

Efficacy, Safety, and Long-term Survival of Concomitant Valve Replacement and Bipolar Radiofrequency Ablation in Patients Aged 70 Years and Older: A Comparative Study With Propensity Score Matching From a Single-Center

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Research article

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Abstract

Background: Concomitant bipolar radiofrequency ablation and valve replacement in the elderly remains controversial. We aim to compare the outcomes of concomitant valve replacement and bipolar radiofrequency ablation with valve replacement alone in elderly patients with atrial fibrillation (AF).

Methods: This was a retrospective study of patients aged ≥ 70 years who underwent valve replacement with or without bipolar radiofrequency ablation in a single-center between January 2006 and March 2015. Early postoperative results and long-term clinical outcomes were compared after propensity score matching.

Results: 34 pairs of patients (73.94 \pm 2.64 years old, 34 in the AF ablated group and 34 in the AF untreated group) were enrolled in the propensity score matching analysis. No significant differences between the two matched groups were found about surgical mortality (5.88% vs. 2.94%, $P=0.555$) and major postoperative morbidity. Kaplan–Meier analysis revealed a significantly better overall survival ($P=0.009$) in the AF ablated group. Cumulative incidence curves showed a lower incidence of cardiovascular death in the AF ablated group ($P=0.025$, Gray's test). Patients in the AF ablated group had a reduced incidence of stroke events compared with patients in the AF untreated group ($P=0.009$, Gray's test). Freedom from AF after 5 years was 58.0% in the AF ablated group, compared with 3.0% in the AF untreated group.

Conclusions: The addition of bipolar radiofrequency ablation is a feasible and safe procedure even in patients aged ≥ 70 years, with a better long-term survival and a reduced incidence of stroke events compared with valve replacement alone. These findings suggest that bipolar radiofrequency ablation should always be considered as a concomitant procedure for elderly patients with AF presenting for cardiac surgery.

Background

Atrial fibrillation (AF) is a common cardiac arrhythmia among older adults[1], which increases the risk of myocardial infarction, heart failure, stroke, dementia, and mortality[2]. Caswell et al.[3] expounded that postoperative AF was a risk factor of cardioembolic stroke after valve replacement. Restoration of sinus rhythm would certainly be beneficial for improving long-term outcomes[4]. Surgery for AF has been shown to be feasible and effective and does not add to perioperative morbidity and mortality when combined with other cardiac procedures[5][6][7]. While effective, the Cox-maze III procedure carries limitations for the treatment of AF as it is invasive and time consuming. Recent techniques such as bipolar radiofrequency ablation (BRFA) have emerged as alternative treatment options for AF.

Patients at advanced age may have more adverse side effects to drugs used in treating AF[8]. Meanwhile age is deemed to be an independent predictor of stroke in patients with AF[9]. Age of ≥ 70 years is frequently accompanied by multiple comorbidities, and is a significant risk factor associated with worse postoperative results[10][11][12][13]. Thus, whether concomitant BRFA should be performed in elderly patients is controversial. A few previous studies have indicated similar success rates and similar low complication rates in the elderly compared with younger patients undergoing concomitant Cox-Maze surgery[14][15]. In an analysis from the Polish National Registry of Cardiac Surgery Procedures [14], neither clinical benefit nor harm was demonstrated in a subgroup of patients older than age 70 years with concomitant surgical ablation during the 12-year study period. Funatsu et al.[16] set inclusion criteria for adding surgical ablation including an age of less than 70 years in their clinical practice. On the other hand, patients with severe conditions may prefer to choose a simplified procedure without surgical ablation. Furthermore, there are no published clinical studies to date specifically designed to compare clinical results of concomitant surgical ablation for atrial fibrillation vs. valve replacement (VR) alone in the elderly. Also, few studies have assessed the effect of surgical ablation on long-term outcomes. So, this study was planned to compare clinical results between concomitant BRFA and no ablation of patients with VR aged ≥ 70 years after adjusting for severity by propensity scores.

Patients And Methods

2.1. Study populations

Between January 2006 and March 2015, a total of 362 consecutive patients (aged ≥ 70 years) of valve disease with AF underwent cardiac surgery at our institution. Among them, 48 patients underwent VR with concomitant Cox-Maze procedure. The inclusion criteria: 1) Patients with AF underwent VR and/or BRFA for AF; 2) Patients with biological valves. The exclusion criteria: 1) Patients with mechanical valves; 2) Patients received repeated cardiac surgery. 3) Patients underwent other forms of surgery for AF. 4) patients who had not completed a follow-up of at least 5 years unless death occurred; 5) patients who were unable to follow the assessment plan. Finally, 276 patients were admitted in the analyses. Preoperative demographic, clinical data, perioperative outcomes and follow-up results were collected on all patients and retrospectively analyzed. Of the 276 patients, 42 patients underwent VR with concomitant BRFA, the remaining 234 patients underwent VR alone. All patients had persistent or long-lasting persistent AF. The diagnosis of AF was confirmed by 24-hour Holter monitoring before surgery. Propensity score matching was performed to achieve balance in covariates between groups.

The study was approved by the ethics committee of Union Hospital, Fujian Medical University and adhered to the Declaration of Helsinki. Due to the retrospective nature of the present study, written informed consent from the patients or their guardians was waived.

2.2. Surgical Procedures

All surgical procedures were undergone through a median sternotomy under general anesthesia

with hypothermic cardiopulmonary bypass (CPB). Medtronic Cardioblate G2 Surgical Ablation System (Medtronic Inc., Minneapolis, MN) and the bipolar radiofrequency clamp were applied for surgical ablation in accordance with the method introduced by Sie et al. [17] (**Figure 2**) The temporary epicardial pacing wire was placed routinely after the surgical ablation. All of the study patients received biological valve prostheses.

