual-energy). Early PFA systems used monophasic waveforms that reduced the skeletal muscle action potential threshold, leading to severe systemic neuromuscular activation and requiring general anesthesia[1718] . Modern circular catheters now use biphasic, bipolar waveforms. The rapid switching of electrical polarity in these systems raises the skeletal muscle stimulation threshold, reducing visible contractions and enabling the possibility of using conscious sedation[19].

Recent studies have begun exploring the feasibility of performing pulsed-field ablation without general anesthesia. However, the findings remain inconsistent. The PF-Beat-AF trial and registry studies showed that circular PFA catheters under conscious sedation achieve success rates and safety comparable to those with general anesthesia[20,21]. Grimaldi et al. used deep sedation (dexmedetomidine plus remifentanil) for PFA ablation using a variable-circular catheter and biphasic pulses. They achieved 100% success without needing to switch to general anesthesia, and patients reported good pain control and satisfaction with sedation[22].

However, Calvert et al. found different results. Patients who received mild sedation with midazolam and fentanyl during Pentaspline (flower-shaped) catheter procedures experienced more pain. About 12.5% of these patients needed to switch to general anesthesia due to procedural intolerance. This led the researchers to recommend caution when using this approach more widely[9]. These different outcomes

show that catheter design and sedation methods both significantly affect patient comfort. None of these studies directly compared PFA with radiofrequency ablation for atrial fibrillation under conscious sedation.

In our prospective randomized controlled trial, the PFA group demonstrated significantly lower intraoperative VAS pain scores compared to the RFCA group, with correspondingly reduced consumption of fentanyl and dexmedetomidine. The non-thermal ablation mechanism of PFA appears to generate less painful stimulation, thereby reducing the need for intensive analgesia and sedation. This characteristic provides an inherent advantage for PFA procedures performed under conscious sedation.

Aligning with findings from the PF-Beat-AF study and several meta-analyses[6,21], our study demonstrated that ablation time for the PFA group (2.86 min) was much shorter than that for the RFA group (21.00 min), reducing the total operation time by almost 30 min. Analysis within the PFA group revealed that procedure time and sedative consumption decreased as operators gained experience. This exploratory finding suggests a potential learning-curve effect, whereby increasing operator experience may be associated with improved procedural efficiency and reduced sedative requirements. The standardized conscious sedation protocol using dexmedetomidine and fentanyl, combined with PFA technology, provided clear benefits for patient comfort during the procedure.

Our study used a circular (loop) PFA catheter with a magnetic sensor. PFA catheters vary significantly in geometric design, pulse waveforms, 3D mapping integration, and multimodal capabilities[23,24]. The differences between PFA platforms in electric field patterns, pulse waveforms, and catheter size affect patient tolerance, making it difficult to draw general conclusions about patient comfort under conscious sedation. Therefore, future studies comparing different PFA catheter designs are needed to better evaluate their clinical use and patient comfort without general anesthesia.

5 Study Limitations

1. This is a single-center randomized controlled trial with a small number of participants.

2.This study specifically evaluated a circular PFA catheter. Given the significant heterogeneity among currently available PFA systems in terms of catheter design and pulse waveforms, these findings cannot be directly extrapolated to other PFA devices.

6 Conclusion and Clinical Implications

To conclude, this study shows that for the treatment of paroxysmal atrial fibrillation under conscious sedation, pulse field ablation with a special circular catheter, as opposed to radiofrequency ablation, leads to a considerable reduction in intraoperative patient pain, less need for sedative drugs, much shorter operation time, and similar acute safety and success rates. These findings confirm the feasibility of pulsed field ablation for the treatment of atrial fibrillation under conscious anesthesia.

Declarations

Funding

Supported by the Construction Project of High-Level Hospital of Jiangsu Province, Project Number: GSPJS202415, Research Code: 2024113015.

Consort

This study was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Ethics Statement

This study was approved by the Ethics Committee of the Affiliated Hospital of Xuzhou Medical University and conducted in accordance with the Declaration of Helsinki. Each participant signed an informed consent form. Ethics approval number: XYFY2024-KL351-01.

Consent for publication

Not Applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflict of interest

The authors declare that they have no competing interests.

