








# Zero-fluoroscopy catheter ablation of premature ventricular contractions: comparative outcomes from the right ventricular outflow tract and other ventricular sites

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## ABSTRACT

**Background:** *The three-dimensional electroanatomic mapping (EAM) system allows performing catheter ablation (CA) without fluoroscopy in patients with premature ventricular contractions (PVCs). The right ventricle outflow tract (RVOT) location is favorable for performing zero-fluoroscopy CA. Non-RVOT zero-fluoroscopy CA is a challenging procedure. The study aimed to evaluate the efficacy and safety of zero-fluoroscopy CA using the EAM in patients with PVCs from RVOT and non-RVOT.*

**Methods:** *Completely zero-fluoroscopy CA of PVCs guided by EAM was performed in 107 patients with PVCs. 54 patients underwent zero-fluoroscopy RVOT CA. The remaining 53 patients underwent zero-fluoroscopy non-RVOT CA. Demographic and clinical baseline characteristics, procedure parameters, and follow-up were obtained from medical records. Primary outcomes were the acute and the permanent success rate (12-month follow-up), complications, and procedure time.*

**Results:** *There were no significant differences between groups regarding baseline characteristics. Acute procedural success was achieved in 52 patients (94,44%) in the RVOT zero-fluoroscopy CA group and in 45 patients (86,54%) in the non-RVOT zero-fluoroscopy CA group (ns). A long-term success rate was achieved in 50 patients (90,74%) in the RVOT zero-fluoroscopy CA group and in 44 patients (84,62%) in the non-RVOT zero-fluoroscopy CA group (ns). The median procedure time was 80.5 minutes in the RVOT group and 90 minutes in the non-RVOT group (ns). There were two complications in the non-RVOT group (ns).*

**Conclusions:** *There were no differences in procedure time efficacy and safety zero-fluoroscopy ablation between RVOT and non-RVOT locations. Non-fluoroscopy CA of PVCs is a feasible, safe, and efficient procedure.*

**Keywords:** zero-fluoroscopy catheter ablation, fluoroscopy elimination, ventricular arrhythmia, right ventricular outflow tract, premature ventricular contractions

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## Background

Catheter ablation (CA) of idiopathic and symptomatic premature ventricular contractions (PVCs) has become the first line of treatment [1]. Because PVCs originate from different sites, this procedure is challenging and requires precise electroanatomic mapping (EAM) and an accurate knowledge of cardiac anatomy. Initially, EAM became additional equipment to conventional ablation with fluoroscopy. However, the modern approach replaces conventional ablation with fluoroscopy and uses only the EAM system in selected arrhythmias. Fluoroscopic navigation is related to ionizing radiation for patients and medical staff. Ionizing radiation associates many complications, especially non-predictable late complications in further life, like cancer risk [2]. Even small doses of radiation could be harmful in pregnancy and young people, especially those under 22 years. But cumulative doses of about 50-60 mGy could at least almost triple the risk of leukemia and brain cancer in young people [3]. Besides, ionizing radiation during organogenesis could lead to severe defects [4]. Individual patient operator protection and using advanced X-ray settings like collimators, adequate angles, and optimal intensity may only reduce, but not eliminate, radiation and late complications [5].

However, in some cases, fluoroscopy is necessary or helpful. Especially during arrhythmia origin near the coronary artery to perform angiography or to perform transseptal puncture.

In modern invasive electrophysiology, there is a possibility not only to reduce but even eliminate ionizing radiation with the use of EAM in various arrhythmia sites. Zero-fluoroscopy CA is a safe and efficient procedure, mainly in arrhythmia originating from the right ventricle (RV). One of the most common locations of idiopathic PVCs is the right ventricle outflow tract (RVOT) [6].

It seems that CA in the RVOT location is much easier, safer, and more successful than in other PVC locations using the zero-fluoroscopy approach [7]. Nevertheless, a few publications present this strategy for non-RVOT locations, especially left-sided PVC [8]. Non-RVOT CA is challenging, but it seems feasible to perform without fluoroscopy using EAM in selected arrhythmias using a modern approach. There is a lack of information about the feasibility and safety of the modern zero-fluoroscopy approach in PVC from different locations of the ventricle and the aorta, especially a comparison of the feasibility, safety, and efficacy of these sites.