2.3. Postsurgical treatment

Postoperative care was similar for both groups. Unless contraindicated, amiodarone infusion was given 5 mg/kg in the first hour and 0.6 mg/kg/h for 72 hours followed by 200 mg orally twice a day for the next 3 weeks and 200 mg orally daily until the end of the first half year to reduce the risk of early atrial arrhythmia recurrence. Patients were advised to continue use of warfarin for 3 months after surgery, unless there was a specific contraindication. Prothrombin time was regularly monitored. The target international normalized ratio was 1.5–2.0 for aortic valve replacement and 2.0–2.5 for mitral or tricuspid valve replacement. Sotalol or metoprolol was given as appropriate to control ventricular rate for patients with a history of side effects of amiodarone or other clinical contraindications.

2.4. Outcome measures

The primary outcomes analyzed included all-cause death, cardiac death, sinus rhythm restoration, and stroke events. The secondary outcome of interest was surgical mortality and major postoperative morbidity. Cardiac death was defined as death due to malignant arrhythmia, stroke, congestive heart failure or sudden unexplained death. Stroke was defined as an ischemic event caused by cerebral embolism. After six months of surgical ablation, any episode of AF, atrial flutter, or atrial tachycardia lasting more than 30 seconds recorded by electrocardiogram or 24-hour Holter monitoring was considered as recurrence of AF. Long-term survival was measured as time (months) to death from the date of surgery.

2.5. Follow-up

Follow-up visits at discharge were made at 3, 6, and 12 months postoperatively and then annually thereafter. A history of health, a physical examination, a 12-lead electrocardiogram and an echocardiography were obtained at each visit. Patients with palpitations or documented atrial arrhythmias by 12-lead electrocardiography underwent 24-hour Holter monitoring for

further confirmation. The period between the next day after patients received surgical operation and death, loss to follow-up, or the predefined date of March 2020 was defined as the follow-up duration.

2.5. Statistical analysis

Continuous variables are expressed as mean \pm standard deviations and categorical variables are presented as count unless otherwise noted. Differences were compared using the Student's t-test or Mann-Whitney U test for continuous variables and the chi-square test for categorical variables. We performed one-to-one pair matching using the caliper-matching method with the variables shown in **Table 1** and imposed a 0.02 propensity score tolerance on the maximum propensity score distance. Overall survival and AF-free survival were analyzed using Kaplan–Meier and log-rank methodology. Cox regression was used to test for differences in survival between groups. Hazard ratios (HR) and 95% confidence intervals (CI) were computed. The incidence of postoperative stroke in the matched population were estimated using the cumulative incidence function with death as a competing risk. The hazard of cardiac death was also analyzed using competing risks method with non-cardiac death as the competing event. The differences between cumulative incidence curves in the competing risk analysis were compared using Gray's tests. Fine and Gray competing risk regression was used to analyze the determinants of postoperative stroke and cardiac death. Subdistribution hazard ratio (SHR) and 95% CI were computed. A two-sided P-value <0.05 was considered statistically significant. The statistical software used throughout the analysis was SPSS 26.0 and R 3.6.2.

Results

3.1. Baseline characteristics

The process used to select patients who match the study is illustrated in **Figure 1**. Patient characteristics and comparison of the data before and after matching are shown in **Table 1**. At our center, about 13.3% of patients (aged ≥ 70 years) of valve disease with AF underwent concomitant Cox-Maze surgery. PSM resulted in two groups of 68 patients (34 pairs) with similar baseline characteristics and a similar risk profile. The mean age of 34 pairs of patients was 73.94 ± 2.64 years. Before PSM, the duration of preoperative AF was significantly longer among patients with VR alone than among patients that underwent VR/BRFA. Besides, age, smoking history, hypertension, left ventricular diastolic diameter, and hypohepatia of the AF untreated group were significantly different from the AF ablated group.

3.2. Operative data and early outcomes in the matched population

Table 2 shows the operative data and early outcomes. The mean duration of CPB (108.94 ± 17.37 minutes vs 82.3 ± 17.47 minutes, $P=0.001$) and aortic cross-clamp (70.85 ± 14.93 minutes vs 48.71 ± 10.68 minutes, $P=0.001$) were significantly higher in the AF ablated group. More patients in the AF ablated group required prolonged mechanical ventilation. The AF ablated group had a slightly longer duration of intensive care unit (ICU) stay (6.68 ± 4.48 days vs 4.47 ± 4.56 days, $P=0.048$) and a significantly longer length of hospital stay (17.76 ± 4.50 days vs 13.44 ± 5.33 days, $P=0.001$) compared with the untreated AF group. There was no significant difference in hospital deaths between the 2 propensity-matched groups (5.88% vs. 2.94%, $P=0.555$). 2 patients died in the AF ablated group (ventricular tachycardia in 1 case, low cardiac output syndrome and multiple organ failure in 1 case), and 1 patient died of pneumonia in the AF untreated group. Other adverse events such as pulmonary complication, neurological complications, renal failure, requiring dialysis, low cardiac output, reoperation for bleeding, pacemaker implantation were similar between the two matched groups. Three patients from the AF ablated group and one from the AF untreated group required pacemaker implantation to treat third-degree atrioventricular block after the operation within 6 months. The remaining 8 patients who underwent concomitant BRFA and were not successfully matched did not experience severe perioperative complications or death, except for 1 patient who had a permanent pacemaker implanted due to third-degree atrioventricular block.

3.3. Late outcomes in the matched population

Follow-up was complete with the median duration of 85.00 months [interquartile range (IQR), 58–98months].

