Journal of Cardiothoracic Surgery

RESEARCH

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Clinical features between paroxysmal and nonparoxysmal atrial fibrillation: a comparative analysis in eastern China

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Abstract

Background Atrial fibrillation (AF) has emerged as a notable public health issue in China due to the aging population and rapid urbanization. This study aimed to describe the characteristics of patients with AF (paroxysmal and nonparoxysmal) and investigate the association between left ventricular ejection fraction (LVEF) levels and AF subtypes to facilitate early prevention in patients with AF.

Method Patients with AF who presented at the cardiology department of the First People's Hospital of Yancheng were recruited in this study. In univariate and multivariate logistic regression analyses, odds ratios (ORs) and 95% confidence intervals (CIs) were calculated to evaluate the relationships between each dependent variable and nonparoxysmal AF. The restricted cubic splines (RCS) curve was employed to explore the linear relationship between LVEF and nonparoxysmal AF on a continuous scale. Subgroup analysis was applied to examine the stability of the results.

Results The study included a total of 2054 patients who were diagnosed with AF. 652 (31.74%) patients had paroxysmal AF, and 1402 (68.26%) had nonparoxysmal AF. Multivariate logistic regression analyses indicated that compared to those with paroxysmal AF, patients with nonparoxysmal AF tended to have a higher prevalence of coronary artery disease, lower levels of LVEF, and an elevated heart rate. Additionally, RCS curves also showed that LVEF was negatively and linearly associated with the nonparoxysmal AF. Furthermore, the association between LVEF and nonparoxysmal AF was stronger among patients with hypertension and obesity (P for interaction < 0.05).

Conclusions Patients with nonparoxysmal AF have a more advanced AF burden and the transition from paroxysmal to nonparoxysmal AF should be recognized in time, especially to treat the corresponding comorbidities (including hypertension and obesity) more consistently.

Keywords Paroxysmal atrial fibrillation, Nonparoxysmal atrial fibrillation, Diabetes, Clinical features

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Background

Atrial fibrillation (AF) has emerged as a significant global health burden, primarily attributed to factors such as economic growth, aging populations, and the prevalence of other related risk factors [1]. AF is traditionally classified as paroxysmal AF and nonparoxysmal AF. Patients with nonparoxysmal AF exhibited a higher burden of AF compared to those with paroxysmal AF. Moreover, nonparoxysmal AF was linked to worse outcomes among AF patients in previous studies [2–4]. However, there was a significant overlap in AF burden between the two groups. Most patients were categorized as having "paroxysmal" AF, even at very high levels of burden. This could be attributed to the independent effect of the patient's comorbidities and other characteristics [5]. Hence, it is essential to characterize nonparoxysmal AF and paroxysmal AF.

The management of patients with AF has been optimized, and comprehensive medical care has been provided [6–8]. Such as catheter ablation, which can reduce the AF load, restore sinus rhythm, and enhance cardiac function even in patients with AF and heart failure(HF) [7]. The EAST-AFNET 4 trial (Early Treatment of Atrial Fibrillation Trial for Stroke Prevention) randomly assigned over 2000 AF patients into two groups: early rhythm control (antiarrhythmic therapy or catheter ablation) and the usual management group, with roughly one-third of each group having stable HF. After two years, early rhythm control significantly lowered the risk of adverse cardiovascular outcomes compared to usual care [9]. Another clinical trial also reached similar conclusions [10]. Therefore, early prevention and prompt cardioversion of heart rhythm in AF patients, even coexist with HF, can effectively enhance quality of life and reduce the incidence of adverse events.

The measurement of LVEF by echocardiography remains essential for quantifying the systolic performance of the left ventricle in clinical practice. Previous researchers have indicated that LVEF may serve as a potential predictor of hospitalization risk for HF in AF patients [11]. However, the relationship between LVEF levels and the traditional classification of AF (paroxysmal and nonparoxysmal) remains unclear. Therefore, this study aimed to describe the characteristics of patients with AF(paroxysmal and nonparoxysmal) and investigate the association between LVEF levels and AF subtypes to facilitate early prevention in patients with AF.

