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Original Article

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Impact of Post-Procedural Atrial Arrhythmia on Long-Term Cardiac Function and Quality of Life Following Patent Foramen Ovale Closure

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Abstract

Background: Patent foramen ovale (PFO) is a common remnant of the embryonic development of the heart with an underestimated potential for morbidity and mortality. This study aimed to investigate the long-term impact of atrial arrhythmia (AA), a common complication after PFO closure, on cardiac function and quality of life (QoL) through a retrospective clinical analysis.

Methods: Patients who underwent percutaneous PFO closure between January 2022 and June 2024 were retrospectively identified. All patients underwent 24-h Holter electrocardiogram (ECG) monitoring prior to the procedure to screen for baseline atrial fibrillation (AF). Cardiac function and QoL were assessed after intervention and at long-term follow-up using echocardiographic parameters and questionnaires (SF-36), respectively.

Results: A total of 215 patients were included in this study. Sinus rhythm was present in all patients at baseline, and 26% developed AA during follow-up after PFO closure. The average follow-up period was 24 ± 7.8 months. Among the 56 patients with post-procedural AA, echocardiographic analysis showed that mitral E/A significantly increased at long-term follow-up compared to the immediate post-interventional period (1.20 ± 0.24 vs. 1.29 ± 0.18, $P < 0.05$). No statistically significant changes were observed in echocardiographic variables other than mitral E/A. In terms of QoL, only the score for social function improved significantly at long-term follow-up (65.21 ± 6.16 vs. 67.98 ± 7.59, $P < 0.05$), while no significant differences were found in the other subdomains.

Conclusions: AA, the common complication of PFO closure, has no impact on the long-term cardiac function and QoL of patients.

Keywords: Atrial arrhythmias; Patent foramen ovale closure; Cardiac function; Quality of life

Introduction

Patent foramen ovale (PFO), present in approximately one-quarter of adults, is a remnant of fetal circulation that allows right-to-left shunting due to incomplete postnatal closure of the interatrial septum.

PFO may contribute to clinical syndromes such as recurrent embolic events and symptoms including headache, dizziness, shortness of breath, or limb weakness. PFO closure is recognized as a cornerstone of ischemic recurrence prevention after a PFO-related stroke in selected patients [1, 2], and its safety has been well established. However, as the PFO occluder is an implantable device, it can exert a prolonged impact on the left atrial structure and neurohormonal responses. Common post-procedural complications include various atrial arrhythmias (AA), such as atrial fibrillation (AF), atrial flutter, atrial premature beats, and atrial tachycardia [3].

Recent studies have indicated that the incidence of AA following percutaneous PFO closure can be as high as 28.5% when continuous and systematic electrocardiogram (ECG) monitoring methods are employed [4], with most arrhythmias occurring within the first month post-procedure [5]. Notably, the multicenter AFLOAT study demonstrated a substantial rate of AA within 6 months of closure when monitored via implantable cardiac devices [6]. It was found in previous studies that AA occurring after PFO closure is not a trivial event, as it may impact on the cardiac function and quality of life (QoL) [7, 8]. Given these concerns, the present study aimed to evaluate the long-term impact of post-procedural AA - the most common complication following PFO closure - on cardiac function and QoL. By retrospectively analyzing echocardiographic and QoL outcomes over an extended follow-up period, this study seeks to provide clinically relevant insights into the safety and functional consequences of PFO closure in real-world settings.

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Materials and Methods

Patients

This study was a single-center retrospective observational study. This study retrospectively analyzed patients who underwent PFO closure at our hospital from January 2022 to June 2024. All patients had PFO closure because of cryptogenic stroke or recurrent transient ischemic attack associated with positive brain magnetic resonance and grade ≥ 2 (scale 0 - 3) atrial right-to-left shunt at contrast-enhanced transthoracic and/or transesophageal echocardiography (TTE and/or TEE). All patients had complete neurological and cardiological examination, pre-procedural 24-h Holter ECG monitoring. AA was defined as any episode of AF, atrial flutter or atrial tachycardia lasting 30 s or more (≥ 30 s), in accordance with the 2012 consensus statement from the Heart Rhythm Society and others [9]. This study was approved by the Ethics Committee of Shanghai Health Medical College Affiliated Zhoupu Hospital and was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration.