3.3.1 Long-term survival and cardiovascular death

Kaplan–Meier analysis revealed a significantly better overall survival ($p=0.009$) in the AF ablated group during clinical follow-up (Cox regression: HR 0.479 (95 % CI 0.235–0.974; $P = 0.042$). The 5- and 10-year survival rate was 82% and 58% for the AF ablated group compared to 68% and 15% for the AF untreated group. Cardiovascular death occurred in 6 (17.6%) patients in the AF ablated group, compared to 17 (50.0%) patients in the AF untreated group. Cumulative incidence curves (**Figure 4**) also showed a lower incidence of cardiovascular death in the AF ablated group ($P=0.025$, Gray's test). Unadjusted and adjusted SHR evaluating the impact of additional BRFA procedures on the risk of cardiovascular death were 0.337 (95 % CI 0.135–0.843; $P = 0.020$) and 0.264 (95 % CI 0.093–0.753; $P = 0.013$), respectively.

3.3.2 Stroke events and sinus rhythm restoration

Patients in the AF ablated group had a reduced incidence of stroke events compared with patients in the AF untreated group ($P=0.009$, Gray's test; **Figure 5**) during clinical follow-up. Stroke events occurred in 5 (14.7%) patients in the AF ablated group, compared to 18 (52.9%) patients in the AF untreated group. Unadjusted and adjusted SHR evaluating the impact of additional BRFA procedures on the risk of stroke events were 0.343 (95 % CI 0.137–0.859; $P = 0.022$) and 0.219 (95 % CI 0.076–0.631; $P = 0.005$), respectively. The AF ablated group had better AF-free survival than the AF untreated group ($P=0.0001$; **Figure 6**). Over time, some patients develop recurrent AF. Freedom from AF after 5 years was 58.0% in the AF ablated group, compared with 3.0% in the AF untreated group.

Discussion

As the population of elderly patients increases progressively in recent years, valve disease with AF in the elderly will become increasingly common. However, surgical treatment of AF at the time of cardiac surgery remains not been widely practiced in elderly patients. Many surgeons believe that the surgical risks can be increased owing to the additional aortic cross-clamp and CPB time for the addition of Cox-Maze procedure.

As a simpler surgical technique that require only a few minutes of operative time, BRFA has been gradually used to create lines of conduction block in patients with AF undergoing other open-heart surgery. Our study aimed to assess the efficacy, safety, and long-term survival of BRFA compared with VR without AF ablation in elderly patients (aged ≥ 70 years) of valve disease with AF.

The results of our matched control study indicate that satisfactory performance can be achieved by BRFA concomitant with VR even in elderly patients considered by many surgeons to be at high risk of ablation failure.

An important finding of our study is that the addition of BRFA procedures did not significantly increase the risk of common postoperative complications and postoperative mortality. One possible explanation is that, in light of better early postoperative hemodynamic stability associated with the treatment of AF, this result is promising for the potential to eliminate the risks of increased CPB time for the addition of BRFA procedure. Our findings are in line with previous studies. A study reported by Ad N and colleagues analyzed the safety and efficacy of concomitant surgical AF ablation according to patients' age, showed that the performance of the Cox-Maze III/IV procedure for patients aged 75 years and older did not add operative risk. [18] Another analysis of Cox-Maze procedure by Kuh JH and colleagues indicated that patients aged ≥ 70 years obtained satisfactory results without major morbidity or mortality.[19] Unfortunately, their study lacked a control group for comparison. Furthermore, we observed some early clinical results that had not been reported in previous studies. We find that BRFA procedures for AF were correlated with an increased risk of prolonged mechanical ventilation after surgery. The length of hospital stay and ICU stay were also significantly longer. These may be related to the impaired lung function due to the increased aortic cross-clamp and CPB time for the addition of the BRFA procedure, which also prolongs the length of hospital stay and ICU stay. The other reason might be that patients in the AF ablated group would need additional hospital

stay to monitor the heart rhythm and heart rate. The incidence of postoperative pacemaker requirement have been reported from 4.5% to 13.3% in several studies[21][22][23]. The proportion of patients receiving a permanent pacemaker within 6 months after surgery .in our cohort was 9.52%, which matched with other studies.

Another notable finding is that elderly patients received better long-term outcomes of RPFA concomitant with VR compared with VR without AF ablation. We show that the proportion of patients achieving sinus rhythm was significantly higher in the AF ablation group compared with the AF untreated group at discharge and during follow-up time, and the cumulative freedom from recurrence of AF was 65.2% at five years. This rate was comparable to that previous study conducted at experienced centers. Kuh JH et al reported that the rate of maintaining sinus rhythm in 27 patients over 70 years old with a concurrent Cox-Maze procedure was 89% at a mean follow-up of 51 months.[15] The study by Lee R demonstrated that 78% of the patients (Age:65.9±12.2years) undergoing surgical ablation were free of AF at 47 months of follow-up, and also proved that restoration of sinus rhythm improved survival.[20] Similar survival results are found for patients over 70 years old in the current study. We find that additional BRFA procedures are associated with a low probability of stroke events and a significant decrease in cardiovascular death events and long-term overall mortality. We believe that, restoration of sinus rhythm in the majority of patients and excision of the left atrial appendage are beneficial to the prevention of stroke, which may lead to a remarkable reduction in long-term mortality. The long-term success in our study would argue strongly for a more widespread adoption of this currently underutilized treatment option for the elderly.