The main objective of this study was to compare the effectiveness and safety of zero-fluoroscopy CA between RVOT and non-RVOT locations.

## Methods

### Study design and study population

One hundred seven patients with symptomatic PVC who underwent a zero-fluoroscopy ablation procedure based on 24-hour ECG Holter monitoring (with more than 10000 PVCs per day) between June 2020 and September 2022 were included in this study. All participants signed written informed consent forms for catheter ablation.

Demographic and clinical data were obtained from the medical records. The main exclusion criteria were structural heart disease, coronary artery disease, heart failure with left ventricular ejection fraction below 40%, and more than moderate valve disease.

### Ablation procedure

In all patients qualified for CA, antiarrhythmic drugs were discontinued for at least five half-lives before hospital admission. The ablations were performed using the EAM system: CARTO (Biosense Webster, Diamond Bar, CA, USA) or EnSite (Abbott Medical, Minneapolis, MN, USA) in the designed study. EAM was performed with an ablation catheter. Procedures with the CARTO system were performed with the SmartAblate RF generator and irrigated ablation catheters (SmartTouch, NaviStar, EZ Steer ThermoCool). Procedures with the EnSite system were performed with the Ampere RF generator, irrigated and non-irrigated ablation catheters (4 mm ablation catheters: Hagmed, Rawa Mazowiecka, Poland or FlexAbility, Abbott Medical, Minneapolis, MN, USA). For irrigated catheters, power outputs during RF applications ranged from 30 to 45 W, with a temperature not exceeding 48°C. Power output for non-irrigated catheters during RF applications was limited to a maximum of 50 W. It was also possible to perform cryoablation in this system with 7 French Freezor catheters (Medtronic, Minneapolis, MN, USA). The cryoablation was preceded by an ice mapping at -30°C to control efficacy and safety. The temperatures during cryoablation reached less than -70°C to achieve a permanent ablation effect.

Arrhythmia characteristics, procedure time, ablation time, number of ablation applications, procedural success rates, and complications were analyzed. Procedure time was measured from the

administration of local anesthesia to the removal of vascular sheaths (skin to skin). PVC location was classified as RVOT or non-RVOT: RV (right-sided PVCs), aortomitral continuity (A-M), aorta (Ao), or LV (left-sided PVCs).

For right-sided PVCs, the RV was accessed through the femoral vein approach with vascular sheath, either 8F or 9F, depending on the type of ablation catheter. The ablation catheter was initially inserted into the femoral vein and subsequently advanced into the inferior vena cava until it reached the right atrium (RA). While mapping the RA in most instances, the ablation catheter was positioned in the RA with the creation of the fast anatomical map (FAM), using anteroposterior and right-lateral projections. Landmarks such as the tricuspid valve and the bundle of His were marked, and depending on the arrhythmia's location, either the RV or RVOT was mapped. The catheter insertion into the RV/RVOT occasionally necessitated specific maneuvers with catheter rotation and straightening or changing the catheter's shape from J to F. The earliest activation site of PVC was identified and marked with a color-coded point in the EAM system.

For left-sided PVCs, retrograde aortic access was achieved by femoral artery puncture. Then, a vascular sheath of 8F or 9F, depending on the size of the ablation catheter, was introduced. Intravenous unfractionated heparin was administered in a bolus dose of 5000 Units, and the infusion rate was based on the activated clotting time (ACT). In cases where PVCs originated from the LV or Ao, firstly, FAM of the descending Ao and arch was performed, followed by FAM of the ascending Ao. Besides, ostia of the coronary arteries were marked. Then, the earliest activation arrhythmia mapping of the aortic bulb, cusps, or LV was created using the ablation catheter. In the case of using a contact force catheter, the contact force sensor was calibrated in the descending Ao or outside the patient. A catheter was curved in a J shape to pass through the aortic valve to reach the LV. In LV/LVOT, a point-by-point map was created to find the earliest local activation of PVC. In LV/LVOT, the pace-mapping method was additionally used to localize adequate ablation sites. Ablation was performed in sites where pace mapping was matched  $\geq 97\%$ .

