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Comparative characteristics of a pacemaker implantation after biatrial or left atrial ablation of atrial fibrillation in combination with coronary artery bypass grafting in patients with ischemic heart disease and long-standing persistent atrial fibrillation

Aim	To compare the incidence of a permanent pacemaker (PP) implantation based on the chosen treatment technology (biatrial ablation, BA, or left atrial ablation (LAA) for long-standing persistent atrial fibrillation (AF) with simultaneous coronary bypass (CB).
Material and methods	The study included 116 patients with long-standing persistent AF and indications for CB. Patients were randomized to two equal groups (58 patients in each). Group 1 underwent BA in combination with CB; group 2 patients underwent isolated LAA with simultaneous CB under the conditions of artificial circulation. Incidence of PP implantation was assessed during the early (to 30 days) and late (to 60 months) postoperative periods.
Results	For the observation period, a total of 9 PPs was implanted in both groups, 6 in the BA group and 3 in the LAA group (odds ratio, OR, 0.5; 95% confidence interval, CI, 0.1–2.4; p=0.490). During the early postoperative period, 5 patients in the BA group and 2 patients in the LAA group were implanted with PP (OR, 0.4; 95% CI. 0–2.5; p=0.438). During the late postoperative period, one (2%) patient of the BA group was implanted with a permanent PP at 30 months of follow-up due to the development of sick sinus syndrome (SSS); also, one (2%) patient of the LAA group required PP implantation at 54 months of follow-up due to the development of SSS. The causes for PP implantation in the BA group included the development of complete atrioventricular (AV) block in 9% of cases (95% CI, 4–19%); sinus node dysfunction and junctional rhythm in 2% of cases (95% CI, 0–9%). Compared to this group, the LAA group showed a statistically significant difference in the incidence of AV block (0 cases, p=0.047). The major cause for PP implantation in the LAA group was the development of sinus node dysfunction in 3 (5%) patients (95% CI, 2–14%).
Conclusion	The use of BA in surgical treatment of long-standing persistent AF with simultaneous myocardial revascularization is associated with a high risk of AV block, which requires permanent PP implantation in the postoperative period. Total incidence of permanent PP implantation for dysfunction of the cardiac conduction system following the combination surgical treatment of long-standing persistent AF and IHD, either CB and LAA or BA, did not differ between the treatment groups both in early and late postoperative periods.

Keywords	Atrial fibrillation; long-standing persistent atrial fibrillation; cardiac pacemaker; biatrial ablation; coronary bypass
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Introduction

Atrial fibrillation (AF) is the most common atrial arrhythmia (2–4% in the general population) that affects patients' quality of life, morbidity and mortality [1]. Associated cardiovascular diseases (including coronary artery disease (CAD) and older age are independent risk factors for AF [1]. In patients with various forms of AF, the incidence of hemodynamically significant coronary artery stenosis is approximately 40% [2].

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According to the 2016 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of atrial fibrillation, which was developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS), concomitant surgical treatment of AF should be performed during a coronary artery intervention (class IIa, level of evidence A) [3].

Several trials [4, 5] have showed the efficacy of biatrial ablation (BA) in preserving sinus rhythm in the postoperative period in up to 90% of cases. An easier to perform option, in which electrical pulses are applied within the left atrium (LA) only, is pulmonary vein (PV) isolation, currently the primary treatment method for AF. According to the European Heart Rhythm Association (EHRA) consensus document, BA should be considered in long-term (persistent and long-lasting persistent) forms of AF [6].

In the randomized trial by Gillinov et al. [7], permanent pacemaker implantation was performed more frequently following ablation. While the findings of a large meta-analysis [8, 9] also showed that BA is more effective compared to isolated left-atrial ablation (LAA), the incidence of the complication of permanent pacemaker implantation was higher in the BA group.

It remains unclear which type of surgical treatment should be preferred in patients with long-lasting persistent AF and indications for coronary artery bypass grafting (CABG) to avoid the development of conduction disorders requiring permanent pacemaker implantation.

Objective

The aim of the study was to compare the rates of permanent pacemaker implantation depending on the treatment option (BA or LAA) of long-lasting persistent AF with concomitant CABG.