Previous clinical results of the concomitant BRFA with VR in the elderly were mostly compared with those in the younger group. Besides, previous studies have generally focused on patients with mitral valve surgery, the outcomes of surgical ablation in patients with other types of valve surgery had not been well researched. To the best of our knowledge, although several previous studies have described the efficacy and safety of concomitant surgical ablation with VR in elderly patients aged 70 years and older, our present study is the first to compare the in-hospital and long-term outcomes of BRFA plus VR with VR alone, which is particularly important in the elderly. Our findings are solid because the duration of follow-up was adequate. Furthermore, we performed a matching-adjusted indirect comparison to remove observed differences in patients' baseline characteristics between the two groups of the current study. PSM is increasingly being used to reduce possible confusion in observational studies[21], which can provide clinical decision-makers with relatively reliable comparative evidence.

We believe that the survival benefits of surgical radiofrequency ablation far outweigh the harmful effects of prolonged myocardial ischemic time and increased surgical complexity. Favorable in-hospital and long-term outcomes in our study add to evidence that age alone should not be considered as a limiting factor for the concomitant bipolar radiofrequency ablation procedure. However, further research is needed to confirm and validate the evidence.

There are several limitations to the current study. This is a retrospective clinical analysis involving a small sample size at a single-center. Furthermore, although using propensity score matching, confounds and selection biases between the two groups cannot be eliminated. A final validation would need a prospective, multi-center, randomized study from larger cohorts of elderly patients. Further research is also needed to assess the quality of life of concomitant VR and BRFA in patients aged 70 years and older. Lastly, no comparison data for a younger population is presented in our study.

Conclusion

In this study with PSM from a single-center, we compared outcomes between concomitant BRFA and no ablation of patients with valve replacement aged ≥ 70 years. Our results indicate that the addition of BRFA procedure is a feasible and safe procedure even in elderly patients, with a better long-term survival and a reduced incidence of stroke events compared with valve replacement alone. These findings suggest that the BRA should always be considered as a concomitant procedure for atrial fibrillation in elderly patients presenting for cardiac surgery.

Abbreviations

AF: Atrial fibrillation; BRFA: bipolar radiofrequency ablation BRFA; HR: Hazard ratios; SHR: subdistribution hazard ratio; CI: confidence intervals; VR: valve replacement; CPB: cardiopulmonary bypass; ICU: intensive care unit.

Declarations

Acknowledgments

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Author contribution

Zhi-qin Lin: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Writing-original draft; Writing-review & editing. **Zeng-rong Luo:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Writing—original draft; Writing-review & editing. **Qian-zhen Li:** Conceptualization; Data curation; Methodology; Writing-review & editing. **Liang-wan Chen:** Conceptualization; Writing-original draft; Writing-review & editing. **Feng Lin:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Supervision; Writing-original draft; Writing-review & editing.

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Availability of data and materials

All data generated or analyzed during this study are included in this published article

Ethics approval and consent to participate

The present study was approved by the ethics committee of Union Hospital, Fujian Medical University and adhered to the tenets of the Declaration of Helsinki.

Consent for publication

Due to the retrospective nature of the present study, written informed consent from the patients or their guardians was waived.

Conflict of interest

none declared.

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Tables

Comparison of characteristics of AF ablated versus AF untreated populations: Total sample and propensity-matched groups.

Variables	Total sample (N= 276)			Propensity-matched sample (N = 68)			
	AF ablated (N = 42)	AF untreated (N= 234)	P value	AF ablated (N = 34)	AF untreated (N= 34)	P value	
Age (mean ±SD)	73.50±2.44	74.89±2.96	0.020	73.74±2.50	74.15±2.79	0.524	
Male(n)	26	133	0.541	21	19	0.622	
BMI	22.10±3.13	21.96±1.91	0.780	21.93±3.01	21.43±3.19	0.510	
Smoking history (n)	15	49	0.037	11	12	0.798	
Diabetes (n)	3	25	0.484	3	1	0.303	
Hypertension (n)	23	87	0.032	16	15	0.808	
LVEF	0.633±0.860	0.635±0.740	0.864	0.632±0.088	0.654±0.070	0.261	
NYHA Ⓜ (n)	4	23	0.951				
LVDD (mm)	52.98±4.62	54.78±6.04	0.030	53.19±4.44	53.34±4.84	0.858	
LA diameter (mm)	39.26±9.13	39.39±8.88	0.926	39.07±8.88	38.86±8.76	0.923	
AF duration (years)	5.24±2.75	9.95±4.48	0.000	5.91±2.58	5.18±3.42	0.320	
Serum creatinine(umol/L)	97.75±22.07	96.69±22.21	0.777	95.58±22.80	94.22±21.74	0.801	
COPD(n)	2	4	0.212	1	0	0.314	
Severe pulmonary hypertension (n)	7	47	0.607	7	3	0.171	
Stroke/TIA(n)	8	23	0.081	7	4	0.323	
CAD(n)	5	41	0.607	5	4	0.720	
Hypohepatia (n)	3	3	0.016	1	0	0.314	
Number of replacement valves (n)	Double valve replacement	19	109	0.872	17	19	0.627
	Single valve replacement	23	125		17	15	

BMI, body mass index; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; LVDD, left ventricular end diastolic dimension; LAD, left atrial dimension; COPD, chronic obstructive pulmonary disease; TIA, Transient Ischemic Attack; CAD, coronary artery disease.

Operative Data and In-Hospital Outcomes in the matched population.

Variables	AF ablated (N = 34)	AF untreated (N= 34)	P value
CPB time (min)	108.94±17.37	82.3±17.47	0.001
Cross-clamp time (min)	70.85±14.93	48.71±10.68	0.001
prolonged mechanical ventilation (>72 hours) (n)	15	7	0.038
Pulmonary complication (n)	29	26	0.355
Neurological complications (n)	5	2	0.231
<u>Renal failure</u> (n)	4	3	0.690
Dialysis (n)	2	1	0.555
ICU stay (days)	6.68±4.48	4.47±4.56	0.048
ICU readmission (n)	4	2	0.393
Length of hospital stay (days)	17.76±4.50	13.44±5.33	0.001
Low cardiac-output (n)	1	2	0.555
Reoperation for bleeding (n)	1	1	1.000
Hospitalized death cases (n)	2,	1	0.555

cardiopulmonary bypass; ICU, intensive care unit.