Proximity to the coronary artery was defined as a distance between one centimeter and two centimeters from the coronary artery.

Acute procedural success was defined as eliminating targeted PVCs within 30 minutes after the

last ablation application. All patients underwent a post-procedural transthoracic echocardiography. Minor and major complications that occurred up to hospital release were included in the study results. Then, 24-hour ECG Holters were performed 3 and 12 months after the procedures. Long-term success was defined as the reduction in targeted PVCs below 1000 in 24-hour ECG Holter after a 12-month follow-up.

### Statistical analysis

The statistical analysis was conducted using Statistica software. Quantitative data is displayed in terms of means and standard errors (SE) or medians with interquartile ranges (IQR). To compare variables among different groups, the ANOVA test was used for normally distributed data, while the Kruskal-Wallis H test was employed for non-normally distributed data. Categorical data is represented as numbers and percentages and were compared using the  $\chi^2$  test. The normality of the data was assessed using the Shapiro-Wilk test, and the equality of variances was evaluated using the Levene test. Statistical significance was determined at a threshold of  $p < 0.05$ .

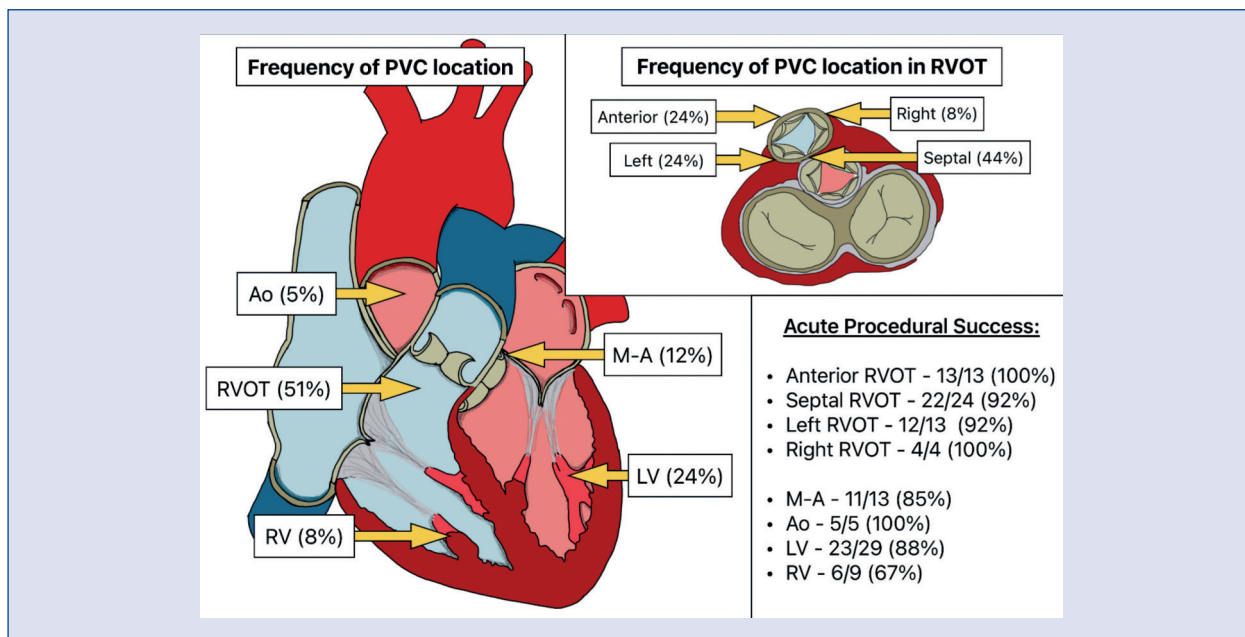
## Results

Zero-fluoroscopy CA was performed in 54 (50.5%) cases in RVOT and 53 (49.5%) cases in non-RVOT locations, presented in Figure 1. This figure displays the precise locations of arrhythmias, their frequency of occurrence, and an assessment of acute procedural success. Characteristics of the two groups, RVOT and non-RVOT, are presented in Table 1. The characteristics of the procedures, including procedure time, number of applications, application time, and procedural success, are shown in Table 2.

