Research Square

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A single center experience and preliminary results on pulsed field ablation: early report from the MENA region

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Abstract

Background

Pulsed Field Ablation (PFA) is a non-thermal method for Atrial Fibrillation (AF) ablation that induces irreversible electroporation of cardiac myocyte without the thermally induced complications. Data regarding PFA's application and safety are scarce in the Middle East and North Africa (MENA) region.

Methods

We conducted a retrospective observational study for all patients who underwent PFA ablation for AF at a tertiary center in Jordan. Patients' characteristics, comorbidities, medications and laboratory measures were retrieved. Recurrence within 6 months after the blanking period was considered the primary endpoint and complications' rates (i.e., access site complications, bleeding requiring transfusion, cardiac tamponade, and phrenic nerve injury) were the secondary endpoint. Data was cleaned and analyzed using SPSS (version 23).

Results

The study included 52 patients, characterized by a mean age of 58.8 ± 16.8 years, and 1.08:1 male-to-female ratio. The cohort's left atrial diameter and volume were 3.8 ± 0.6 cm, and 106.6 ± 33.0 ml, respectively. Hypertension was the most reported comorbidity (55.8%). Beta blockers and oral anticoagulants were the most utilized medications (86.5% and 86.5%, respectively). Across a follow up period of 6 months, 4 patients (7.7%) had experienced AF recurrence with no reported complications.

Conclusion

The attenuated rate of early AF recurrence in our cohort can be considered as a safety signal with possible promising outcomes. However, this is a preliminary reports and these findings should be investigated across a larger sample size and a longer temporal frame for confirmation. Nonetheless, these findings are considered among the earliest reports of PFA efficacy and safety in the MENA region.

Clinical Trail Number: not applicable.

Background

Atrial Fibrillation (AF) is considered a global health burden in the 21st century reaching a prevalence of 59 million worldwide (1). In the United States, there are 3 to 6 million people living with AF and the number is projected to reach 6-to-16 million by 2050 (2). Estimations from the European Union indicate that there were around 8.8 million adults with AF in 2010 and is expected to reach 17.9 million by 2060 (3). AF is considered the most prevalent cause of sustained cardiac arrhythmia, significantly contributing to morbidity, mortality, and rising healthcare costs (4). Moreover, AF is associated with a substantial increase in the risk for multiple morbidities such as stroke, dementia and heart failure (5).

Medical treatment of AF with antiarrhythmic and anticoagulant agents have been studied thoroughly and been the mainstay of treatment for chronic and paroxysmal AF for decades (6). Nevertheless, Catheter Ablation (CA) is being increasingly utilized recently as a definitive treatment for AF, given its demonstrated efficacy in achieving sustained rhythm control (7). Any ablation procedure is dependent on the electrical isolation of pulmonary veins irrespective of surgical technique. Traditional methods (e.g., radiofrequency or cryothermy) rely on thermal energy sources to promote percutaneous pulmonary vein isolation (8). Thermal-based technologies lack the necessary sensitivity to ensure safety (i.e., damage to surrounding structures) or effectiveness (pulmonary vein reconnection) (9).

Pulsed Field Ablation (PFA) presents itself as a novel technology for AF ablation that utilizes non-thermal energy to induce cardiac cell death through increased cell membrane permeability without protein denaturation or any significant collateral damage to the adjacent structures (10); a process known as irreversible electroporation. This distinct therapeutic principle of PFA conferred a favorable safety profile, evidenced by the attenuated rates of esophageal injury, pulmonary vein stenosis and phrenic nerve injury when compared to conventional approaches (11). Furthermore, PFA demonstrated superior clinical performance compared with thermal ablation, achieving both a statistically significant reduction in the rate of AF recurrence and a shorter total procedural duration (12).

Despite the established evidence on efficacy and safety profile of PFA, clinical data regarding its utilization and long-term outcome remain sparse in the Middle East and North Africa (MENA) region, particularly in Jordan. In this study, we present the clinical characteristics of one of the earliest MENA PFA cohorts conducted in Jordan. Our primary objectives are focused on elucidating the rate of early AF recurrence following the index PFA procedure and highlighting its overall safety profile.