Figures

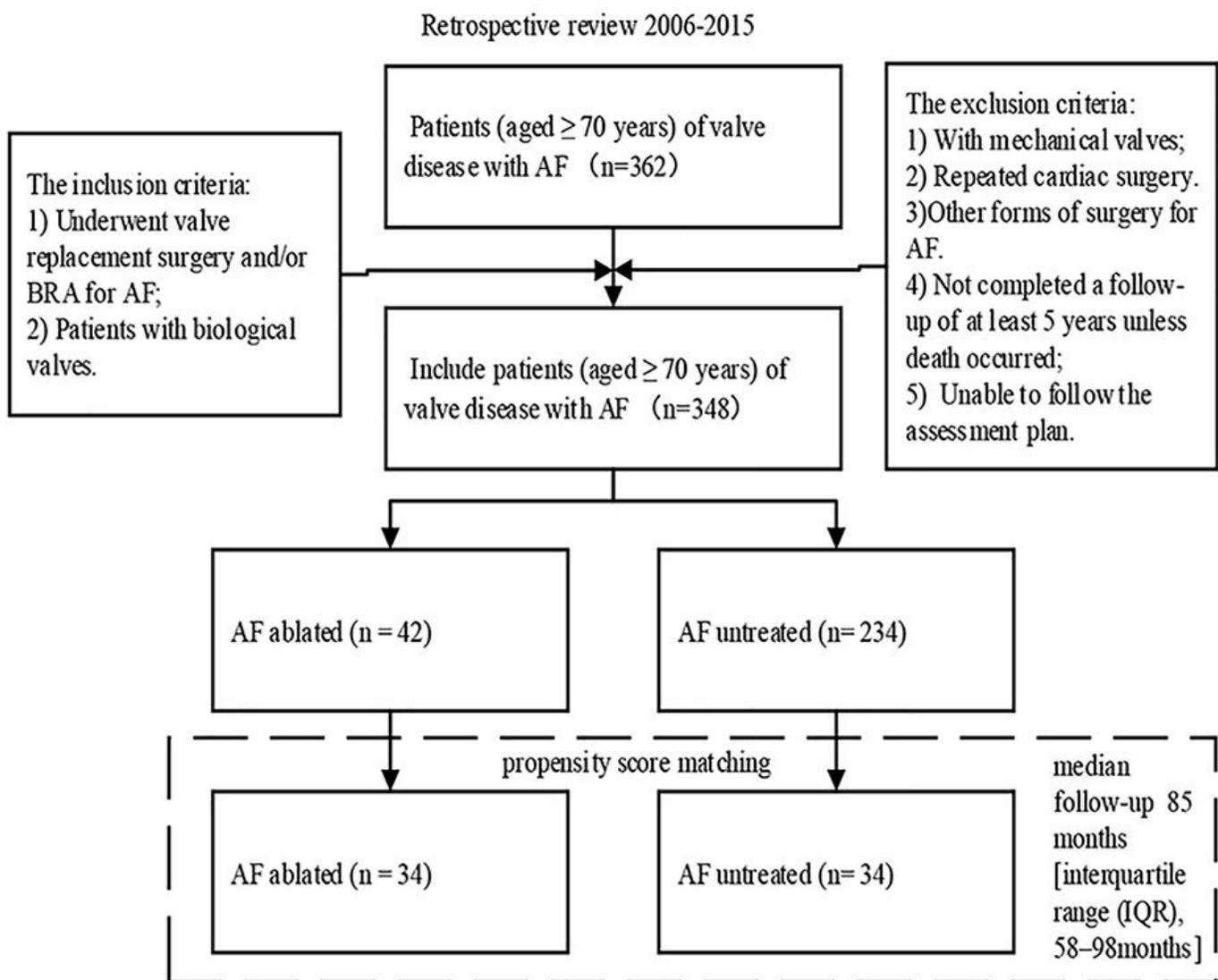


Figure 1

Flow diagram of the current study cohort.

