

Efficacy of posterior pericardiotomy in prevention of atrial fibrillation and pericardial effusion after aortic valve replacement: a randomized controlled trial

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Aim

Postoperative atrial fibrillation is one of the most frequent complications in cardiac surgery. The aim of this trial was to evaluate the effectiveness of posterior pericardiotomy in the prevention of postoperative atrial fibrillation and pericardial effusion in patients undergoing isolated primary aortic valve replacement.

Methods

The trial was approved by the local ethics committee. It included adult patients under 70 y.o. who had signed the informed consent for participation in the study and who were planned to undergo isolated primary aortic valve replacement. Exclusion criteria were a history of atrial fibrillation, hyperthyroidism, amiodarone intake, severe chronic obstructive pulmonary disease, left ventricle ejection fraction less than 30%, the size of the left atrium exceeding 50 mm, active infective endocarditis, the presence of adhesions in the pericardium and/or left pleural cavity and mini-sternotomy. From October 2013 to April 2015 607 patients in our clinic underwent different aortic valve procedures. 507 patients were excluded from the study because of the inclusion and exclusion criteria. The remaining 100 patients were randomized into two groups: 49 patients underwent posterior pericardiotomy and 51 patients made up the control group. In both groups the frequency of postoperative atrial fibrillation, pericardial effusion greater than 5 mm, surgery-discharge time, as well as posterior-pericardiotomy-related complications were studied.

Results

There were no deaths, stroke or cardiac tamponade during the postoperative stay. Neither were there any complications associated with the performance of posterior pericardiotomy. The incidence of atrial fibrillation, pericardial effusion and average duration of the postoperative stay were similar in both groups: 16% in posterior pericardiotomy group vs. 14% in the control group ($p = 0.71$), 10% in posterior pericardiotomy group vs. 12% in the control group ($p = 0.80$) and 12.4 ± 4.3 days in posterior pericardiotomy group vs. 11.9 ± 4.1 days in the control group ($p = 0.27$), respectively.

Conclusion

The trial did not confirm the effectiveness of posterior pericardiotomy in preventing postoperative atrial fibrillation and pericardial effusion during the in-hospital period after isolated primary aortic valve replacement in low risk patients. However, further investigations are needed.

Keywords:

posterior pericardiotomy; pericardial effusion; postoperative atrial fibrillation; cardiac surgery; complications

Trial registration

The trial is registered with ISRCTN, number ISRCTN11129539.

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Introduction

Postoperative atrial fibrillation (POAF) is one of widespread complications in cardiac surgery [1, 2]. According to some large trials, POAF incidence during aortic valve replacement comes to 35–38% [3–5]. Like other procedures, POAF caused by aortic valve replacement might result in unstable hemodynamics, longer and more expensive in-patient stay, as well as the risk of re-hospitalization, ischemic stroke and death during both early and late follow-up [2, 4].

Postoperative atrial fibrillation pathogenesis has not been studied well enough and is associated with some mechanisms which include predisposing, intra- and postoperative factors, as well as triggers [6]. Pericardial effusion is also referred to as one of such factors [7, 8]. To eliminate pericardial effusion and prevent postoperative atrial fibrillation, in 1995 A. Mulay et al. suggested to use posterior pericardiotomy (PP) [9]. The efficacy of PP in prophylaxis of postoperative atrial fibrillation was successfully confirmed in many studies including meta-analyses [10–13]. As a result, PP was recommended to be used in cardiac surgery for prevention of POAF by American College of Chest Physicians, ACCP, 2005 [14] and European Association for Cardio-Thoracic Surgery, EACTS, 2006 [15]. However, the present-day ideas on the efficiency of PP in POAF prevention are mainly based on the results obtained during coronary artery bypass grafting.

The study focused on the evaluation of posterior pericardiotomy efficacy to prevent postoperative atrial fibrillation in patients who had undergone aortic valve replacement.

Methods

The paper meets the CONSORT 2010 guideline for the reporting of randomized controlled trials [16].

A randomized controlled parallel group study was approved by the local Ethics Committee. All participants gave written informed consent before enrollment in the study. The first author was in charge of the randomization procedure carried out by using random digit tables and sequentially numbered sealed envelopes. There was no “blinding” of participants and researchers. The trial was registered with the ISRCTN Register and assigned an individual number ISRCTN11129539.