Material and methods

A prospective randomized trial was carried out from 2016 to 2020 in the Center for Aortic, Coronary, and Peripheral Artery Surgery of the Academician Meshalkin National Medical Research Center. A total of 116 patients having indications for CABG and long-lasting persistent AF documented by electrocardiogram (ECG) (according to the ESC Guidelines, longer than 12 months at the time of considering a rhythm management strategy) [1] underwent CABG with concomitant AF ablation.

Inclusion criteria were: age from 18 to 70; CAD with indications for CABG; long-lasting persistent AF; signed informed consent.

Exclusion criteria were: other forms of AF; emergency life-saving surgery; severe post-operation adhesions, history of chest injuries; contraindications to anticoagulant therapy; severe diseases of other organs and systems with adverse short-term prognosis (life expectancy less than 5 years after surgery); previously implanted pacemaker; conduction disorders (atrioventricular (AV) blocks degree II and III, sick sinus syndrome (SSS)); contraindications to antiarrhythmic therapy.

Each patient signed informed consent. The study was approved by the Ethics Committee of the Academician Meshalkin National Medical Research Center (Protocol No. 52 as of 21/11/2018)

The study included 116 patients with 1:1 block randomization at 4 patients per block using randomizeR v1.3 in Rstudio [10]. In group 1, patients (n=58) underwent atrial BA in combination with CABG, while in Group 2, patients (n=58) were subjected to isolated LAA with CABG. The groups were comparable in demographic and clinical characteristics (Table 1). All patients had an implanted subcutaneous continuous ECG monitor (REVEAL LINQ ICM System) for recording cardiac conduction disturbances, postoperative pauses (which may be surgery-associated and require pacemaker implantation), as well as any cardiac rhythm disturbances, for up to 3 years. Moreover, all patients underwent 24 hour Holter ECG monitoring and 12-lead ECG before and after surgery.

The number of pacemaker implantation procedures was estimated in the early (up to 30 days) and long-term (up to 60 months) postoperative periods (Figure 1).

The indications for permanent pacemaker implantation were determined by REVEAL, Holter monitoring and ECG results: SSS (HR less than 60 bpm without adequate adaptation to physical activity); complete AV block; AV junctional rhythm less than 60 bpm and symptomatic dyspnea during physical exercise; the presence of pauses lasting more than 3.5 seconds.

Surgical technique of atrial ablation

Surgical access to the heart was performed through a longitudinal sternotomy, aortic cannulation, individual cannulation of the venae cavae (superior vena cava was cannulated using an L-shaped cannula as far as distal from the right atrium, without injuring the appendage). Cardiopulmonary bypass (CPB) was performed in the normothermic setting. Cardioplegia was carried out through the aortic root.

The first step of the ablation procedure, performed using a parallel CPB without cardioplegia, could be only performed without aortic cross-clamping if an LA clot had been ruled out before the surgery. First, the right and left PVs were isolated by the dissector and retracted. Once the left PVs had been isolated, a diatermocoagulator was used to cut the ligament of Marshall located between the left pulmonary artery and the left upper lobe PV. After using the retractor to pull the PV basin and place the bipolar forceps, the retractor was removed. First, the right PV basin was ablated with the bipolar forceps, followed by the left

Table 1. Preoperative clinical characteristics of patients

Parameter	BA group (n = 58)	LAA group (n = 58)	Difference / OR	p
Age, years	65 [61; 67.75]	62 [58; 66]	-2 [-4; 0]	0.050
Male	48 (83)	49 (84)	OR: 1.1 [0.4; 3.5]	> 0.999
Duration of AF, months	48 [12; 120]	36 [13.5; 114]	0 [-24; 12]	0.759
Duration of CAD, months	66 [36; 132]	60 [24; 180]	0 [-24; 24]	0.803
LVEF, %	55 [48; 61]	58 [47.25; 63.75]	2 [-2; 6]	0.410
LA short axis, mm	4.85 [4.4; 5.27]	4.7 [4.4; 5.4]	0 [-0.3; 0.2]	0.916
LA long axis, mm	6 [5.7; 6.5]	5.9 [5.3; 6.4]	-0.2 [-0.5; 0.1]	0.186
RA short axis, mm	4.5 [4.12; 4.9]	4.3 [4.03; 4.8]	-0.1 [-0.4; 0.1]	0.351
RA long axis, mm	5.65 [5.2; 6.2]	5.65 [5; 6.18]	-0.1 [-0.4; 0.2]	0.611
BCA involvement according to ultrasound	7 (12)	7 (12)	OR 1 [0.3; 3.5]	> 0.999
History of CVA/TIA	10 (17)	3 (5)	OR 0.3 [0; 1.1]	0.074