Materials and Methods

Study Design and Patient Population

A retrospective observational study was conducted on all patients who underwent PFA ablation in a single center between January and June 2025. All patients aged 18 or older with established diagnosis of paroxysmal or persistent AF who underwent initial PFA ablation during the study period were included. Inclusion was predicated on a minimum of 6-month follow-up period after the blanking period; however, extended data beyond this timeframe were analyzed where available. Patients with missing records required for primary endpoint were excluded. Patients who underwent PFA procedures outside of our center were also excluded.

The study protocol was conducted in accordance with the Declaration of Helsinki and approved by the local Institutional Review Board (IRB). The committee waived the need for informed consent.

Data Collection and Outcome Definition

Included patients' charts and operation notes in Al-Abdali hospital/Hajjiri Heart Clinic were reviewed. Data regarding participants' basic demographics, comorbidities, medications history, two-dimensional echoes, follow-up, and procedural metrics were extracted. Left Atrial Volume (LAV) was derived from Left Atrial Diameter (LAD) in the parasternal long-axis view for all patients using the following formula:

$$LAV = 45 + LAD^3$$

Where LAV is expressed in mL and LAD is expressed in cm (13). This approach was adopted due to limited availability of the complete biplane volume data in the patients' charts and the retrospective nature of the data-collection's methodology. After the completion of a standardized 90-day blanking period after the procedure, the rate of recurrence of atrial tachyarrhythmia including AF, Atrial Flutter (AFL) or Atrial Tachycardia documented on 12-lead Electrocardiogram (ECG) or 24-hour Holter within the follow-up period was defined as the study's primary endpoint. It is noteworthy to mention that Photoplethysmography (PPG) alerts from commercially-available wearable devices were not considered diagnostic for recurrence on their own, but rather were used to prompt further diagnostic testing. Additionally, the rate of peri-procedural and acute post-procedural complications including cardiac tamponade, cerebrovascular accidents or transient ischemic attack, major bleeding requiring transfusion, pericarditis, phrenic nerve injury, esophageal complications or vascular access complications requiring intervention, were considered as the study's secondary endpoints.

Procedural characteristics

As part of pre-operative preparation, patients were maintained on Novel Oral Anticoagulants (NOAC). Left atrial appendage thrombus was ruled out either by pre-procedural Cardiac Computed Tomography (CCT) or intra-procedural Trans-Esophageal Echo (TEE). General Anesthesia was administered by a board-certified anesthesiologist for the duration of the procedure.

Medtronic PulseSelect PFA system was utilized in all patients. Ultrasound-guided femoral venous access was obtained in all patients followed by introduction of the trans-septal 8-French sheath and trans-septal micro-puncture was performed. PulseSelect ablation catheter was utilized for delivering PFA and performing Pulmonary Vein Isolation (PVI) and Posterior Wall Isolation (PWI) for all patients (Fig. 1). Three-Dimensional (3D) electro-anatomic mapping was utilized in 12 patients (23.1%) (Fig. 2).

Post-procedurally, patients were admitted to the telemetry units for mandatory 24 hours of continuous cardiac monitoring. A 12-leads electrocardiogram ECG was performed on all patients prior to discharge to confirm Normal Sinus Rhythm (NSR). Clinical follow up was conducted at 1 week and a 24-hour Holter monitor was performed at 3 (the end of the blanking period), 6 and 9 months for all asymptomatic patients.

Statistical Analysis

The results were presented using descriptive analysis. Continuous variables were expressed as means ± standard deviations, while categorical variables were expressed as frequencies with associated percentage values. The primary endpoint was calculated as the proportion of patients experiencing a recurrence within the follow up period and time-to-first recurrence was assessed and presented using Kaplan-Meier analysis. The secondary endpoint was calculated as the proportion of patients experiencing peri-procedural and acute post-procedural complications as defined in the aforementioned sections. Data was cleaned, organized, and analyzed using SPSS (version 23).

Results

A total of 52 patients were included in the final analysis. Baseline demographic and clinical characteristics are summarized in Table 1. Of the included patients, 27 (52%) were males while 25 (48%) were females. Median age at presentation was 62 [48–72] years. Only 22 patients (42%) were insured.