Enrolled in the trial were patients aged 18 to 69 years old who underwent primary isolated aortic valve

replacement. A history with atrial fibrillation events and thyroid function abnormalities, amiodarone intake, pericardial effusion with more than 5 mm separation of the pericardial layers, severe chronic obstructive pulmonary disease, ejection fraction of the left ventricle less than 30%, size of the left atrium exceeding 50 mm, active infective endocarditis, presence of adhesions in the pericardial cavity and/or left pleural cavity and ministernotomy performance were used as exclusion criteria.

Preoperatively, a conventional examination was carried out followed by selection of patients according to the exclusion and inclusion criteria.

Surgical intervention

All patients underwent standard surgery. Full midline sternotomy was done, the aorta and right atrium were cannulated. Cardiopulmonary bypass was applied under spontaneous cooling. All patients received retrograde cardioplegia with Custodiol® HTK Solution (Dr. F. Koehler Chemie GmbH, Bensheim, Germany). As prosthetic valves, both mechanical prostheses Carbomedics Orbis Aortic (Sorin Biomedica Cardio S.p.A., Saluggia, Italy) and biological ones Bovine Pericardium Organic Valvular Bioprosthesis (Braile Biomedica, São José do Rio Preto, Brazil) were used. After closing the aorta incision, prior to weaning from cardiopulmonary bypass, the envelopes were opened and randomization was carried out. If a patient satisfied the criteria for posterior pericardiotomy, he/she underwent a procedure described by A. Mulay et al. [9].

Chest tubes were placed through the pericardium in the left pleural cavity, as well as via a retrosternal approach. No PP was performed in the control group, chest tubes were introduced in the oblique pericardial sinus and via a retrosternal approach. The volume of daily drainage, 100 mm and less, was considered as a criterion for removing the chest tubes. Pacing leads were sutured to all patients and just a few of them received temporary pacing. The electrodes were removed at 5–7 days after surgery. The pericardium was partially closed in all cases. Irrespective of a prosthesis type used, target international normalized ratio 2.5 warfarin was given to all patients in the immediate postoperative period. In case there was no clinically significant bleeding via the chest tubes, warfarin dosing was started a day after surgery, with low molecular weight heparins administered to reach the target international

normalized ratio value. In addition, all patients received ketoprofen 100 mg I.M. for at least 5 days postoperatively.

Clinical outcomes

A POAF event was chosen as the primary end-point, while death, ischemic stroke and cardiac tamponade were regarded as secondary end-points. Besides, pericardial effusion, resternotomy related to bleeding, puncture of the left pleural cavity, duration of inotropic support, length of stay at intensive care unit, as well as the period from surgery to discharge were also recorded and analyzed.

When at intensive care unit, patients had continuous electrocardiographic monitoring for 48 hours. Further on, it was performed every day and during arrhythmia events as well. Echocardiography was postoperatively carried out at least twice: immediately after removing the drains and prior to discharge.

Postoperative atrial fibrillation was taken into account as clinically significant and recorded, if it happened at the background of normokalemia (≥ 4.0 mmol/l), caused hemodynamics discrepancies and required amiodarone infusion. Short-term POAF events taking place spontaneously or against the background of potassium solution infusion were neglected. As POAF occurred, the rhythm was controlled by means of amiodarone infusion (without electric cardioversion).

Pericardial effusion was recorded on the basis of echocardiography data, when the maximum separation of the pericardial layers at the level of the mitral valve was equal to or exceeded 0.5 cm.

Statistical analysis

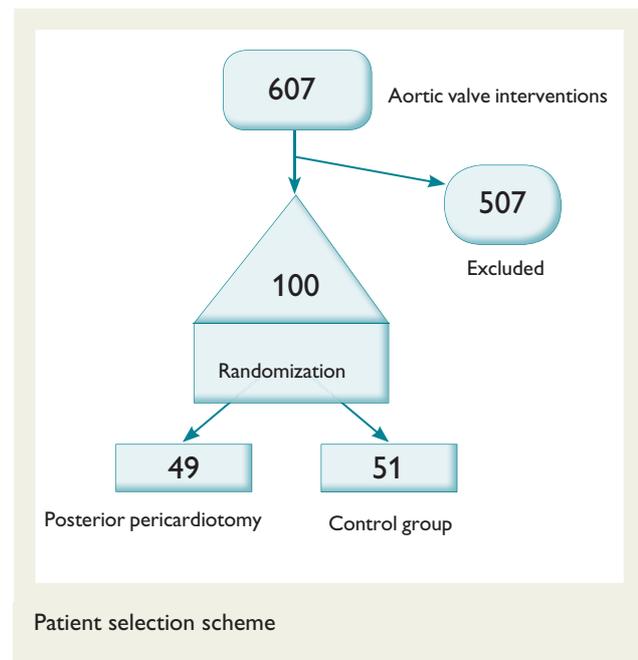
Main statistical characteristics are presented as mean values with standard deviations or a percentage share of patients in each group. The χ^2 test was used to compare discrete variables, while Kruskal–Wallis test and Van der Waerden test enabled us to analyze continuous ones. Statistical analysis was performed by means of SAS/STAT® software, Version 9.1 (SAS Institute Inc., Cary, North Carolina, USA), with $p < 0.05$ regarded as a significant value.