The data are presented as the median and interquartile range (Me [Q1; Q3]) or the absolute value and percentage (n (%)); CI – confidence interval; OR – odds ratio; BA – biatrial ablation; LAA – left atrial ablation; AF – atrial fibrillation; CAD – coronary artery disease; LVEF – left ventricular ejection fraction; LA – left atrium; RA – right atrium; BCA – brachiocephalic artery; CVA – cerebrovascular accident; TIA – transient ischemic attack.

PVs (2–3 parallel ablation lines were applied on each basin) until the transmural effect was achieved.

The left-atrial ablation lines were applied following the Cox-Maze IV procedure, which included circular isolation of the PVs and applying the junction lines between the myocardial tissue areas in base and posterior bottom walls of both PVs (box lesion; Figure 2, A, adapted from [11]).

The isolation lines in the right atrium included the upper and lower vena cava lines, the lines applied to the tricuspid annulus at the twelve-o'clock position, and the lateral lines (see Figure 2, B).

The ablation lines were applied using irrigated bipolar forceps (CardioBlate).

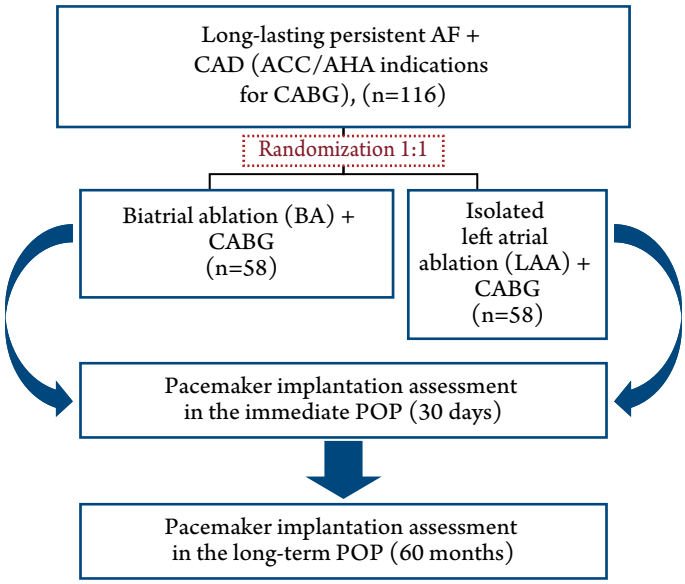
Postoperative management

In the postoperative period, all patients received anticoagulant therapy (warfarin to achieve and maintain the target international normalized ratio levels of 2–2.5) or direct oral anticoagulants (dabigatran, apixaban, apixaban) for at least 8 weeks after surgical ablation (class IIa, level of evidence C).

According to the ESC Guidelines for the diagnosis and management of atrial fibrillation [1], despite successful labyrinth surgery and closure of the LA appendage (class I, level of evidence C), long-term oral anticoagulant therapy is recommended in all patients at high risk of developing thromboembolism as per CHA2DS2 VASc scale.

Scheduled postoperative examinations were carried by a cardiologist in 30 days, 8 weeks, 12, 24 and 60 months. The cardiologist evaluated the risk of thromboembolism using the CHA2DS2 VASc score. In our study, 100% of patients were at high risk of developing thromboembolism due to comorbidities (chronic heart failure, arterial hypertension, diabetes mellitus, a history of transient ischemic attack, and peripheral atherosclerosis). Consequently, all patients received anticoagulant therapy for a long time even after successful (no recurrence) surgical ablation of AF (class IIa, level of evidence C).