PFO closure

The PFO closure procedure was performed by the femoral venous approach under local anesthesia with sedation, or under general anesthesia. TTE or TEE guidance was used throughout the procedure for placement and assessment of the septal occluder. A 0032″ wire was advanced across the PFO and into the left upper pulmonary vein in most patients. Sizing balloon interrogation of the PFO was performed to determine the anatomy of the septum secundum and septum primum during contrast injection. The closure device consists of two discs linked together by a short connecting waist. The size of implanted closure device was at the discretion of the operator and based on the size of the PFO. It was advanced along the wire and was opened once in position. Then the atrial septum was located between the two discs obtaining PFO closure. After observation and testing of its correct positioning and stability, it was left in place (Fig. 1). Unfractionated heparin was used for periprocedural anticoagulation. Patients were treated with dual antiplatelet therapy for 3 months after the procedure, followed by single antiplatelet therapy in the absence of any indication for anticoagulant therapy [10].

Echocardiography

Patients received echocardiographic examinations at the pre-interventional stage, 1-day post-intervention, 3-month and 1-year post-intervention. We collected 1-day post-intervention data for post-intervention group and 1-year post-intervention data for long-term follow-up group. Patients were placed in the supine or the left lateral position. Based on the guidelines for echocardiographic measurements in Chinese adults [11], the anteroposterior diameter of the left atrium (LA), left ventricular end-diastolic volume (LVEDV), left ventricular end-systolic volume (LVESV), interventricular septal thickness (IVS), and left ventricular posterior wall thickness (LVPW) were measured via parasternal left-ventricular long-axis and short-axis views. The left ventricular ejection fraction (LVEF) was measured by the dual plane Simpson method. Pulmonary artery systolic pressure (PAPs) can be detected noninvasively with continuous Doppler echocardiography [12].

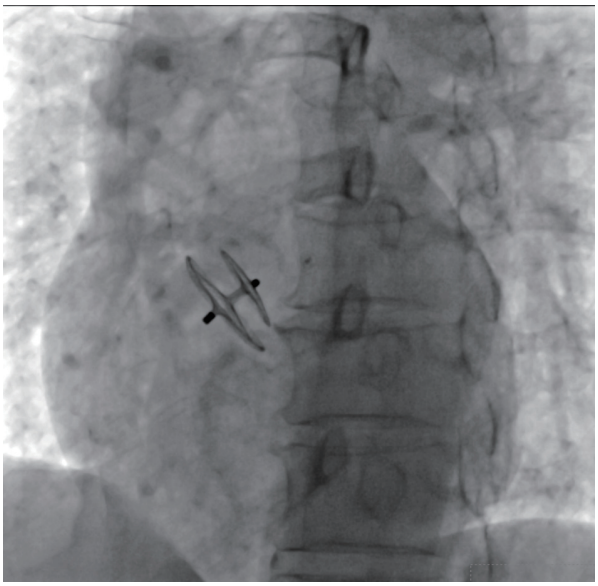

Figure 1. PFO closure procedure. Intraoperative image demonstrating transcatheter deployment of a double-disc occluder device across the atrial septum.

Measurement of QoL

Data on QoL were obtained prospectively by sending the patients the validated translations in Chinese of the questionnaires by phone: the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The SF-36 is a set of generic, coherent, and easily administered quality-of-life measures, consisting of eight sub-domains: overall health score, physical health score, physical function, emotional function, social function, physical pain, energy and mental health. For each domain, the score ranges from 0 (worst) to 100 points (best). The results can be compared with the averages in the Medical Outcomes Study [13]. To minimize potential bias, we selected two different time points to administer the SF-36 questionnaire to patients via telephone for their post-interventional data and 1-year post-interventional data for long-term follow-up QoL assessments, respectively. We selected an appropriate time point, clarified inform the purpose of the investigation and the confidentiality principle, maintained a neutral attitude during the questioning, avoided using leading or suggestive questions, and accurately recorded the data collected.

Data processing and confidentiality

Data collection of all patients in our hospital was performed in the same way. First, the informed consent was sent to the patients. After their approval, the retrospective data were retrieved from the electronic patient database, and the SF-36 were performed by phone. Those who did not answer within 1 month received a reminder by phone. All patients signed informed consent to participate, and collected data were kept confidential. Refusing to participate without any justification had no impact on future care. Patients were informed that they could withdraw from the study at any stage without penalty or denial of treatment.

Statistical analysis

The data were analyzed using SPSS Statistics, version 20 (Chicago, IL, USA). The Kolmogorov-Smirnov test was applied to determine whether the data followed a normal distribution. Continuous data with normal distributions are presented as means ± standard deviations and were compared by independent-sample *t*-tests (two groups). Categorical data are presented as percentages (%). A P value of < 0.05 was considered statistically significant.