Table 1
Baseline Demographics and Clinical Characteristics of the Study Population (N = 52)

Characteristic	Value
Demographics	
Gender (Male), n (%)	27 (51.9%)
Age (Years), mean ± SD	58.8 ± 16.8
Family History [a], n (%)	11 (21.2%)
Social History	
Smoking [b], n (%)	20 (42.6%)
Alcohol [c], n (%)	7 (14.9%)
Caffeine [d], n (%)	26 (55.3%)
Medical History	
Hypertension, n (%)	29 (55.8%)
Diabetes Mellitus, n (%)	15 (28.8%)
Heart Failure, n (%)	8 (15.4%)
Cardiac Surgical History [e], n (%)	22 (42.3%)
Non-cardiac Surgical History	29 (55.8%)
CHA_2DS_2-VASc score, mean ± SD	1.9 ± 1.8
Clinical and Echocardiographic Parameters	
Systolic Blood Pressure (mmHg), mean ± SD	139.2 ± 19.1
Diastolic Blood Pressure (mmHg), mean ± SD	78 ± 9.4
Left Atrial Diameter (mm), mean ± SD	3.8 ± 0.6
Left Atrial Volume (mL), mean ± SD	106.6 ± 33

Notes: [a] Defined as first-degree relative with atrial tachyarrhythmia. [b] Defined as currently smokes or ever smoked within the last 6 months. [c] Defined as consuming at least 1 units of alcohol daily for women and 2 units daily for men. [d] Defined as the consumption of more than 3 caffeinated beverages per day. [e] Defined as having any previous history of cardiac intervention excluding atrial fibrillation ablation. Abbreviations: SD: Standard Deviation

Hypertension was present in 29 patients (56%), while diabetes mellitus type II was recorded in 15 cases (29%). Mean systolic and diastolic blood pressure values were as follows: 139.2 ± 19.1 and 78 ± 9.4, respectively. Non-cardiac surgical history was observed in 29 patients (56%), while previous cardiac

surgical interventions, excluding AF ablation, were documented for 22 cases (42%). Across the included cohort, 20 (43%) were smokers, 7 (15%) were consistent alcohol drinkers, and 26 (55%) were daily caffeine users.

In terms of pharmacological history, data regarding study participants' medications profile are summarized in Table 2. Beta blockers and oral anticoagulants were the most common used medications at 87% (n = 45) each. These were followed by ARBs (40%), anti-arrhythmic class I medications (42%), and lipid lowering agents (38%). ACE inhibitors (3.8%) and insulin (3.8%) were the least commonly reported medications among the cohort.

Table 2
Medication Profile of the Study Participants

Medication	Value, n (%)
β blockers	45 (86.5%)
Calcium Channel Blockers	16 (30.8%)
Renin-Angiotensin System inhibitors	23 (44.2%)
Diuretics	17 (32.7)
Anti-Arrhythmic [a]	32 (61.5%)
Metformin	9 (17.3%)
Oral Hypoglycemic Agents	11 (21.2%)
Insulin	2 (3.8%)
Anti-Platelets	17 (32.7%)
Oral Anti-coagulants	45 (86.5%)
Lipid Lowering Agents	20 (38.5%)
Notes: [a] including class I and III anti-arrhythmic drugs.	

Selected cohort's parameters are presented in Fig. 3. The cohort's left atrial diameter was 3.8 ± 0.6 cm, while their left atrial volume was 106.6 ± 33.0 ml. Additionally, mean ejection fraction for the sample was 56.7 ± 7.34. Mean CHA_2DS_2-VASc score was 1.92, ranging from 0 to 7.0.

Procedural and recurrence metrics are summarized in Table 3. The mean procedural duration was 77 ± 12.3 minutes, with a mean fluoroscopy time 16 ± 1.7. Across a follow up period of 6 months, only 4 out of 52 patients (7.7%) had experienced AF recurrence. At the end of the follow-up period, the estimated freedom from atrial tachyarrhythmia was 85.6% (95% CI: 70.5% − 100%; Fig. 4). The median time from the end of the blanking period to first recurrence was 121 days (Range: 2–136) days. None of the study participants experienced any peri or post-operative complications.