The power of the groups was assessed on the basis of literature relating to POAF incidence when performing aortic valve replacement, which constitutes about 35% [3–5], and the assumption that PP surgery reduces POAF incidence when doing aortic valve replacement in the same way as it does during coronary artery bypass grafting, i.e., down to 11% [8, 10]. The confidence level was 5% and

power 80%. The number of observations to be included in each group was estimated as equal to 45.

Results

Over a period from October 2013 to April 2015, 607 patients underwent aortic valve interventions at Ochapowski Regional Hospital (Krasnodar, Russian Federation). Five hundred and seven patients were removed from the trial because of inclusion and exclusion criteria. One hundred patients were randomized, with 49 of them making up the posterior pericardiotomy group and 51 the control group (see the figure below).



Demographic and other preoperative characteristics are given in Table 1.

In both groups, the patients did not significantly differ by sex, age, nosology and other preoperative data. Surgery characteristics are given in Table 2.

There were no deaths, strokes or cardiac tamponade during the in-hospital stay in both groups. The difference in the incidence of POAF and pericardial effusion was statistically insignificant. Among all postoperative characteristics, only the time of chest tubes removal differed significantly in the groups (4.4 ± 1.4 days in the PP group vs. 3.3 ± 0.6 days in the control one; $p < 0.0001$). Detailed postoperative characteristics are given in Table 3.

Table 1. Baseline characteristics

Variable		Posterior pericardiectomy (n = 49)	Control group (n = 51)	p	
Age (years)		56.6±9.9	55.4±10.5	0.564 ²	0.456 ³
Sex (male)		28 (57%)	33 (65%)	0.438 ¹	
Diagnosis	bicuspid aortic valve degenerative disease	27 (55%)	29 (57%)	0.425 ¹	
	chronic rheumatic heart disease	18 (37%)	17 (33%)		
	inactive infective endocarditis	1 (2%)	1 (2%)		
	syphilitic disease	1 (2%)	4 (8%)		
Disease	stenosis	2 (4%)	0 (0%)	0.495 ¹	
	insufficiency	38 (76%)	36 (72%)		
	combined	8 (16%)	13 (26%)		
		3 (6%)	2 (2%)		
Diabetes mellitus		2 (4%)	3 (6%)	0.680 ¹	
Body mass index (kg/m ²)		27±4	26±4	0.251 ²	0.308 ³
Smoking		11 (22%)	14 (28%)	0.563 ¹	
Hypertension		31 (62%)	39 (78%)	0.150 ¹	
LVEF (%)		53±4.6	53±4.7	0.834 ²	0.786 ³
Left atrium size (mm)		40±4	40±5	0.939 ²	0.860 ³
Medication	β-blockers	23 (46%)	22 (44%)	0.702 ¹	
	statins	9 (18%)	10 (20%)	0.874 ¹	
Cholesterol (mmol/l)		5.3±1.2	5.25±1.1	0.868 ²	0.767 ³
Creatinine (μmol/l)		90±13	95±17	0.139 ²	0.116 ³

Data are presented as mean ± standard deviation and n (%). ¹ χ^2 test; ² Kruskal–Wallis test; ³ Van der Waerden test; LVEF, left ventricular ejection fraction.

Discussion

The effectiveness of PP in prevention of POAF has been demonstrated in a number of cohort and randomized studies in patients who underwent coronary artery bypass grafting [9, 17–22]. However, some studies showed no effect of PP on POAF [23–25]. Nevertheless, the results of several meta-analyses [10, 12, 13] and Cochrane review [11] confirmed the reduction of the risk of POAF with PP in patients undergoing coronary artery bypass grafting.