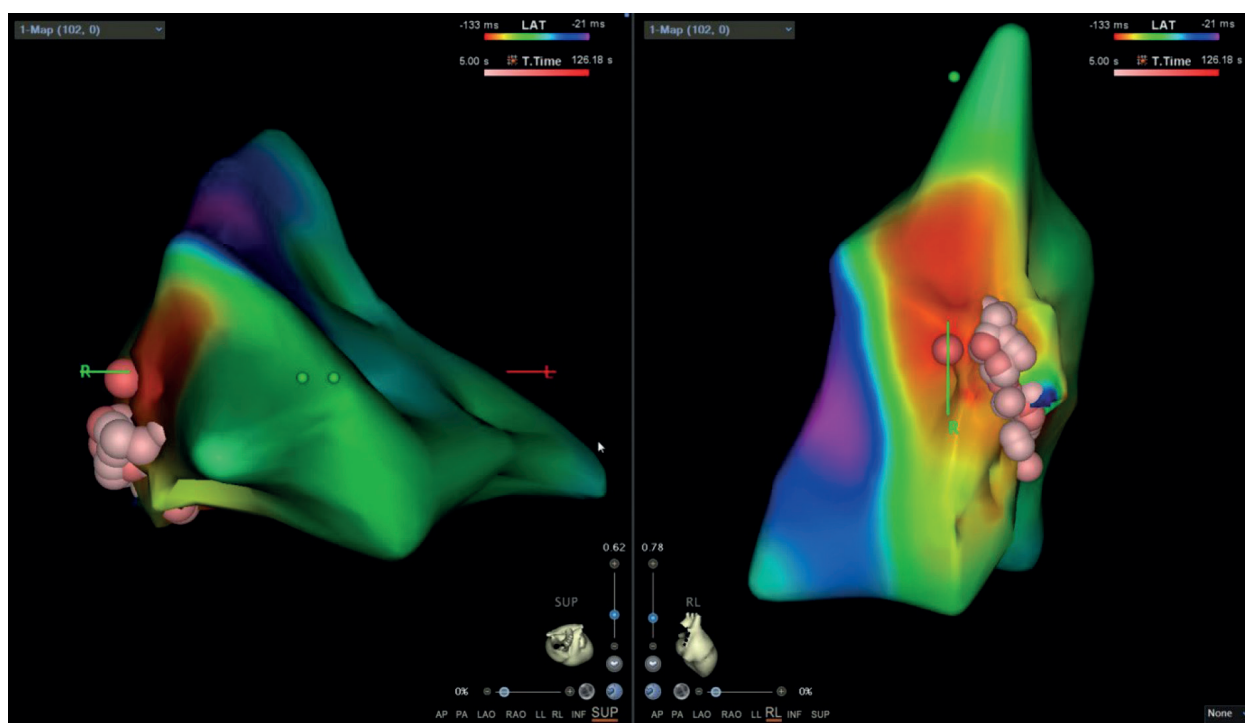
In the RVOT group, a greater acute and long-term success rate was noted than in the non-RVOT group; however, this difference did not reach statistical significance.

In the general population, there were cases with challenging locations of arrhythmia, such as the proximity to the coronary artery (6.5%), the para-Hisian location (9.3%), and the epicardial location (13.1%).

In the case of proximity to the coronary artery, the acute success rate was 7/7 (100%), and the long-term success rate was 6/7 (85.7%). Two procedures were performed using the EnSite system, one by the cryoablation method. This procedure proved ineffective during a one-year follow-up.



**Figure 1.** Visual presentation of the location of Premature Ventricular Contractions and their percentage frequency of occurrence, as well as acute procedural success



**Figure 2.** CARTO electroanatomic mapping of premature ventricular contraction from right ventricular outflow tract. The pink dots indicate the locations of successful radiofrequency catheter ablation

In this group, one major complication occurred, consisting of a tamponade that was effectively managed through pericardial puncture.

All procedures in the para-Hisian location (10/10) were successful, regardless of whether they

were in the RVOT or non-RVOT locations. In this group, there were no complications. In three cases, the EnSite system with the cryoablation method was utilized. All of these three cases were in the RVOT location.