Methods

Study population

We recruited patients with AF who presented at the cardiology department of the First People's Hospital of Yancheng, regardless of their hospitalization status or outpatient treatment. The inclusion criteria for the subjects were as follows: (i) aged ≥ 18 years; (ii) had a diagnosis of nonvalvular AF (paroxysmal, persistent, or permanent); and (iii) signed an informed consent form. Exclusion criteria: (i) no echocardiography or unqualified echocardiography. Ultimately, we enrolled 2054 participants (1165 males and 889 females) whose information was complete (Fig. 1).

Diagnosis of AF

The diagnosis of AF necessitates the documentation of rhythm using an electrocardiogram (ECG) tracing that demonstrates AF. According to the convention, an episode lasting at least 30 s is considered diagnostic for clinical AF [7,12]. In the medical registry, experienced clinicians categorize patients with AF at the time of diagnosis as paroxysmal (lasting ≤ seven days), persistent (lasting seven days to one year), permanent (lasting ≥ one year or failure of electrical cardioversion), following AF guidelines [7]. In this study, we merged persistent and permanent AF into nonparoxysmal AF.

Transthoracic echocardiography

The GE Vivid E9 ultrasound diagnostic instrument was utilized with the M5S probe, operating within a frequency range of 1 MHz to 5 MHz. Throughout the examination, the patient maintained a left decubitus position while connected to chest lead ECG. LVEF was measured by two experienced sonographers following the guidelines of the American Society of Echocardiography [13].

Demographic, behavioral, and clinical information collection

The demographic information, medical history and behavioral habits of all the subjects were obtained through a standard questionnaire. The absolute values of white blood cells, red blood cells, hemoglobin, and platelets were determined through routine blood tests using a Sysmex XN 2000 automated hematology analyzer (Sysmex, Japan) and its corresponding reagents. Traditional coagulation biomarkers, such as prothrombin time (PT), international normalized ratio (INR), thrombin time (TT), D-dimer (DD), and fibrinogen (FIB), were measured using a Sysmex coagulation analyzer (Sysmex, Japan) along with their respective detection kits. N-terminal pro-B-type natriuretic peptide (N-pBNP) was also measured in a standard laboratory.

Definitions of variables

Hypertension was identified by elevated blood pressure, either a systolic blood pressure (SBP) equal to or exceeding 140 mm Hg or a diastolic blood pressure (DBP) equal to or exceeding 90 mmHg, and self-reported current antihypertensive medications taken for hypertension ([14]. Diabetes was defined as a fasting plasma glucose level