Table 3
Procedural and Recurrence Metrics

Procedural Characteristics	Value
Procedure Duration (Minutes), mean ± SD	77 ± 12.3
Fluoroscopy Time (Minutes), mean ± SD	16 ± 1.7
3D Mapping Usage, n (%)	12 (23.1)
Recurrence Parameters	
Recurrence Rate, n (%)	4 (7.7%)
Days-to-recurrence, median (range)	121 (2–136)

Discussion

Recently, catheter ablation has been gaining increased popularity for the treatment of AF –both paroxysmal and persistent– due to its proven effectiveness and relative safety profile (14, 15). However, this effectiveness is critically dependent on the successful PVI which often compromised by the need for prolonged, meticulous point-by-point heating or freezing required by radiofrequency or cryoablation (16). This was circumvented by the introduction of PFA systems which often utilizes circular or pentaspline catheters capable of delivering near-instantaneous, circumferential PVI via IRE. The utilization of pentaspline catheters in PFA systems significantly reduced left atrial dwell time by at least 19.9 minutes (17). In our study cohort, the average procedure time was around 77 ± 12.3 minutes which significantly outperforming its thermal counterparts. In a meta-analysis done by deepen et al. the procedure time for PFA was 21.68 minutes shorter than average thermal ablation duration. (18)

This advantage was evident by the attenuated rate of early recurrence of AF following the index PFA procedure in our cohort (7.7%). On the other hand, the rate of early recurrence following either cryoballoon or radiofrequency ablations were comparable (21.8% vs. 28.9%, p = 0.26) (19). On a longer temporal frame, data from the German ablation registry showed that AF recurrence within a one-year follow up period after both ablation modalities were even higher and reached up to 45% (20). Moreover, higher rates of early recurrence were associated with increased risk of late recurrence among patients with AF who underwent different ablation modalities (21, 22). This appears to be due to the post ablation induced inflammation (19). This inflammation is mitigated by the introduction of PFA systems that relies on IRE to increase cell membrane permeability and induce cardiac cell apoptosis without triggering excessive inflammatory response (10).

this substantial increase in efficiency is not merely an operational benefit but translates directly into an improved patient safety profile. In our cohort of 52 patients, we observed no instances of any peri-procedural or acute post procedural complications. This is favorable when compared to the reported incidence of cardiac tamponade following thermal ablation in large registries and surveys which ranged from 0.8% to 2.4% for both RF and Cryoablation procedures (23, 24). Also, the occurrence of peri-

procedural thromboembolic events is dependent on presence or absence of left atrial thrombus and the maintenance of uninterrupted anticoagulation throughout the procedure. And although this is shared among all modalities, the reported incidence of thromboembolic events following thermal ablation reached 0.9% (23). The absence of phrenic nerve injury incidences in our cohort highlight early safety signal of the PFA systems that stems from the nature of energy utilized which spares nerve tissue. This is especially evident when compared with Cryoablation, where the reported rate is higher reaching up to 11% (25). Crucially, we observed no instances of esophageal injuries in our entire cohort as well (0%). This observation aligns with novel, non-thermal principle of PFA that mitigate the thermal risks associated with thermal ablation modalities where reported incidence of esophageal injuries reached 0.25% (23).

From an economical point of view, a meta-analysis done by Wattanasukcahi et al. showed that CA is a cost effective choice for the treatment of AF on the long term in high income countries when compared to medical therapy (26). However, in a lower to middle income country like Jordan, it is of great importance to gauge the cost effectiveness of CA especially with the introduction of the PFA systems. In the analysis done on the JOFIB registry, the rate of re-admission to the hospital among patients with AF due to cardiac causes reached 14.6% within a one-year follow-up period, among which heart failure exacerbation was the single most common cardiac cause (7.7%) (27). These findings along with the results of our study -in term of efficacy and safety- and its future implications need to be taken into consideration when assessing the cost effectiveness of PFA procedure in lower and middle income countries.

Despite the relatively small sample size of this investigation, results from our single-center cohort supports the growing consensus that PFA significantly mitigate the risks caused by thermal energy utilized by other ablation modalities and consequently enhances overall patient safety profile while maintaining favorable effectiveness evidenced by a low rate of early recurrence which is consistent with the internationally reported PFA statistics. This study is a preliminary analysis that is meant to be followed up and to lay the foundation for subsequent future project to highlight the effectiveness and safety of this novel technology in the MENA region where published data on this technology remain sparse.

Our findings should be interpreted within the context of important limitations. First and foremost, the retrospective design, recruitment from a single center, and the small sample size restrict the statistical power and the generalizability of our findings especially when observing zero incidence of critical, low frequency complications. Also, the recurrence data are limited to early follow-up since this is a preliminary report, necessitating caution when projecting these rates to long term efficacy. Future collaborative studies with extended follow-up periods are needed to confirm the effectiveness and safety of PFA in MENA region.

Declarations

Ethics approval and consent to participate

The study protocol was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (IRB) of Abdali Medical Center. Informed consent was waived by the IRB due to the retrospective nature of the study and the use of de-identified patient data.