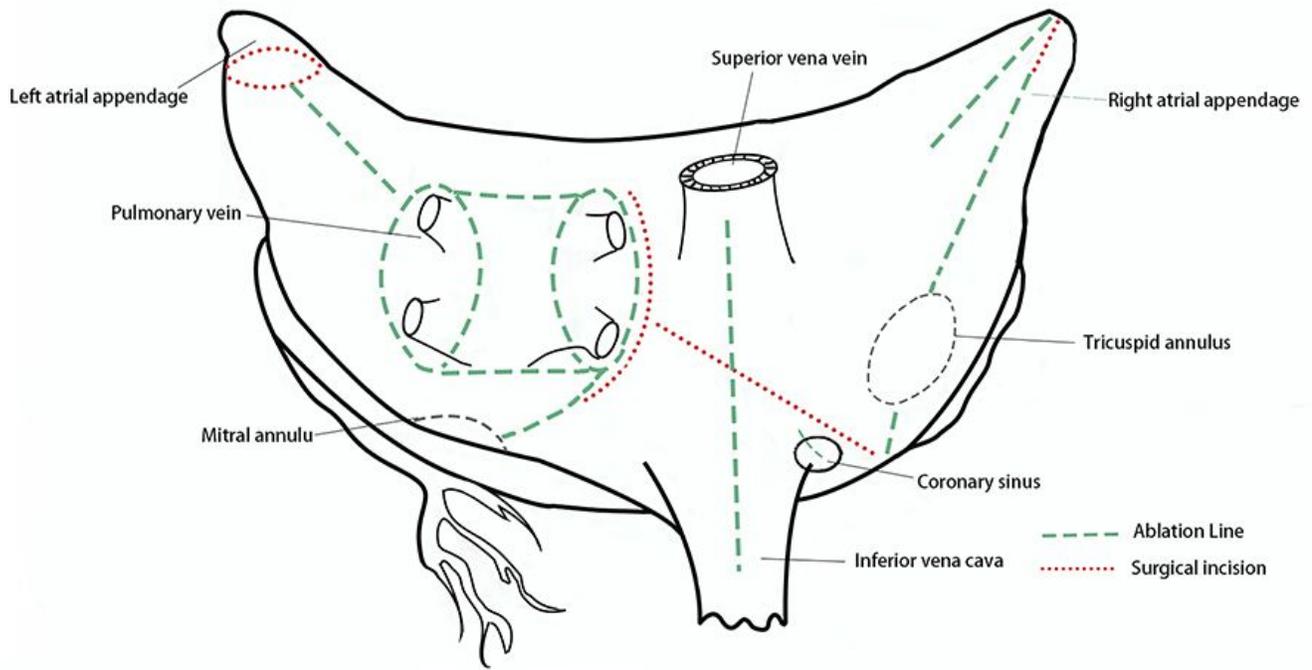


Figure 2

The lesion sets of bipolar radiofrequency ablation procedure.

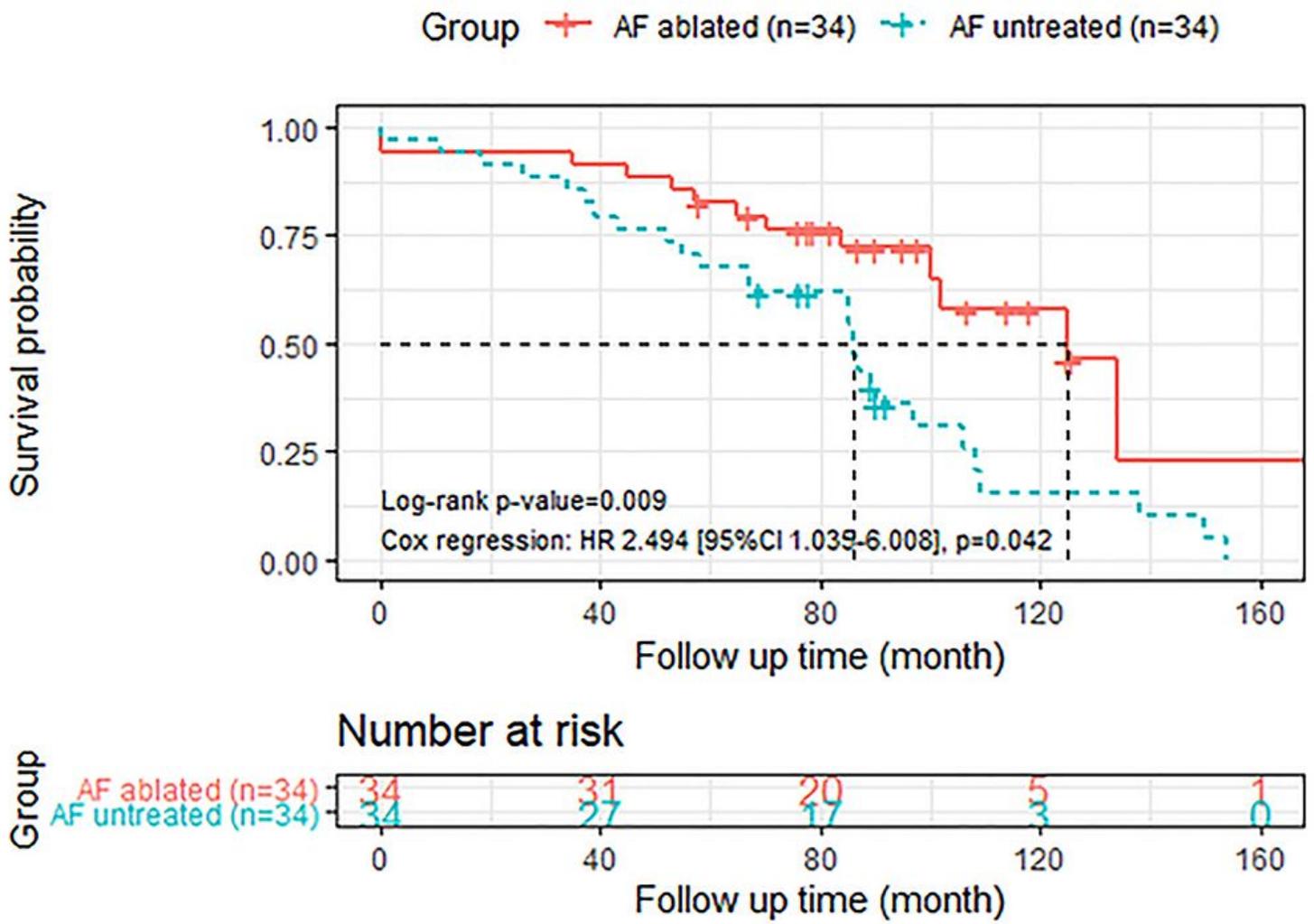


Figure 3

The survival of the matched AF ablated group and AF untreated group.