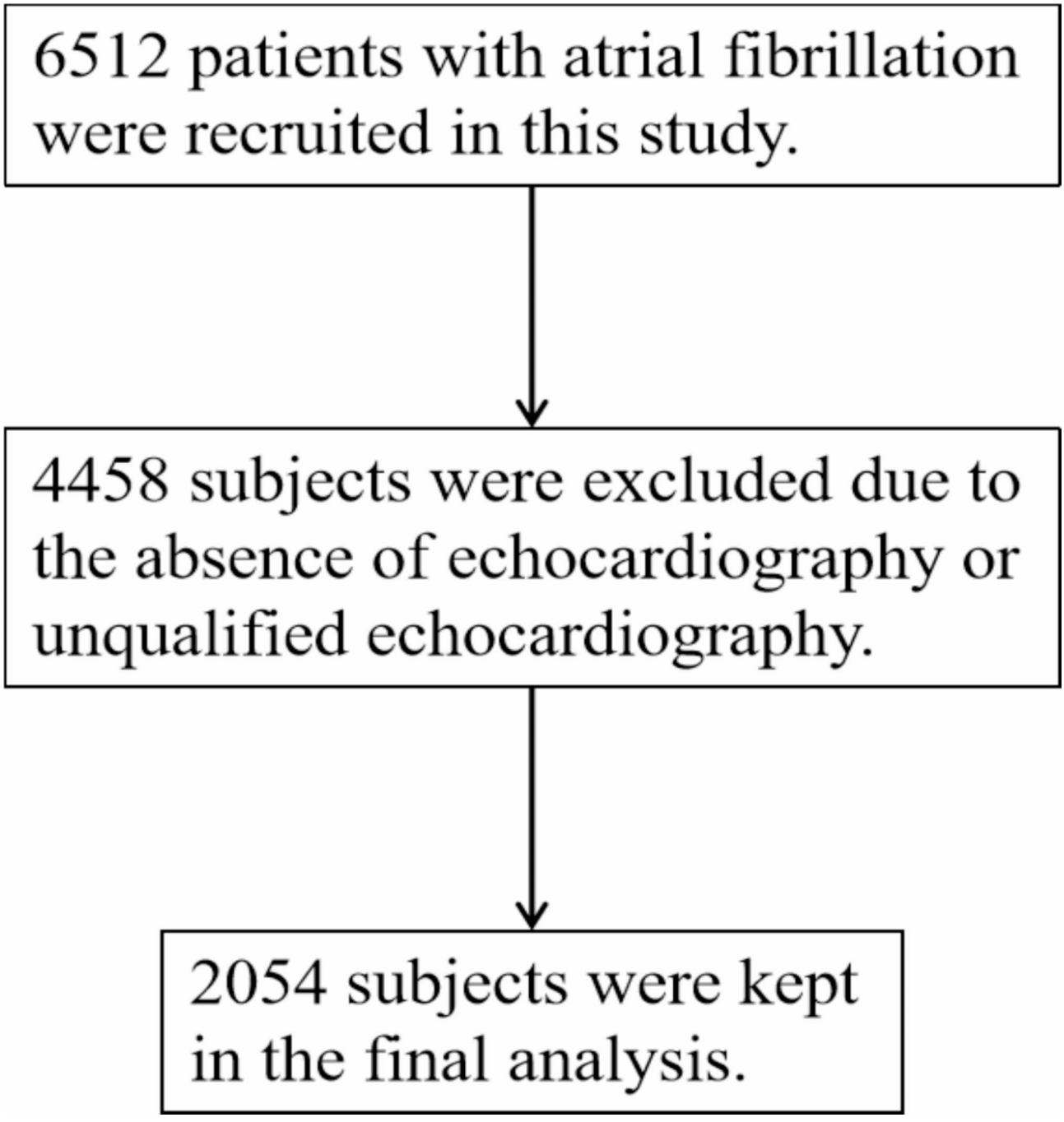

Fig. 1 Flow chart of the selection process for eligible participants

equal to or greater than 7.0 mmol/L or a self-reported diagnosis of diabetes ([15]. Obesity was regarded as a condition in which a person's BMI was greater than 30 kg/m$^{[2\,[16]]}$.

Statistical analysis

Subgroup comparisons of normally distributed continuous variables were conducted using a *t*-test or one-way analysis of variance (ANOVA). Categorical variables were analyzed utilizing a chi-squared test. The odds ratios (ORs) and 95% confidence intervals (CIs) were determined in univariate and multivariate logistic regression analyses to evaluate the relationship between the LVEF levels and nonparoxysmal AF, with paroxysmal AF serving as the reference group. Moreover, subgroup analyses were performed to examine the stability of the results. Finally, we also employed restricted cubic splines (RCS) curves to explore the linear relationship between LVEF

and nonparoxysmal AF on a continuous scale. Collinearity was assessed by variational inflation factor (VIF), with VIF ≥ 2.0 considered significant. We established the significance level α at 0.05, and a two-tailed test was employed in our statistical analysis. All the statistical analyses were performed using R 4.1.2 (https://www.r-project.org/).