Consent for publication

Not applicable

Competing interests

All authors declare no conflict of interests.

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Author Contribution

Al-slaimieh (AAS), A. H. and M. H. contributed to conceptualization, supervision and project administrationAAS performed data curation, formal analysis and methodology formulationAAS, N. H., K. A., J. A., A. A., A. H., and M. H. were involved in data extraction, and participated in drafting and revising the main manuscript textAll authors read and approved the final manuscript

Acknowledgment

Not applicable

Data Availability

All data generated and analyzed in the current study are available from the corresponding authors upon reasonable request.

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Figures



Figure 1

Fluoroscopic visualization of the circular (loop) PFA ablation catheter during the procedure.

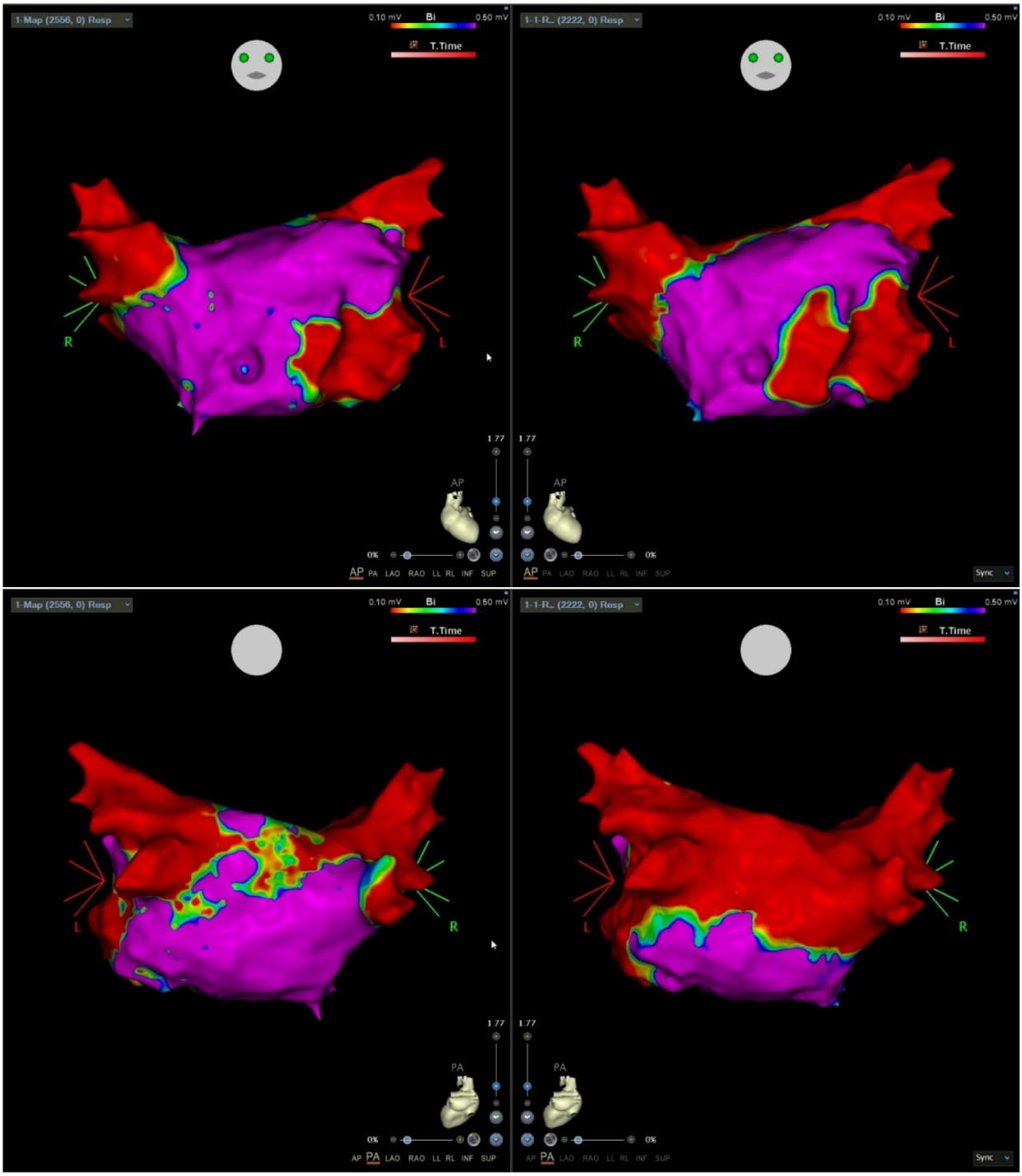


Figure 2

Three-dimensional electro-anatomic mapping of the left atrium in the anterior-posterior (above) and posterior-anterior (below) projections. Red indicates regions of low voltage (< 0.1mV), while purple indicates high voltage regions (> 0.5mV). Left panels: pre-ablation; right panels: post-ablation.