**Table 1.** Baseline patient characteristics and clinical assessment

	<b>RVOT location (n = 54)</b>	<b>Non-RVOT location (n = 53)</b>	<b>p-value</b>
Male sex, n (%)	17 (31)	22 (42)	0.239
Age, years, mean (SE)	49.5 (1.9)	53.5 (2.2)	0.143
Left ventricular ejection fraction, %, mean (SE)	54.62 (0.86)	54.22 (1.14)	0.778
Hypertension, n (%)	19 (35)	23 (44)	0.329
Obesity, n (%)	6 (11)	4 (8)	0.552
Lipidemic disorders, n (%)	16 (29)	17 (33)	0.851
Thyroid disease, n (%)	6 (11)	9 (17)	0.344
Diabetes mellitus, type 2, n (%)	4 (7)	6 (11)	0.667
Coronary Artery Disease, n (%)	7 (13)	11 (21)	0.250
History of Atrial Fibrillation, n (%)	3 (6)	2 (4)	0.644

**Table 2.** Procedure and arrhythmia characteristics

	<b>RVOT location (n = 54)</b>	<b>Non-RVOT location (n = 53)</b>	<b>p-value</b>
Procedure time, minutes, median (IQR)	80.5 (60–97.5)	90 (62.4–123.5)	0.232
Application time, minutes, median (IQR)	5.9 (3.73–11.9)	5.52 (2.09–14.87)	0.674
Number of applications, median (IQR)	6 (2–10)	5 (2–11)	0.445
Radiofrequency ablation with $\geq 40W$ , n (%)	11 (20)	22 (42)	0.069
EAM CARTO, n (%)	49 (91)	48 (91)	0.903
EAM EnSite NavX, n (%)	5 (9)	5 (9)	0.903
Pace-mapping, n (%)	31 (57)	27 (52)	0.428
Matching score $>95\%$ , n (%)	29 (94)	23 (85)	0.264
Isoproterenol, n (%)	16 (29)	15 (29)	0.882
Cryoablation, n (%)	3 (6)	2 (4)	0.646
Radiofrequency catheter ablation, n (%)	51 (94)	51 (96)	0.646
Change in premature ventricular contractions morphology after the first application, n (%)	12 (22)	19 (37)	0.157
Acute procedural success, n (%)	51 (94)	45 (85)	0.093
Long-term success, n (%)	49 (91)	44 (83)	0.211
Major complication, n (%)	0	2 (4)	0.510
Precise location			
Para-hisian location, n (%)	5 (9)	5 (9)	0.903
Epicardial location, n (%)	5 (9)	9 (17)	0.211
Coronary artery proximity, n (%)	0	7 (13)	0.005

The epicardial location was associated with lower efficacy (50%) compared to non-epicardial (96%) ( $p < 0.0001$ ). In two patients with an epicardial location, late recurrence occurred despite an initially successful procedure. In this group, there was one major complication involving a tamponade that was effectively managed through pericardial puncture. This is a previously mentioned patient because the origin of the PVC was both epicardial and in proximity to the coronary artery.

The ablation efficacy did not differ depending on the chosen catheter type (cryoablation catheters, non-irrigated or irrigated catheters).

After excluding the EnSite system from the statistical analysis (which included five catheter cryoablations and five radiofrequency CA) and considering only the CARTO system, acute procedural success remained at 94% (RVOT) and 83% (non-RVOT) ( $P = 0.101$ ). In contrast, long-term success was 90% (RVOT) and 83% (non-RVOT),

respectively ( $p = 0.350$ ). A tendency toward a longer procedure duration was observed in the non-RVOT group, with a mean of 96.99 minutes (6.09), compared to the RVOT group, with a mean of 82.29 minutes (4.95) ( $P = 0.064$ ).

A subgroup analysis was performed for CARTO with  $RF \geq 40W$  compared to  $RF < 40W$ , regardless of location. Both the procedure time, 12.43 (1.60) vs. 6.72 (1.03) ( $p = 0.0027$ ) and the number of applications, 5 (9–17) vs. 4 (2–7.25) ( $p = 0.0006$ ), were higher in the  $RF \geq 40W$  group compared to the  $RF < 40W$  group. Acute procedural success was 77% in the  $RF \geq 40W$  group and 94% in the  $RF < 40W$  group, with a  $P$ -value of 0.016.