Results

Patients' basic information

A total of 215 patients with PFO closure were included in this study, and their clinical characteristics at baseline are shown in Table 1. Mean age at time of closure was 59 ± 12.3 years, and 51.2% of patients were male. The occurrence rate of preoperative sinus rhythm was 100.0%, while the occurrence rate of AA after PFO closure was 26.0%. Mean New York Heart Association (NYHA) functional classification was 2 ± 0.6. The presence of atrial septal aneurysm (ASA) was observed in 5.1% of patients. The average follow-up period was 24 ± 7.8 months (range: 12 - 36 months).

Table 1. Clinical Characteristics of Study Participants (N = 215)

Variables	Results
Age (years)	59 ± 12.3
Male gender, n (%)	110 (51.2%)
BMI, kg/m^2	25 ± 3.6
Smoking, n (%)	95 (44.2%)
Alcohol, n (%)	138 (64.2%)
Hypertension, n (%)	97 (45.1%)
Coronary artery disease, n (%)	73 (34.0%)
Diabetes mellitus, n (%)	24 (11.2%)
Stroke, n (%)	160 (74.4%)
Sinus rhythm preoperative, n (%)	215 (100.0%)
AA after PFO closure, n (%)	56 (26.0%)
Atrial fibrillation, n (%)	47 (21.9%)
Atrial flutter, n (%)	6 (2.8%)
Atrial premature beats, n (%)	52 (24.2%)
Atrial tachycardia, n (%)	38 (17.7%)
NYHA functional class	2 ± 0.6
Spontaneous shunt, n (%)	32 (14.9%)
ASA, n (%)	11 (5.1%)
Follow-up, months	24 ± 7.8

Data are presented as mean ± standard deviation (SD) or number (percentage), as appropriate. BMI: body mass index; ASA: atrial septal aneurysm; AA: atrial arrhythmia; NYHA, New York Heart Association.

Comparison of post-interventional and long-term cardiac function after PFO closure by echocardiography

We selected 56 patients who developed AA after PFO closure for the study. We set the data collected 1-day after PFO closure as the post-interventional group, and the data collected 1-year after PFO closure as the long-term follow-up group. Then we compared the data on cardiac function by echocardiography of the two groups (Table 2).

The echocardiographic parameters of post-interventional group and long-term group were compared, including LA, LVEDV, LVESV, IVS, LVPW, LVEF, mitral E/A, PAPs, and the presence of ASA. The study found that compared with post-interventional group, mitral E/A was significantly increased in long-term group (1.20 ± 0.24 vs. 1.29 ± 0.18, $P < 0.05$). There were no statistically significant changes in LA, LVEDV, LVESV, IVS, LVPW, LVEF, and PAPs. These results indicate that cardiac function did not change despite the presence of AA.

Comparison of post-interventional and long-term QoL after PFO closure

Mean scores of the patients after PFO closure for the different domains of the SF-36 are shown in Figure 2 and in the supplementary data (Supplementary Material 1, cr.elmerpub.com). Overall, all scores after PFO closure exceeded the threshold of 50 points, suggesting a favorable change in QoL. The results showed that compared with post-interventional group, the score of social function was significantly increased in long-term group (65.21 ± 6.16 vs. 67.98 ± 7.59, $P < 0.05$). There were no statistically significant changes in overall health score, physical health score, physical function, emotional function, physical pain, energy and mental health.

Discussion

Percutaneous PFO closure is considered the gold standard for

Table 2. Echocardiographic Parameters Following PFO Closure in Patients With Atrial Arrhythmia (N = 56)

	Post-intervention	Long-term follow-up	P value
LA (mm)	39.75 ± 4.48	39.05 ± 3.90	0.382
LVEDV (mL/m^2)	53.25 ± 5.05	52.71 ± 4.45	0.553
LVESV (mL/m^2)	21.16 ± 3.12	21.55 ± 2.54	0.466
IVS (mm)	7.68 ± 0.96	7.73 ± 0.88	0.759
LVPW (mm)	7.82 ± 0.96	7.88 ± 0.92	0.763
LVEF (%)	60.61 ± 4.37	61.05 ± 4.03	0.576
Mitral (E/A)	1.20 ± 0.24	1.29 ± 0.18	0.025*
PAPs (mm Hg)	21.41 ± 1.91	21.84 ± 1.87	0.232
ASA, n (%)	3 (5.3%)	2 (3.6%)	0.647