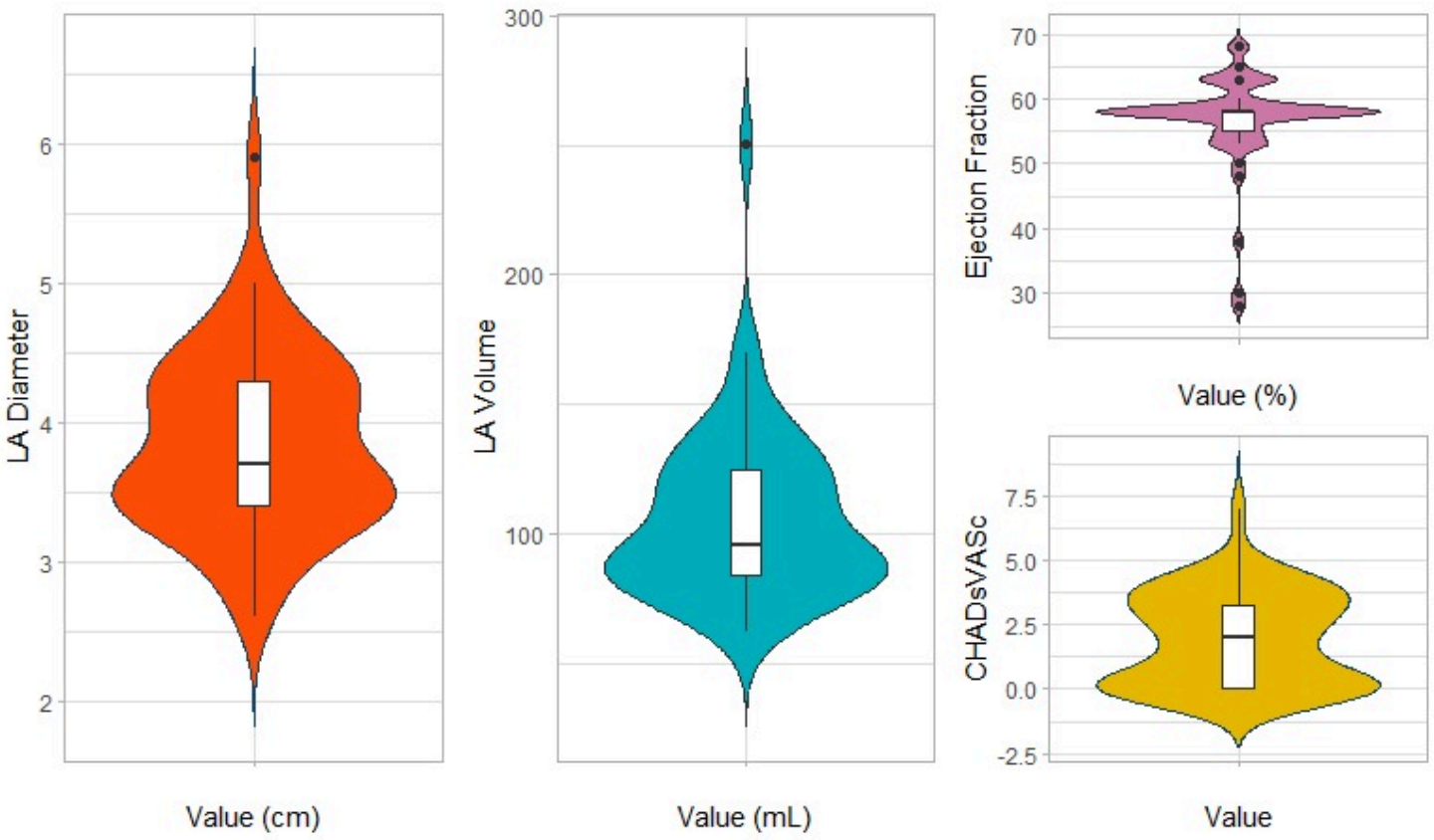


Figure 3

Violin charts of selected cohort's characteristics. Abbreviations: LA: Left Atrial.