A statistical analysis was conducted for pace-mapping, comparing it to using activation mapping alone. The application time for procedures using pace-mapping was shorter, with a mean of 7.35 (0.84), compared to procedures without pace-mapping, which had a mean of 11.49 (1.83) ( $p = 0.033$ ). The use of pace-mapping was not associated with a significant difference in acute procedural success.

Acute procedural success significantly differed between the groups with a single PVC morphology before the procedure (88/93, 95%) and those with more than one PVC morphology (8/14, 57%) ( $p < 0.0001$ ). Among patients with variable PVC morphology, recurrence of arrhythmia was observed in 3 individuals during long-term follow-up.

If patients with a history of PVCs also had non-sustained ventricular tachycardia (nsVT), there was a trend toward lower efficacy (78%) compared to cases where nsVT was absent (92%) ( $p = 0.067$ ). The administration of isoproterenol did not affect the procedure's efficacy, with 90% success compared to 89% without ( $p = 0.896$ ).

## Discussion

There is no established safe threshold for radiation exposure. Therefore, it is imperative to make concerted efforts to eliminate the use of fluoroscopy during CA. An experienced cardiologist can perform the CA without requiring fluoroscopy, both in the right and left ventricles. Eliminating ionizing radiation should not be limited to simple CA procedures. Still, it should also extend to various arrhythmic substrates where the utilization of EAM or additional equipment like intravascular echocardiography has been contemplated.

Ionizing radiation affects human cells through two primary mechanisms: direct and indirect exposure. Direct exposure to ionizing radiation leads

to deoxyribonucleic acid alterations and nucleotide structure changes. Indirect exposure triggers the formation of free oxygen radicals, which can induce changes in adjacent nucleotides, resulting in damage at multiple sites. Furthermore, ionizing radiation can hinder the effectiveness of repair mechanisms, potentially leading to cell apoptosis or the development of cancer [9]. Radiation-induced leukemia usually requires a minimum of 2 years to manifest, while solid cancers typically take around five years to develop due to radiation exposure [10]. The impact of ionizing radiation on humans varies depending on the tissue type. Red bone marrow and brain are highly radiosensitive tissues, especially in childhood. Therefore, leukemias and brain tumors are the most common childhood cancers [11]. Certain groups, such as young people and pregnant women, are at a higher risk of complications from ionizing radiation exposure.

The researchers suggest that even low doses of radiation can be harmful to pregnant women, especially during early embryonic development and organogenesis stages [12, 13]. Exposure to ionizing radiation during organogenesis can lead to severe congenital disabilities, including organ deformities and functional impairments [14]. Therefore, it is so important to avoid that risk.

The factor that facilitated the execution of this study, involving procedures without fluoroscopy for both RVOT and non-RVOT ablations, was the availability and capability of CARTO and EnSite EAM systems, allowing for both cryoablation and RF ablation. Guided by the ALARA (As Low As Reasonably Achievable) principle, an experienced cardiologist using the EAM can effectively and safely perform PVC ablation procedures in various cardiac locations. In modern electrophysiology, fluoroscopy is no longer a necessary addition to the EAM system, unlike in the past times when EAM was an adjunct to fluoroscopy. Procedures without fluoroscopy are feasible not only in patients with arrhythmias originating from the RVOT but also from the LV, RV, Ao, or even epicardial locations.

RVOT locations can be divided into four walls. In the presented study, there were no statistically significant differences in the effectiveness and safety of ablation among these four locations in RVOT. Used herein, were low-power applications ( $< 40W$ ) on the anterior wall, also known as the free wall, due to its thinner structure. On the posterior wall, which is in contact with the LVOT and has a thicker myocardium, high-power applications ( $\geq 40W$ ) may be necessary, especially for arrhythmias occurring at the RVOT-LVOT border. In such

cases, focusing between the RVOT and LVOT and using high-power applications can lead to a successful procedure. However, in deep myocardial origin, especially in the left ventricle or epicardial location, high-power applications do not guarantee effectiveness.

Generally, low-power applications are sufficient in common endocardial locations. In the present study, high-power applications were used more frequently in non-RVOT locations (42%) compared to RVOT (20%). Although the difference was on the borderline of significance ( $p = 0.069$ ), it is worth noting.