Results

Baseline characteristics of participants

This study recruited 2054 patients with AF, of whom 1165 (56.72%) were males and 889 (43.28%) were females. The median age of these subjects was 73.00 [65.00, 80.00] years. 652 (31.74%) patients were diagnosed with paroxysmal AF and 1047 (68.26%) patients had nonparoxysmal AF. More characteristics of subjects are delineated in Table 1. Compared to those with paroxysmal AF, patients with nonparoxysmal AF had faster heart rates (84.00 [75.00, 98.00] vs. 80.00 [72.00, 92.00] beats per minute), had higher levels of INR (1.06 [0.98, 1.21] vs. 1.05 [0.97, 1.18]), along with a higher prevalence of coronary artery disease (CAD) (19.04% vs.15.03%) but a lower incidence of stroke (7.13% vs. 9.82%). Furthermore, patients with nonparoxysmal AF had a lower level of LVEF (%) than those with paroxysmal AF (61.00 [54.00, 67.00] vs. 62.00 [55.00, 68.00]).

The association between LVEF levels and nonparoxysmal AF

Univariate logistic regression analysis revealed that the history of stroke, CAD, ln(HR) and LVEF levels were significantly associated with nonparoxysmal AF (all $P<0.05$). The results after adjustment for demographic characteristics, comorbidities, and clinical indicator variables in the multivariate logistics analysis are shown in Table 2. Patients with nonparoxysmal AF tended to have lower levels of LVEF (OR: 0.82, 95%CI: 0.68–0.99, $P=0.040$). Moreover, the visual representation of the association between the LVEF and the odds ratio of nonparoxysmal AF was explored utilizing the multivariate RCS model. The model uncovered a linear relationship between

Table 1 Baseline characteristics of subjects

Characteristics	Paroxysmal AF	Non-paroxysmal AF	*P*-value
	N = 652	N = 1402	
Age (years)	73.00 [65.00, 80.00]	73.00 [66.00, 80.00]	0.816
Gender			
Female, n(%)	280(42.94)	609(43.44)	0.871
Male, n(%)	372(57.06)	793(56.56)	
Current smoking	71 (10.89)	187 (13.34)	0.137
Drinking	56 (8.59)	133 (9.49)	0.567
Stroke	64 (9.82)	100 (7.13)	**0.045**
CAD	98 (15.03)	267 (19.04)	**0.031**
Hypertension, n(%)	278 (42.64)	544 (38.80)	0.109
Diabetes, n(%)	74 (11.35)	203 (14.48)	0.062
Obesity, n(%)	250 (38.34)	543 (38.73)	0.905
SBP (mmHg)	130.00 [120.00, 142.00]	130.00 [120.00, 142.00]	0.199
DBP (mmHg)	80.00 [70.00, 88.00]	80.00 [72.00, 90.00]	0.078
HR(bpm)	80.00 [72.00, 92.00]	84.00 [75.00, 98.00]	**< 0.001**
Sinus rhythm,n(%)	458 (54.35)	939 (53.28)	0.754
WBC (10^9/L)	6.49 [5.19, 8.22]	6.39 [5.01, 8.41]	0.425
RBC(10^9/L)	4.20 [3.78, 4.60]	4.16 [3.73, 4.56]	0.167
PLT(10^9/L)	160.00 [122.00, 198.00]	155.00 [118.25, 199.00]	0.414
INR	1.05 [0.97, 1.18]	1.06 [0.98, 1.21]	**0.033**
TT (s)	17.80 [16.60, 19.30]	17.90 [16.70, 19.30]	0.255
FIB(g/L)	2.60 [2.19, 3.26]	2.59 [2.13, 3.26]	0.573
DD (mg/L)	0.60 [0.29, 1.34]	0.62 [0.29, 1.41]	0.670
NT-proBNP (pg/ml)	2020.50 [954.75, 4137.25]	2253.00 [1128.00, 4698.00]	0.230
LVEF (%)	62.00 [55.00, 68.00]	61.00 [54.00, 67.00]	**0.024**
LVEFgroup			**0.034**
≤60%	274(42.02)	661(47.15)	
>60%	378 (57.98)	741 (52.85)	

Note: Bold *P* values indicate significance

Abbreviations: Coronary Artery Disease, CAD; HR, Heart Rate; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; WBC, White Blood Cell; RBC, Red Blood Cell; PLT, Platelet; INR, International Normalized Ratio; TT, Thrombin Time; FIB, Fibrinogen; DD, D-dimer; LVEF, Left Ventricular Ejection Fractions