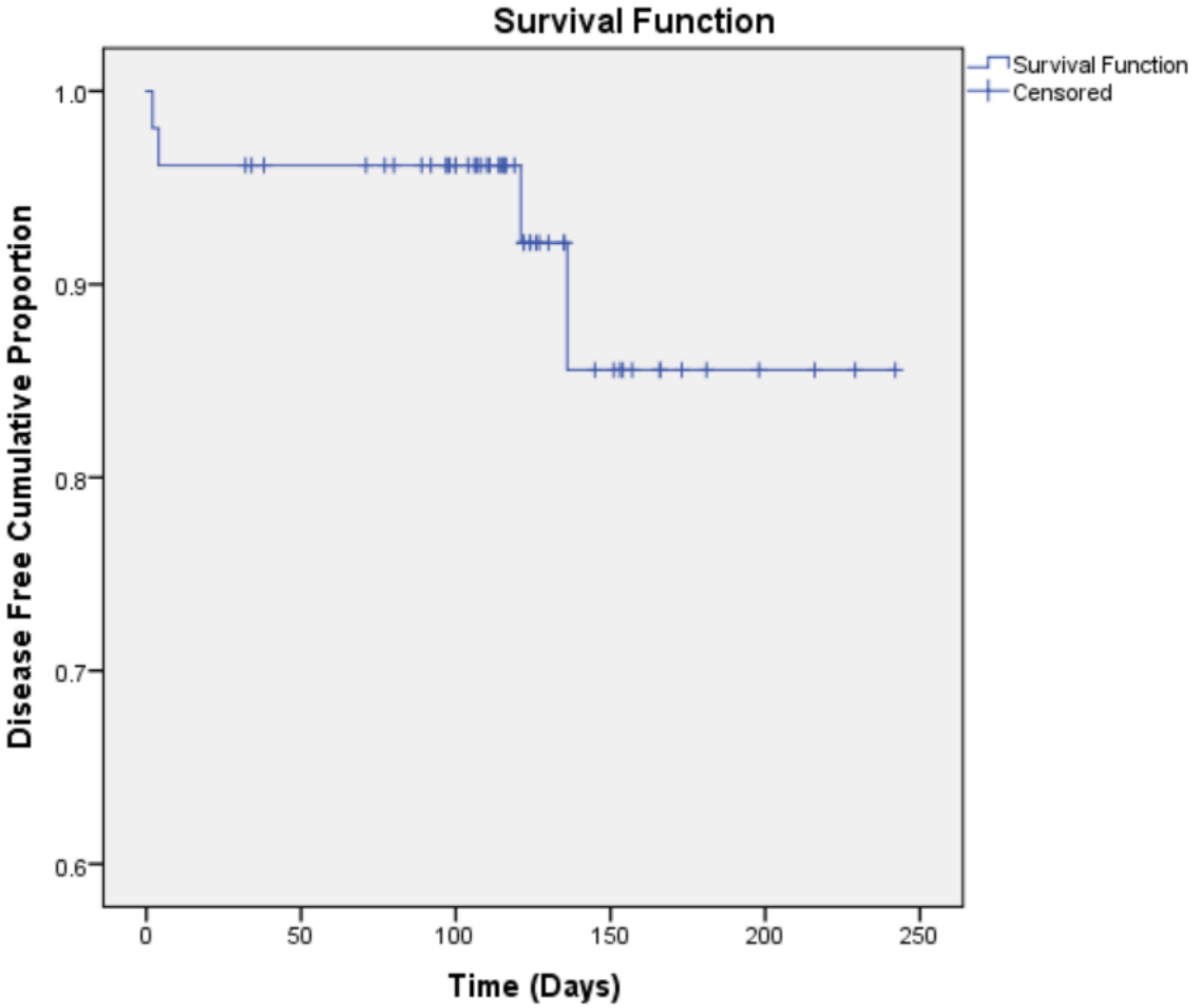


Figure 4

Kaplan-Meier Curve for Freedom from Atrial Tachyarrhythmia recurrence. Data presented in the figure represent follow up data starting from the end of the standardized 90-days follow up period.