In today's electrophysiology, procedures in the RVOT are more frequently carried out without fluoroscopy (approximately 80%) [15]. This is due to the straightforward venous access and the direct transition from the RA to the RV. Even a high RVOT location beneath the pulmonary valve does not pose a technical-anatomical problem. On the other hand, locations outside the RVOT present a challenge, but experienced cardiologists can perform ablations of them safely and effectively. A higher success rate in RVOT procedures compared to other locations was observed, but this difference was not statistically significant. Complications were observed only in non-RVOT procedures. In one case, there was tamponade, which was effectively managed by pericardial puncture, and pericardial effusion in another case, which was conservatively treated.

The limitation of RF ablation in the Ao can be the proximity to the coronary artery and the His bundle branches in the RV or LV. RF ablation in proximity to the His bundle branch can permanently damage physiological conduction pathways, while near the coronary artery, it can induce both constriction and thrombosis. However, in these scenarios, cryoablation allows safe application near the physiological conduction system and also near the coronary arteries because it is reversible in the first 60 seconds of the application (while ice mapping), which is an additional advantage for safety [16].

It seems that even the epicardial location is not a limitation to performing a safe zero-fluoroscopy procedure. In this case, the issue lies in the depth of the arrhythmia location, resulting in low efficacy regardless of the use of fluoroscopy. In the epicardial location, high-power applications were used in 8 out of 14 cases (57%), and the acute and long-term success rate for this location was 50%. This location had the lowest success rate, longer procedure, and application times. Moreover, using high-power applications was not a guarantee of pro-

cedure success. For such locations, other methods, such as alcohol ablation, direct current, or pulsed field electroporation, should be considered [17, 18].

Epicardial location, as well as variable PVC morphology, can be associated with a source of arrhythmia located deeper within the myocardium and potentially covering a broader area. The current study linked this to a lower acute success rate and correlated with delayed arrhythmia recurrences.

The efficacy of ablation using different catheters did not differ because the choice was tailored to individual anatomical conditions. However, the number of cases using non-irrigated and cryoablation catheters was relatively small, which may lead to underestimated statistical calculations and make it impossible to draw firm endpoints.

Pace-mapping was carried out in 58 (54%) cases when the clinical arrhythmia was not sufficiently prevalent during the procedure. Even the need for pace-mapping did not extend the procedure time. It was also not associated with a lower success rate, demonstrating that even a small amount of clinical arrhythmia allows for effective ablation. Pace-mapping is particularly important to locate RVOT arrhythmias precisely, while the aortic location makes pace-mapping unfeasible. It also seems that pace-mapping has less value in the LV and RV due to its complex anatomy, numerous muscular trabeculae, and the induction of non-clinical arrhythmias, which can reduce map accuracy and translate into a lower procedure success rate.

In each case, an ablation catheter with a contact force sensor seems beneficial and provides safety. Additionally, the CARTO system gives an advanced tool like an ablation index, which enhances the procedure's safety. This tool assesses contact force, electrode stability, application duration, and power.

In cases where PVCs induce the occurrence of nsVT, the arrhythmia location may be more extensive. This can lead to a decrease in the effectiveness of ablation, a finding corroborated by the results of other studies [19].

Patients with a history of myocardial infarction, cardiomyopathies, or significantly reduced LVEF were excluded from this study. All patients underwent transthoracic echocardiography, although other imaging modalities, such as positron emission tomography (PET) or cardiac magnetic resonance imaging (CMR), could be utilized in specific cases. Abnormalities in PET-CT were more commonly associated with nsVT and multiform PVCs than monomorphic PVC [20]. CMR provides valuable information regarding myocardial scars.

Gadolinium is washed out rapidly in healthy tissue, which can be used in detecting late gadolinium enhancements (LGE) scars, which are independent predictors of mortality and inducibility of ventricular tachycardia (VT) at electrophysiology study regardless of LVEF [21]. At the border between scar tissue and healthy myocardium, arrhythmogenic origins may develop.

### Conclusions

The development of new technologies in electrophysiology and the availability of modern tools enable the performance of efficient and safe PVC CA without fluoroscopy in various cardiac locations.

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