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Figures

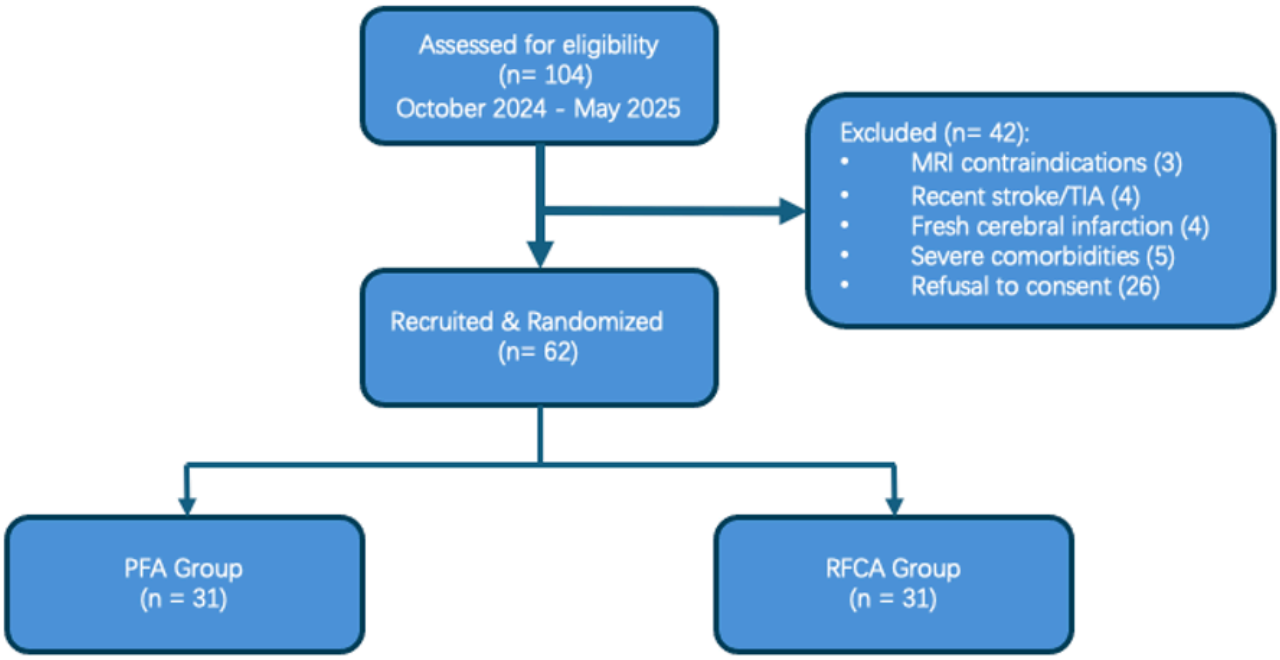


Figure 1

Cohort diagram.

MRI: Magnetic Resonance Imaging; TIA: Transient Ischemic Attack; PFA: Pulsed Field Ablation; RFCA: Radiofrequency Catheter Ablation.

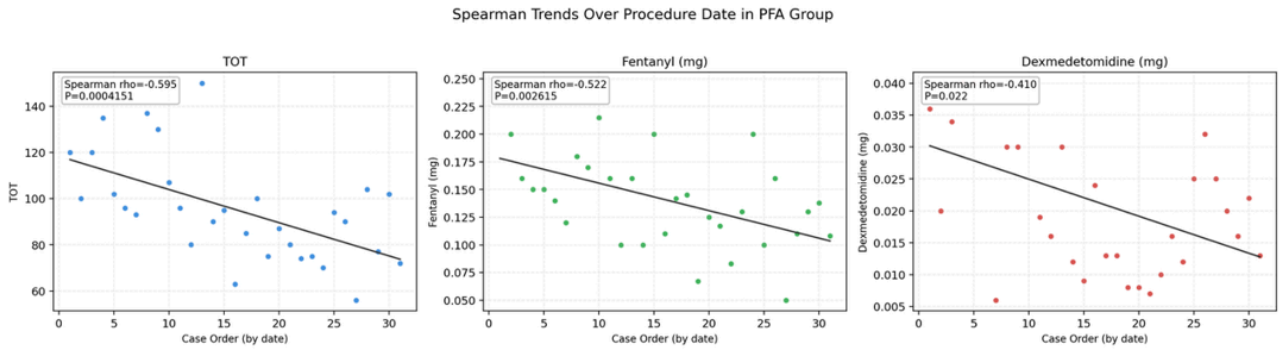


Figure 2

Spearman correlation analysis in PFA group.

TOT, total operation time; PFA, pulsed field ablation.