Table 2 Logistic regression of the factors for having nonparoxysmal AF

Characteristics	Univariate analysis		Multivariate analysis	
	OR(95% CI)	*P*-value	OR(95% CI)	*P*-value
Age (years)		0.892		0.978
<75	Reference		Reference	
≥75	0.99(0.82, 1.19)		1.00(0.82, 1.23)	
Gender		0.834		0.867
Female	Reference		Reference	
Male	0.98(0.81, 1.18)		0.98(0.80, 1.20)	
History of smoking		0.120		0.117
Never	Reference		Reference	
Current	1.26(0.94, 1.68)		1.40(0.93, 2.17)	
History of drinking		0.513		0.415
Never	Reference		Reference	
Current	1.12(0.80, 1.55)		0.82(0.51, 1.32)	
Stroke		**0.038**		0.091
No	Reference		Reference	
Yes	0.71(0.51, 0.98)		0.75(0.53, 1.05)	
CAD		**0.027**		**0.024**
No	Reference		Reference	
Yes	1.33(1.03, 1.71)		1.37(1.04, 1.80)	
Hypertension, n(%)		0.099		0.087
No	Reference		Reference	
Yes	0.85(0.71, 1.03)		0.84(0.69, 1.03)	
Diabetes, n(%)		0.054		0.148
No	Reference		Reference	
Yes	1.32(1.01, 1.76)		1.25(0.93, 1.71)	
Obesity, n(%)		0.867		0.920
No	Reference		Reference	
Yes	1.02(0.84, 1.23)		1.01(0.82, 1.24)	
ln(SBP)	1.47(0.79, 2.73)	0.219	1.97(0.87, 4.46)	0.105
ln(DBP)	1.57(0.88, 2.80)	0.123	1.07(0.50, 2.32)	0.858
ln(HR)	3.18(2.07, 4.86)	**<0.001**	3.86(2.45, 6.14)	**<0.001**
ln(WBC)	0.92(0.75, 1.14)	0.458	0.85(0.67, 1.09)	0.203
ln(RBC)	0.72(0.43, 1.21)	0.216	0.56(0.30, 1.01)	0.055
ln(PLT)	0.99(0.79, 1.23)	0.897	1.04(0.82, 1.33)	0.724
ln(INR)	1.33(0.98, 1.79)	0.067	1.44(1.06, 1.99)	**0.021**
ln(TT)	0.84(0.54, 1.31)	0.449	0.90(0.57, 1.44)	0.657
ln(FIB)	0.91(0.69, 1.20)	0.489	0.85(0.62, 1.16)	0.309
ln(DD)	1.01(0.93, 1.08)	0.940	1.00(0.92, 1.09)	0.983
LVEFgroup		**0.030**		**0.040**
≤60%	Reference		Reference	
>60%	0.81(0.67, 0.98)		0.82(0.68, 0.99)	

Note: Bold *P* values indicate significance

Abbreviations: Coronary Artery Disease, CAD; HR, Heart Rate; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; WBC, White Blood Cell; RBC, Red Blood Cell; PLT, Platelet; INR, International Normalized Ratio; TT, Thrombin Time; FIB, Fibrinogen; DD, D-dimer; LVEF, Left Ventricular Ejection Fractions; OR, Odds Ratio; CI, Confidence Interval

the LVEF and the likelihood of nonparoxysmal AF, as depicted in Fig. 2 (*P* for nonlinearity=0.548).

Subgroup analysis

The subgroup analysis based on different variables, including sex, age, history of hypertension, diabetes, stroke, CAD, smoking status, alcohol consumption history, and obesity status, are outlined in Table 3. The analysis demonstrated that the LVEF levels have a significant negative correlation with nonparoxysmal AF in these subgroups: never smoking (OR: 0.80, 95%CI: 0.65–0.97, *P*=0.026), never drinking (OR: 0.81, 95%CI: 0.66–0.99, *P*=0.035), hypertension (OR: 0.70, 95%CI: 0.52–0.95, *P*=0.020), obesity (OR: 0.71, 95%CI: 0.52–0.96, *P*=0.029), without stroke (OR: 0.81, 95%CI: 0.67–0.99, *P*=0.038), without CAD (OR: 0.79, 95%CI: 0.64–0.97, *P*=0.022).