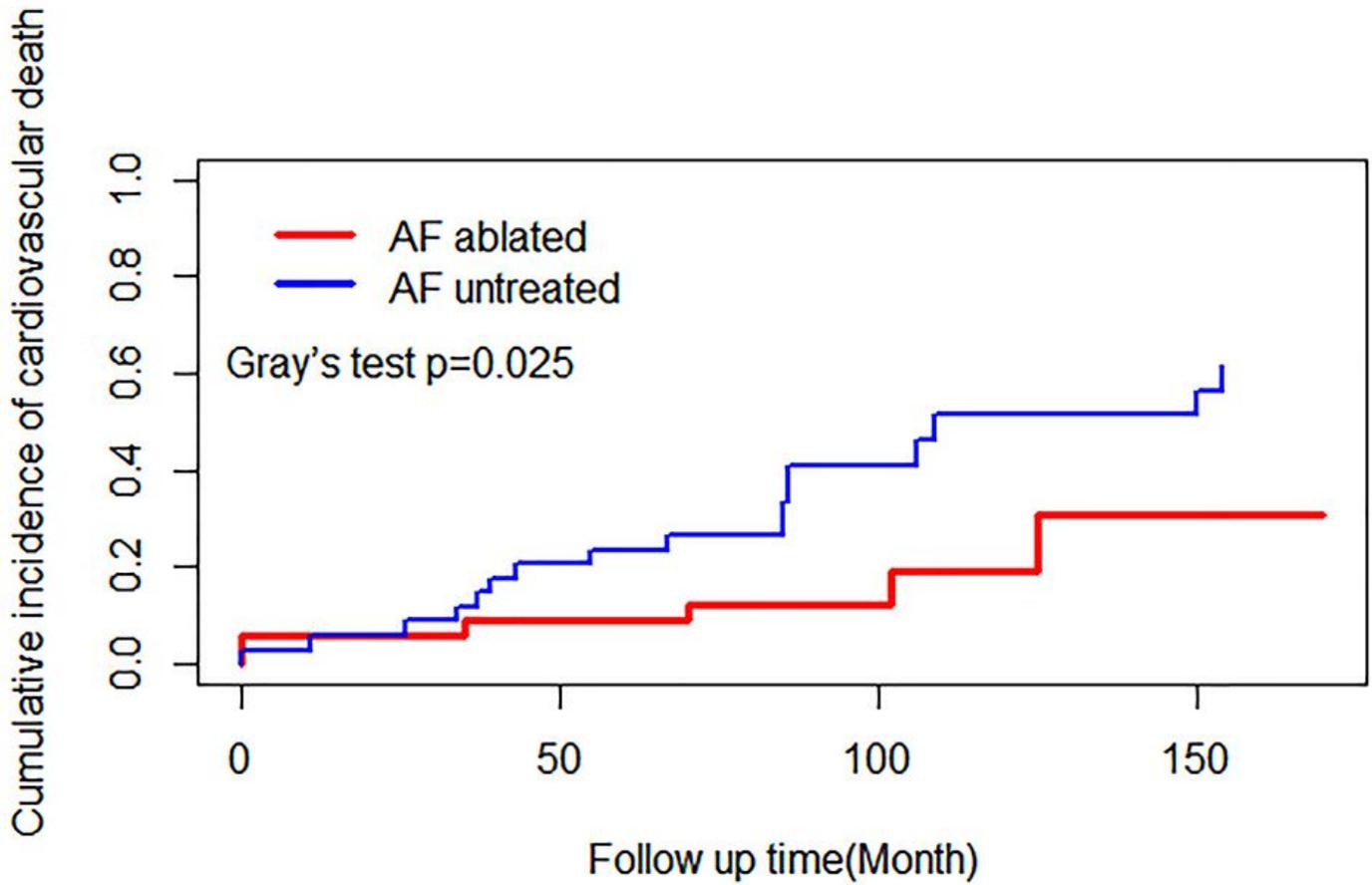


Figure 4

Cumulative incidence of cardiovascular death during follow up of the two propensity-matched groups.