Data are presented as mean ± standard deviation (SD). *P < 0.05 was considered statistically significant. PFO: patent foramen ovale; LA: left atrial anteroposterior diameter; LVEDV: left ventricular end-diastolic volume; LVESV: left ventricular end-systolic volume; IVS: interventricular septal thickness; LVPW: left ventricular posterior wall thickness; LVEF: left ventricular ejection fraction; PAPs: pulmonary artery systolic pressure; ASA: atrial septal aneurysm.

the secondary prevention of stroke in patients aged 18 - 65 years following ischemic stroke. However, PFO closure may be associated with several adverse events. One of the most frequent complications is AA after operation [14]. The incidence of AA occurring after percutaneous PFO closure is likely underestimated in randomized trials and literature data, since only symptomatic AA is detected in most reports. The rate of new-onset AA after PFO closure reported earlier in clinical trials ranges from 3% to 7.4% [15]; however, when systematic external Holter monitoring or implantable cardiac monitors devices are used to monitor AA, incidence rises to nearly 22% within the first month after PFO closure [16, 17]. Some clinical trials have revealed that the rate of new-onset AA is significantly higher in patients undergoing PFO closure compared with patients receiving medical therapy alone, with an increase of more than four times the risk [18, 19]. Recent studies have shown that PFO closure is not associated with any substantial increased long-term risk of developing AA beyond the well-known procedure-related short-term risk [20]; however, it may be associated with decreased QoL in

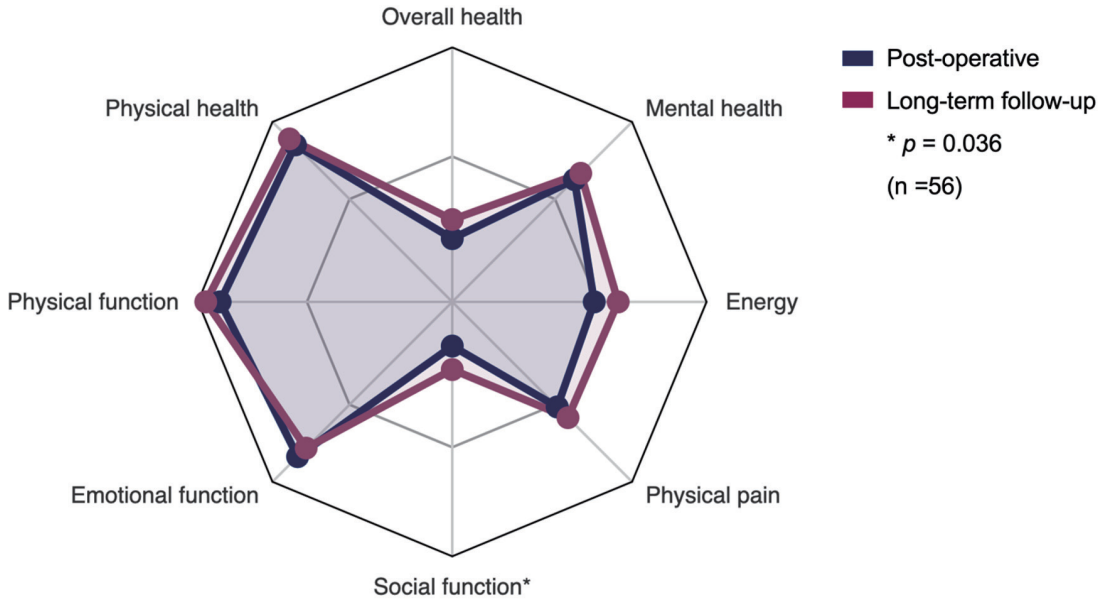

Figure 2. Comparison of SF-36 quality of life sub-domain scores between post-intervention and long-term follow-up periods in patients undergoing PFO closure. Radar chart displays eight sub-domains of the SF-36 questionnaire: overall health, physical health, physical function, emotional function, social function, physical pain, energy, and mental health. The purple line represents scores at long-term follow-up, while the navy line represents scores at the post-interventional period. Social function improved significantly at long-term follow-up (P < 0.05), highlighted by an asterisk. The inner and outer octagonal frames correspond to 60% and 90% of the maximum score range, respectively, providing a visual reference for relative domain performance. Source data are provided here (Supplementary Material 1, cr.elmerpub.com).

mid-term follow-up [21].