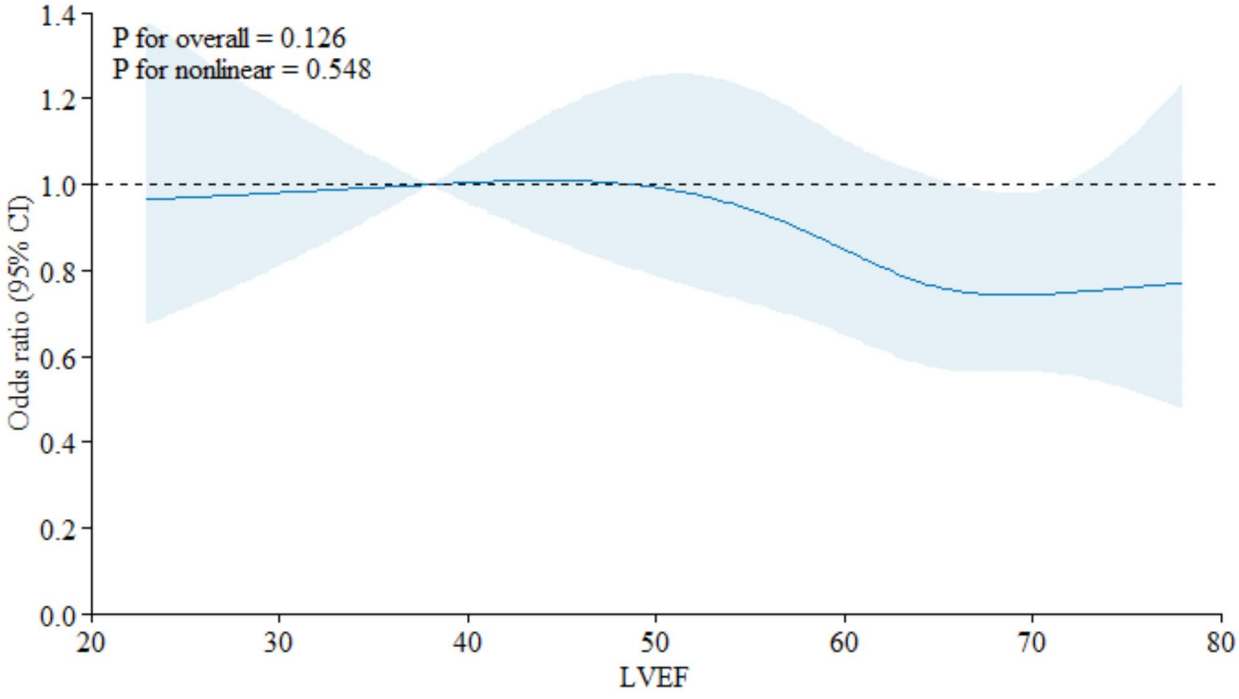

Fig. 2 Association between the levels of LVEF and nonparoxysmal AF

Notably, significant interactions were identified between hypertension (*P* for interaction=0.015), obesity (*P* for interaction=0.032), and LVEF levels.

Discussion

This study found that patients with nonparoxysmal AF may have a higher prevalence of CAD, lower levels of LVEF, and an elevated heart rate, compared to those with paroxysmal AF. Additionally, RCS analysis showed a negative linear relationship between the levels of LVEF and the risk of nonparoxysmal AF. Furthermore, subgroup analysis suggested that the interaction effects exist between hypertension, obesity, and lower levels of LVEF, indicating that the coexistence of lower levels of LVEF and obesity, as well as decreased LVEF in hypertensive patients, may collectively elevate the risk of nonparoxysmal AF synergistically.