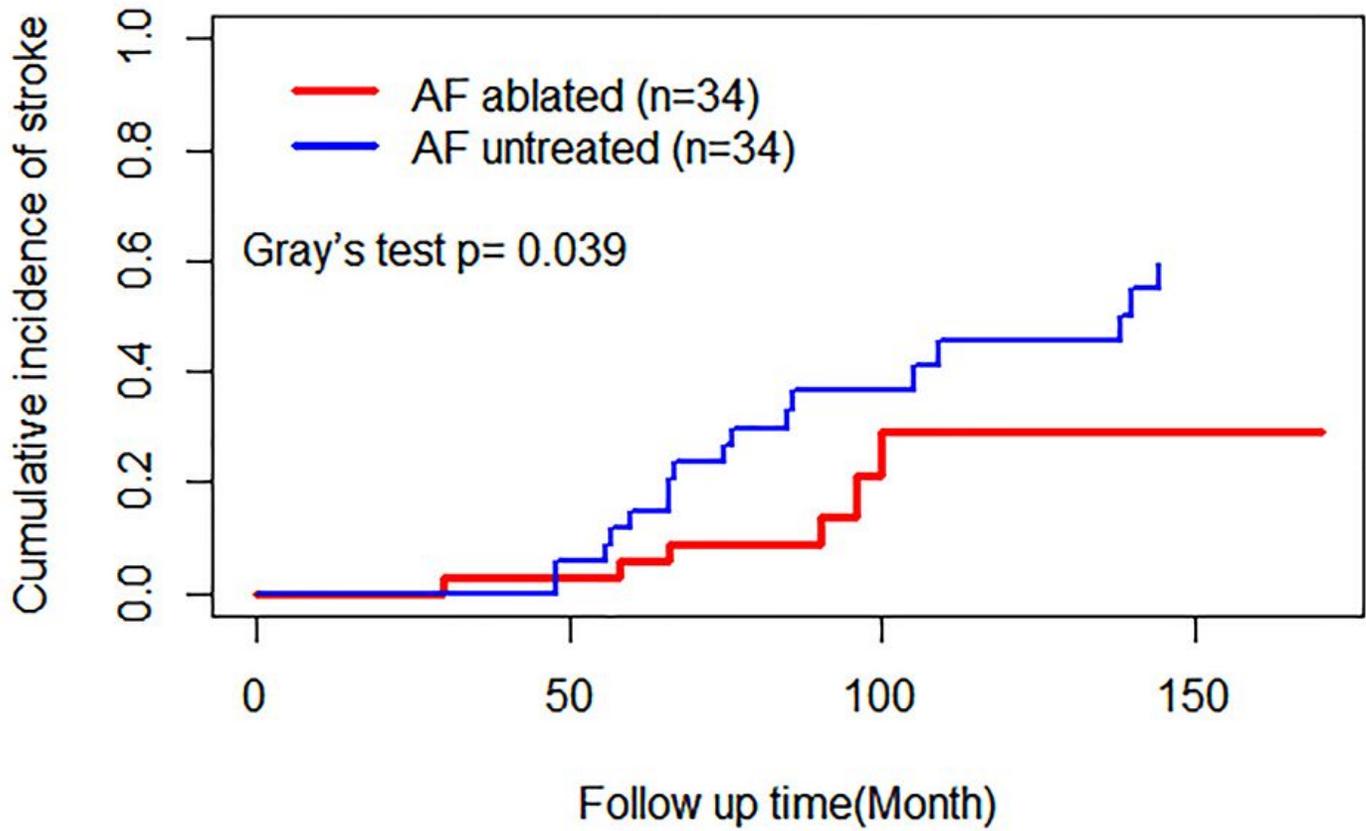


Figure 5

Cumulative incidence of stroke during follow up of the two propensity-matched groups.

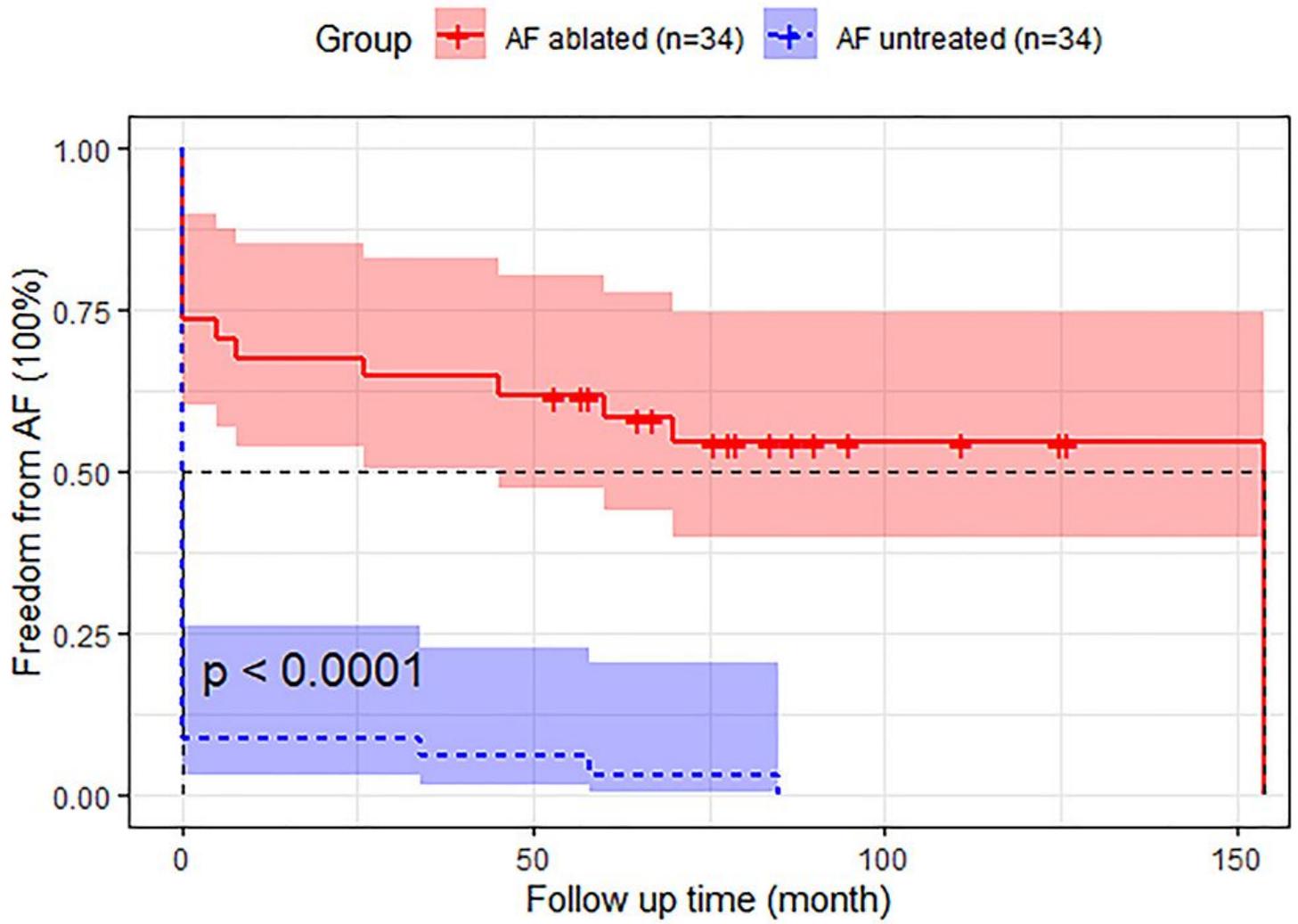


Figure 6

Freedom from AF during follow up of the two propensity-matched groups.