Figure 1. Study design



AF – atrial fibrillation; CAD – coronary artery disease; CABG – coronary artery bypass grafting; BA – biatrial ablation; LAA – left-atrial ablation; POP – postoperative period; ACC/AHA, indicated following the American College of Cardiology and the American Heart Association Clinical Practice Guidelines.

All patients received amiodarone 200 mg/day for at least 3 months after discharge from the hospital to prevent iatrogenic cardiac arrhythmias. Antiarrhythmic therapy was canceled if there was no AF recurrences. In 3 months, antiarrhythmic therapy was discontinued in 46.6% of the patients in both groups.

The data obtained were processed in the Rstudio suite (version 1.3.959 – © 2009–2020 Rstudio, Inc., USA) using the R language (version 4.0.2). The continuous variables were compared using the non-parametric Mann-Whitney U-test. An intergroup distribution shift estimate was constructed for detecting clinically significant differences. All constant characteristics are describable in the median and inter-quartile range (Me [Q1; Q3]). The complications of the pacemaker

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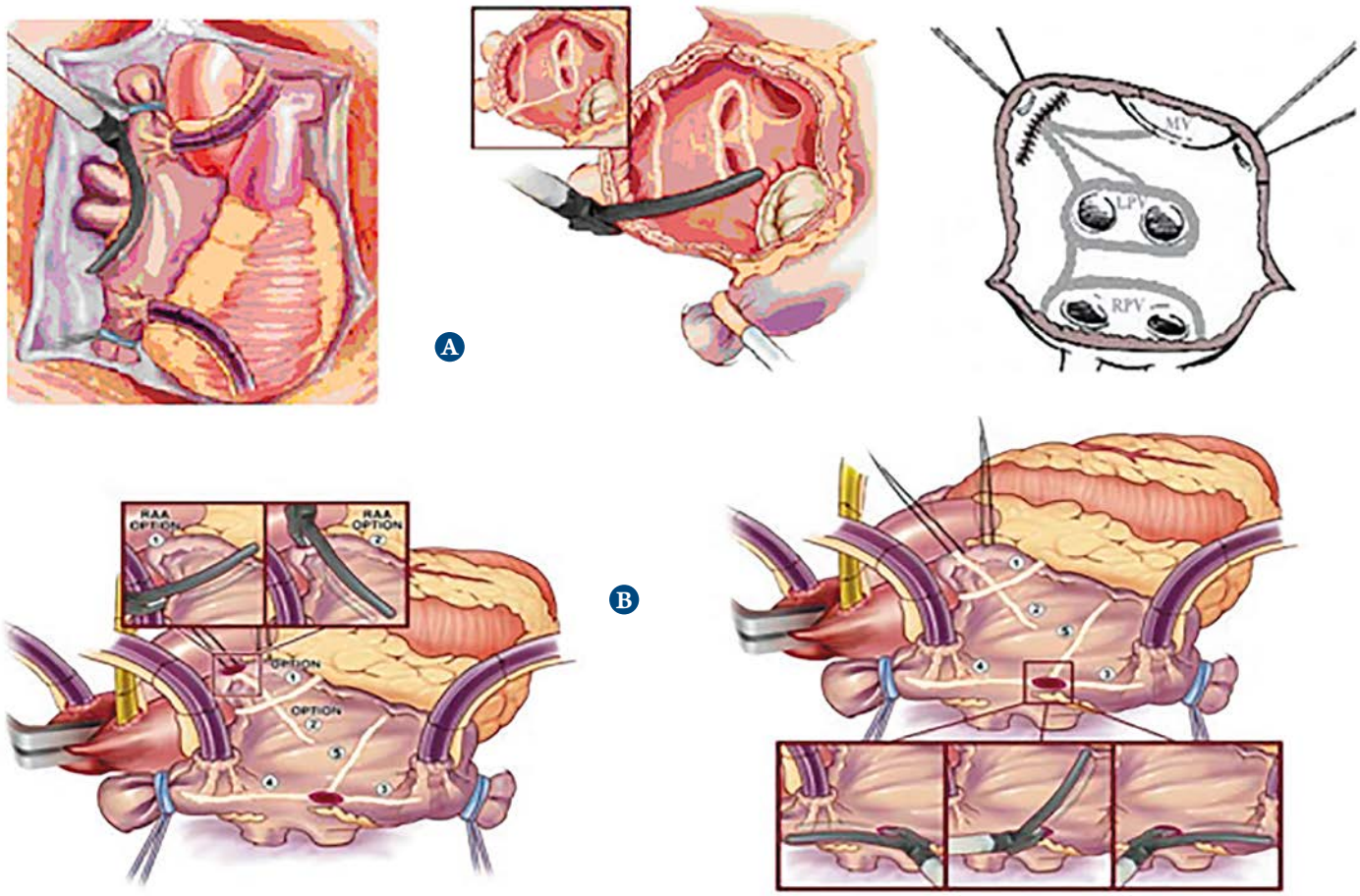
Figure 2. Schema of ablation lines for left-atrial (A) and biatrial (B) ablation (adapted from [11])