The Global Burden of Disease Study estimates that AF affects at least 33.5 million people worldwide ([17] and previous findings have indicated that nonparoxysmal AF poses a greater risk for thromboembolism and stroke compared to paroxysmal AF ([18,19]. We noted that patients with nonparoxysmal AF exhibited a higher prevalence of CAD, lower levels of LVEF, and an elevated heart rate in comparison to patients with paroxysmal AF. A prospective multicenter cohort study involving 486 AF patients revealed that those with an elevated heart rate were prone to having nonparoxysmal AF within 2 years following the diagnosis of recent-onset AF ([20]. The exact mechanism that causes this difference may be related to changes in the atrioventricular node and/or the influence of autonomic tone ([21]. The results of our analysis demonstrated that the levels of LVEF have a negative association with nonparoxysmal AF. AF without atrial contraction results in decreased cardiac output and functional capacity. In the presence of atrial disease, the function of the left atrial blood storage pool and emptying capacity is typically diminished, which may be the reason for the lower LVEF in patients with non-paroxysmal AF ([22]. Nonparoxysmal AF is a progressive and important disease among elderly individuals. A prospective study enrolling over 25,000 healthy participants concluded that older age was strongly associated with the progression of nonparoxysmal AF ([23]. Similar findings were reported in the Women's Health Study ([24] and the Basel AF Cohort Study ([20]. Diabetes stands as a major risk factor for nonparoxysmal AF. A cohort study suggested that higher hemoglobin A1c levels were preferentially associated with the occurrence of nonparoxysmal AF, even in subjects without overt clinical or undiagnosed prediabetes ([24]. However, our study did not identify an association between age, diabetes, and nonparoxysmal AF. These discrepancies may also stem from variations in subject characteristics, and study sample sizes.

Moreover, interactive effects were also found between hypertension, obesity, and low levels of LVEF in the

Table 3 The association between LVEF and nonparoxysmal AF

Variables	Model 1		Model 2		Model 3		*P* for interaction
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	
Gender							0.175
Female	0.78 (0.58, 1.04)	0.089	0.77(0.58, 1.03)	0.079	0.76(0.57, 1.01)	0.063	
Male	0.84(0.65, 1.07)	0.162	0.83(0.65, 1.07)	0.148	0.83(0.65, 1.07)	0.152	
Age (years)							0.058
<75	0.85(0.66, 1.09)	0.209	0.84(0.65, 1.08)	0.184	0.83(0.64, 1.07)	0.160	
≥75	0.77(0.58, 1.02)	0.066	0.76(0.58, 1.01)	0.061	0.76(0.58, 1.01)	0.061	
History of smoking							0.691
Never	0.80(0.66, 0.98)	**0.033**	0.80(0.66, 0.98)	**0.033**	0.80(0.65, 0.97)	**0.026**	
Current	0.90(0.52, 1.55)	0.696	0.88(0.50, 1.53)	0.649	0.89(0.51, 1.55)	0.681	
History of drinking							0.443
Never	0.82(0.67, 1.00)	**0.046**	0.82(0.67, 1.00)	**0.046**	0.81(0.66, 0.99)	**0.035**	
Current	0.76(0.40, 1.42)	0.396	0.73(0.38, 1.39)	0.344	0.75(0.39, 1.45)	0.399	
Hypertension							**0.015**
No	0.92(0.72, 1.17)	0.500	0.91(0.72, 1.17)	0.500	0.91(0.71, 1.16)	0.436	
Yes	0.68(0.51, 0.92)	**0.011**	0.68(0.51, 0.92)	**0.011**	0.70(0.52, 0.95)	**0.020**	
Diabetes							0.090
No	0.83(0.68, 1.02)	0.076	0.83(0.68, 1.02)	0.076	0.84(0.69, 1.03)	0.088	
Yes	0.65(0.37, 1.12)	0.127	0.67(0.38, 1.15)	0.152	0.67(0.38, 1.19)	0.177	
Obesity							**0.032**
No	0.87(0.69, 1.11)	0.264	0.87(0.69, 1.10)	0.254	0.87(0.68, 1.10)	0.251	
Yes	0.72(0.53, 0.98)	**0.037**	0.72(0.53, 0.98)	**0.039**	0.71(0.52, 0.96)	**0.029**	
Stroke							0.390
No	0.82(0.67, 0.99)	**0.043**	0.82(0.67, 0.99)	**0.043**	0.81(0.67, 0.99)	**0.038**	
Yes	0.75(0.40, 1.40)	0.365	0.74(0.39, 1.40)	**0.360**	0.81(0.42, 1.55)	0.517	
CAD							0.747
No	0.78(0.64, 0.96)	**0.018**	0.78(0.64, 0.96)	**0.018**	0.79(0.64, 0.97)	**0.022**	
Yes	0.94(0.59, 1.51)	0.809	0.96(0.59, 1.53)	0.854	0.95(0.59, 1.53)	0.845	