Although newer data from numerous randomized trials and meta-analyses have shown that the incidence of AA is increased after PFO closure [22], the pathophysiological mechanism remains not very clear. There are several pathogenetic mechanisms that have been proposed and could explain the increased likelihood of early transient AA seen after transcatheter PFO closure: 1) The placement of a foreign device (a PFO occluder) via the interatrial septum could cause local atrial irritation, and the device itself could trigger an inflammatory response or scarring with subsequent anisotropic conduction [23]. 2) The frame of the devices used for PFO closure is constructed by nitinol, which contains both nickel and titanium. Nickel hypersensitivity could play an important role for AA pathogenesis. Before the endocardialization of the device, which requires 1 to 3 months, a considerable quantity of nickel is released into the bloodstream as potential allergens [24]. 3) Device placement could cause tissue mechanical stretch, which has been documented as a possible mechanism for AA pathogenesis. This theory could probably explain why the incidence of AA was higher after the placement of first-generation, more bulky devices [25]. 4) Device placement could affect left atrial biomechanics, which could be evaluated with novel echocardiographic parameters, such as the left atrial strain [26, 27].

In our study, we found that there were no statistically significant changes in LA, LVEDV, LVESV, IVS, LVPW, LVEF, and PAPs in long-term group as compared with post-interventional group, which indicated that AA after PFO closure has no impact on the long-term cardiac function. In addition, the results of QoL analysis showed that there were no statistically significant changes in most sub-domains, including overall health score, physical health score, physical function, emotional function, physical pain, energy and mental health. Previous studies have shown a short-term decrease of QoL after PFO closure [8, 21, 28], which may be related to the procedures itself. However, our study focused on QoL of the patients with AA after PFO closure and explored the impact of post-procedural AA on QoL. Our results revealed that AA after PFO closure has no impact on the long-term QoL. The increased mitral E/A and the score of social function probably resulted from the hemodynamic improvement of the closure of PFO.

Data from a Danish nationwide cohort showed that patients treated with PFO closure had the same risk of AF as subjects with PFO diagnosis during a 5-year follow-up [20]. The technique of percutaneous PFO closure has been reported to be safe [29], and the present data confirm this finding. Indeed, no major procedure-related complications were observed, and the overall mortality was numerically lower after PFO closure [30] and statistically reduced after a 10-year follow-up [31]. In our study, percutaneous PFO closure did not appear to increase the long-term risk of developing AA. To our knowledge, this is the first study to specifically evaluate the long-term impact of post-procedural AA on QoL following PFO closure. Our findings indicate that AA, although the most common complication after PFO closure, does not negatively affect patients' long-term QoL.

The limitation of our study was that information for all questionnaires was obtained by phone at varying time points, resulting in substantial variation in the interval between PFO closure and QoL assessment. Another limitation of our study is the small sample size, which may result in unstable statistical outcomes and potential bias. To partially address this limitation, we analyzed AA as a broader category instead of AF alone, thereby increasing the sample size through data integration. In addition, the inherent limitations of a retrospective, single-center study design may affect the generalizability of our findings. Additionally, we acknowledge that the mitral E/A ratio may be unreliable in patients with persistent AF due to the absence of organized atrial contraction. However, in our study, E/A was assessed during periods of sinus rhythm in patients with intermittent arrhythmias. The E/E' ratio was not analyzed due to incomplete tissue Doppler data across all follow-up time points. Finally, the statistically significant improvement observed in the social function score may be attributable to multiple comparisons or random variation, given the relatively small effect size, and should therefore be interpreted with caution.

Conclusions

Our results reveal that AA after PFO closure has no impact on the long-term cardiac function and QoL of patients. This study will further enrich the clinical research data of PFO closure and provide a better reference for the subsequent clinical work of interventional treatment for PFO.

Supplementary Material

Suppl 1. Quality of life according to the SF-36 after PFO closure (n = 56).

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Conflict of Interest

The authors declare that there is no conflict of interest.

Informed Consent

Written informed consent was also obtained.

Author Contributions

Zhong Ping Ning and Sai Hua Wang conceived and designed the project. Zhao Xia Wang, Jun Luo, and Ying Biao Wu interpreted the results and wrote the manuscript. Xin Xin Fu and Jia Hui Fang collected data. Ce Shi analyzed data. All authors reviewed the manuscript.

Data Availability

Any inquiries regarding the availability of supporting data for this study should be directed to the corresponding author.

Abbreviations

PFO: patent foramen ovale; AA: atrial tachyarrhythmias; QoL: quality of life; BMI: body mass index; ASA: atrial septal aneurysm; NYHA: New York Heart Association; LA: left atrial anteroposterior diameter; LVEDV: left ventricular end-diastolic volume; LVESV: left ventricular end-systolic volume; IVS: interventricular septal thickness; LVPW: left ventricular posterior wall thickness; LVEF: left ventricular ejection fraction; PAPs: pulmonary artery systolic pressure

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