implantation were compared between groups at the same time point (at the end of the follow-up period) using a two-tailed Fisher's exact test.

Changes in the complications of the pacemaker implantation were compared between groups at 60-month time point by constructing Kaplan–Meier survival curves (no need for pacemaker implantation) with 95% confidence intervals (CI). The curves were compared using the log-rank test and odds ratio (OR) assessment using the Cox proportional risk model. The differences were statistically significant at $p<0.05$.

Results

The mean duration of long-term follow-up was 45 [32.75; 74.75] months and 47 [30.75; 70.75] months in the LAA and BA groups, respectively ($p<0.001$). The mean age of patients up was 65 [61; 67.75] years and 62 [58; 66] years in the BA group and the LAA group, respectively ($p=0.050$). Of those, males accounted for 83% and 84% in the BA group and in the LAA group, respectively ($p=0.999$) (Table 1).

Two patients (one patient in the BA group and another one in the LAA group) with epicardial electrodes implanted for temporary atrial stimulation due to the development of the AV junctional rhythm recovered a sinus rhythm by the time they were discharged from the hospital.

A total of 9 pacemakers were implanted in both patient groups during the follow-up period: 6 and 3 in the BA and LAA groups, respectively (OR 0.5; 95% CI 0.1–2.4; $p=0.490$) (Table 2). In the early postoperative period, pacemakers were implanted more often in the BA group than in the LAA group, 5 vs. 2 (OR 0.4; 95% CI 0–2.5; $p=0.438$). Only 1 (2%) patient in each group required the implantation of a pacemaker in the long-term postoperative period. A permanent pacemaker was implanted in 1 (2%) patient in the BA group in month 30 of follow-up due to the development of SSS, while 1 (2%) patient required the implantation of the pacemaker in the LAA group in month 54 of follow-up also due to the development of SSS.

The reasons for the pacemaker implantation in the BA group in our study were the development of complete AV block in 9% of cases (95% CI 4–19%), sinus node dysfunction, and AV junctional rhythm in 2% of cases (95% CI 0–9%). The rate of AV block was statistically significantly different in the LAA group versus the BA group (0; $p=0.047$). The main reason for the pacemaker implantation in the LAA group was sinus dysfunction in 3 (5%) patients (95% CI 2–14%).

The provided Kaplan-Meier plot (Figure 3) shows that there were no statistically significant differences in the implantation of permanent pacemaker ($p=0.237$) in both the early and late postoperative periods during the 60-month follow-up period

Table 2. Comparison of pacemaker indicators between the BA and LAA groups

Parameter	BA group, n = 58, n (%)	LAA group, n = 58, n (%)	Two-sided Fischer's exact test	
			OR (95% CI)	p
Early pacemaker implantation	5 (9)	2 (3)	0.4 (0–2.5)	0.438
Late pacemaker implantation	1 (2)	1 (2)	1 (0–79.8)	> 0.999
Pacemaker	6 (10)	3 (5)	0.5 (0.1–2.4)	0.490
SND	1 (2)	3 (5)	3.1 (0.2–165.9)	0.618
AV block	5 (9)	0	0 (0–0.78)	0.047
AV junctional rhythm	1 (2)	2 (3)	2 (0.1–122.1)	> 0.999

BA – biatrial ablation; LAA – left atrial ablation; OR – odds ratio;
CI – confidence interval; SND – sinus node dysfunction; AV – atrioventricular.