Note: Bold *P* values indicate significance. Model 1, crude model. Model 2 was further adjusted for sex and age. Model 3 was further adjusted for smoking status, history of drinking, diabetes, hypertension, and obesity in Model 2

P for interaction based on Model 3

Abbreviations: Coronary Artery Disease, CAD; LVEF, Left Ventricular Ejection Fractions; OR, Odds Ratio; CI, Confidence Interval

present study. A multicenter study demonstrated that hypertension served as a predictor for the progression from paroxysmal to persistent AF in patients undergoing pacemaker implantation ([25], indicating that hypertensive patients with lower LVEF levels are more likely to have nonparoxysmal AF and should receive blood pressure monitoring and LVEF control. Overweight and obesity often coexist with various other cardio-metabolic risk factors ([26,27]. Epidemiological evidence suggests that individuals who are overweight or obese have a greater prevalence of AF and are more likely to progress from paroxysmal to persistent forms of arrhythmia ([28–30]. Excessive pericardial fat has been proposed as a potential mechanistic link between obesity and AF ([31,32]. Weight loss can attenuate the AF substrate to decrease the AF burden and prevent the progression to more persistent forms of AF ([26]. Thus, clinicians should consider individual patient characteristics in treatment decision-making.

Strengths and limitations

First, the relatively large sample size is a notable strength of this study. In addition, we described more clinical features between paroxysmal and nonparoxysmal AF patients, and our study provided an in-depth analysis of the relationship between LVEF and nonparoxysmal AF. Limitations of the research investigation: Some limitations to our investigation should be considered: (a) Our first limitation is that this is a retrospective study conducted at a single site. (b) We did not prospectively collect data on laboratory and echocardiography test results.

Future directions

Future studies should prioritize the establishment of multicenter, large population cohorts to follow outcome events in patients with paroxysmal and nonparoxysmal AF. Additionally, it is crucial to explore the factors and related mechanisms that lead to the transition from paroxysmal AF to nonparoxysmal AF.

Conclusion

Patients with non-paroxysmal AF have a more severe AF burden and lower LVEF levels. The transition from paroxysmal AF to nonparoxysmal AF should be recognized in time, especially for AF patients with hypertension and obesity.

Abbreviations

AF	Atrial Fibrillation
CAD	Coronary Artery Disease
HF	Heart Failure
OR	Odds Ratio
CI	Confidence Interval
BMI	Body Mass Index
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
LVEF	Left Ventricular Ejection Fraction

Acknowledgements

I am indebted to my tutors and team members for their efforts and support.

Author contributions

LL, ZW, ZW, and JS conceived, initiated, and led the study. LL, WK and BQ collected the data. ZW and BQ analyzed the data with input from all the authors. LL and ZW prepared the manuscript. ZW and JS revised the manuscript. All authors reviewed and approved the manuscript.

Funding

This study has no funding.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was performed according to the Declaration of Helsinki, 1964 convention. The research protocol was approved by the ethics committee or review committee of the First people's Hospital of Yancheng, and all the subjects signed the informed consent form.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Received: 13 June 2024 / Accepted: 15 September 2024
Published online: 04 October 2024

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