(hazard ratio estimated using the Cox proportional risk model 0.44; 95% CI 0.11–1.78).

Discussion

Literature evidences a higher rate of pacemaker implantation in the postoperative period, including with concomitant surgical treatment of AF, for BA ablation compared to isolated LAA ablation due to the application of lines on the right atrium and subsequent development of conduction disorders [12, 13].

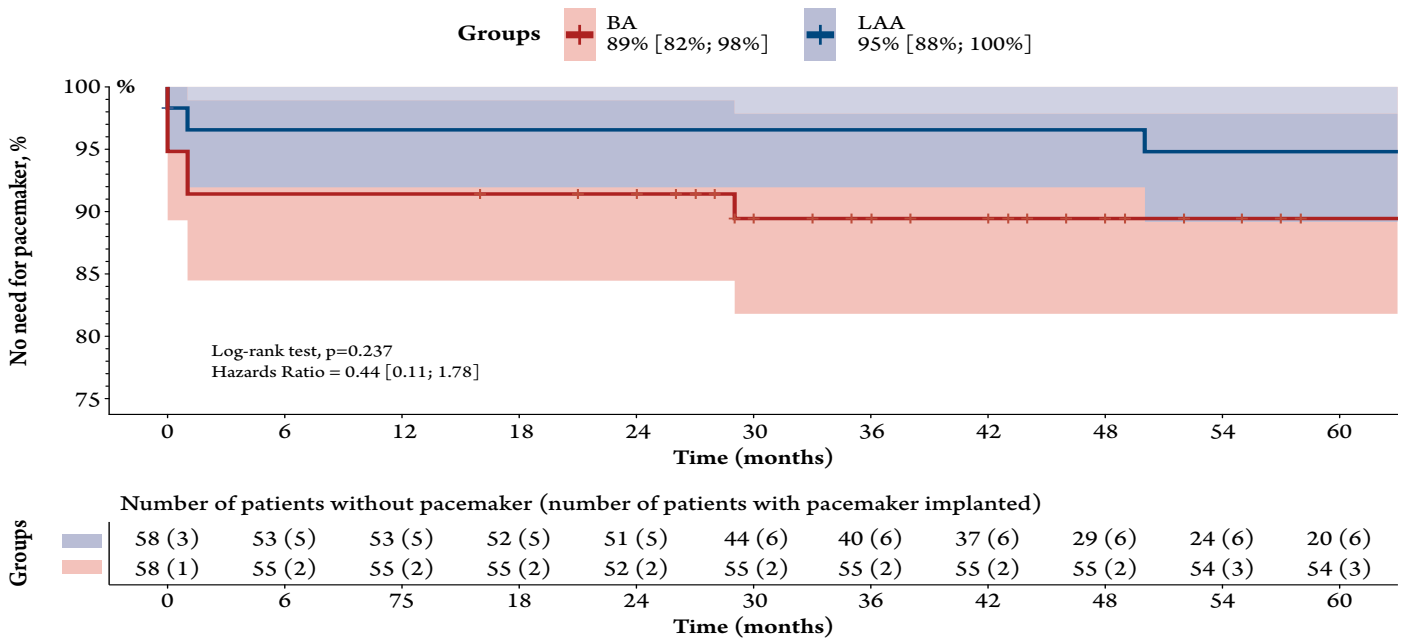
Comparing the efficacy of different atrial ablation techniques in long-lasting persistent AF during CABG, Cherniavskiy et al. [14] did not detect any significant differences in the rates of pacemaker implantation between the groups of patients exposed to PV isolation, ganglion plexus ablation or modified Mini–Maze procedure (p=0.72).

According to Takasaki et al., the Labyrinth cryoablation proved to be relatively effective in permanent AF with concomitant intervention on mitral and tricuspid valves compared to isolated PV ablation. In the postoperative period, 1 (2.5%) of 40 patients in the PV isolation group had a pacemaker implanted, another 1 (2.9%) of 35 patients in the Labyrinth group underwent pacemaker implantation due to bradycardia (<50 bpm) [15].

Wang et al. [16] reported a significantly higher rate of postoperative implantation of permanent pacemakers in the BA group. Only two (1.4%) patients in the BA group and one patient in the PV isolation group needed pacemaker implantation (p=0.25).

In the Pecha et al. trial [17], the rate of postoperative pacemaker implantation was 10.1% in surgical AF ablation concomitant with CABG (n=24), aortic valve replacement

Figure 3. Kaplan-Meier curve: no need to implant an pacemaker in patients who have undergone atrial ablation in long-lasting persistent AF in combination with CABG, up to 60 months during the follow-up period



BA – biatrial ablation; LAA – left-atrial ablation; log-rank test is a logarithmic rank test used to compare two survival curves; hazard ratio is an assessment used in the Cox proportional risk model.

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(n=20), mitral valve replacement (n=22), combination CABG and valve surgery (n=43), and other surgical procedures (n=15).

In the comparative characteristic of biatrial and isolated left-atrial cryoablation, Gualis et al. [18] showed that there were no statistically significant intergroup differences in the postoperative implantation of permanent pacemakers: 4 (5.9%) and 10 (15.9%) patients in the BA and LAA groups, respectively.

In a large-scale meta-analysis [19], the causes of permanent pacemaker implantation were reported for 8 (28.6%) trials, the most frequent of which were dysfunctions of AV node (54.1%) and sinoatrial node (45.9%). Examining the causes of pacemaker implantation, the authors discovered that the risk of sinoatrial node dysfunction in the BA group was 3 times higher (4.9% vs. 1.7%, respectively) than in the LAA group (OR 3.01; 95% CI 1.49–6.07; p=0.002). The risk of AV node dysfunction (p=0.09) was also statistically significantly higher in the BA group.

Stulak et al. [20] compared different methods of correction of paroxysmal and persistent AF, in which biatrial (68%), isolated LAA (9%) and isolated LV ablation (23%) were prevalent. There were also more early pacemaker implantations (p=0.003) in the BA group compared to other groups. However, since the BA group included more patients at baseline than the rest of the groups, the results of this trial are controversial.

A previous study carried out in our hospital [21], which examined the treatment methods of persistent and long-lasting persistent AF with concomitant mitral valve surgery, demonstrated the efficacy and safety of BA. However, a retrospective comparative analysis [22] showed that the BA fragmentation pattern compared to LAA was associated with a higher rate of pacemaker implantation (17.3% vs. 3.8%, respectively; p<0.001) due to the frequent development of sinus node dysfunction. It should be noted that there are no significant intergroup differences in the rates of atrioventricular conduction disorders (7.0% vs. 3.2%, respectively; p=0.211).

Over the past 5 years, several trials have found no differences in the rates of postoperative implantation of permanent pacemakers after fragmentation on one or two atria. Churyla et al. [23] showed no difference in the rates of pacemaker implantation in patients with AV node dysfunction (12% vs. 12%, respectively; p=0.57). Gillinov et al. [7] demonstrated statistically insignificant differences between the two groups (LAA and BA) in the rates of pacemaker implantation (14.9% vs. 24.2%, respectively; p=0.22). In our study, the efficacy of BA was higher than that of isolated LAA; however, the rate of permanent pacemaker implantation was higher in this group (BA).

Thus, while the atrial BA technique improves sinus rhythm recovery, there is a higher incidence of pacemaker implantation due to the development of cardiac conduction disorders.

Conclusion

The use of biatrial ablation in the surgical treatment of long-lasting persistent atrial fibrillation with concomitant myocardial revascularization is associated with a higher rate of complete atrioventricular block followed by pacemaker implantation compared to isolated left-atrial ablation. The total rate of permanent pacemaker implantation due to cardiac conduction dysfunction following combination surgical treatment of long-lasting persistent AF and CAD using CABG and LAA or BA did not differ in the two groups in the early and long-term postoperative periods.

No conflict of interest is reported.

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