In their randomized clinical trial, N. Erdil et al. proved PP efficacy in pericardial effusion prevention when conducting isolated heart valve procedures. The effect of PP on POAF prevention in this trial was not evaluated [26]. Several studies were performed in a mixed population of patients who underwent coronary bypass surgery and heart valve procedures, however, their authors focused on the effect of PP on pericardial effusion and not on postoperative atrial fibrillation [27, 28]. Some authors used a modified technique

Table 2 Surgery characteristics

Variable	Posterior pericardiectomy (n = 49)	Control group (n = 51)	p	
Cardiopulmonary bypass time (min)	64±16	64±20	0.664 ²	0.873 ³
Cross-clamp time (min)	45±13	46±12	0.844 ²	0.751 ³
Mechanical prosthesis	35 (70%)	40 (80%)	0.419 ¹	

Data are presented as mean ± standard deviation and n (%). ¹ χ^2 test; ² Kruskal–Wallis test; ³ Van der Waerden test; LVEF, left ventricular ejection fraction.

Table 3 Postoperative characteristics

Variable	Posterior pericardiectomy (n = 49)	Control group (n = 51)	p	
Resternotomy	1 (2%)	4 (8%)	0.183 ¹	
Inotropic support (hours)	7.1±14	7.7±9	0.458 ²	0.422 ³
LOS at ICU (days)	2.6±1.6	2.3±1.0	0.312 ²	0.224 ³
Pacemaker implantation	0 (0%)	1 (2%)	0.324 ¹	
Postoperative LOS (days)	12.4±4.3	11.9±4.1	0.276 ²	0.263 ³
Chest tubes removal (POD)	4.4±1.4	3.3±0.6	<0.0001 ²	<0.0001 ³
POAF	8 (16%)	7 (14%)	0.716 ¹	
AF onset (POD)	3.6±2.5	3.0±2.6	0.551 ²	0.568 ³
AF on discharge	1 (2%)	1 (2%)	0.977 ¹	
Pericardial effusion ≥5 mm	5 (10%)	6 (12%)	0.803 ¹	
Left pleural puncture	0 (0%)	1 (2%)	0.324 ¹	

Data are presented as mean ± standard deviation and n (%). ¹ χ^2 test; ² Kruskal–Wallis test; ³ Van der Waerden test; LOS, length of stay; ICU, intensive care unit; POD, postoperative day; POAF, postoperative atrial fibrillation; AF, atrial fibrillation.

of PP with the removal of a fragment of the pericardium (“pericardial window”). Thus, J. Zhao et al. in a randomized study on a mixed group of patients showed the effectiveness of this technique in the prevention of POAF and cardiac tamponade [29]. K. Uzun et al. in a non-randomized trial in patients who underwent heart valve procedures confirmed the effectiveness of the “pericardial window” in prevention of postoperative cardiac tamponade [30].

Thus, our research might be the first to place emphasis on prevention of POAF by means of PP in patients undergoing isolated heart valve interventions.

However, in our trial there was no significant difference in the incidence of POAF in both groups. Evidently, this happened due to an extensive list of exclusion criteria and enrollment of only those patients who initially had a very low risk of POAF, so that PP could hardly impact the outcome.

It should be noted that in most cases the first paroxysm of POAF occurred prior to removing the chest tubes, which contradicts the hypothesis of the existence of a causal relationship between POAF and pericardial effusion in the above patients. Concerning pericardial effusion, the study revealed no significant difference between the groups (see Table 1). However, if in the control group pericardial effusion was localized predominantly behind the posterior surface of the heart, in some PP group patients it was localized over the right heart. This indicates the possibility of limited fluid accumulation over the right heart that can't drain into the left

pleural cavity through the hole in the posterior pericardium. Probably, a standard technique of PP surgery fails to always prevent right heart compression and cardiac tamponade. However, cardiac tamponade is a very rare complication and it is impossible to make a conclusion on the efficacy of cardiac tamponade prophylaxis by means of PP on the basis of our results.

Study limitations

Some important factors that could potentially influence the occurrence of POAF (including the inhibitors of angiotensin converting enzyme, level of thyroid-stimulating hormone and postoperative leukocytosis) have not been analyzed in our research. Several exclusion criteria were based just on the patients' history without strong confirmation (including the presence of preoperative episodes of atrial fibrillation). Continuous postoperative electrocardiographic monitoring and follow-up were short. In addition, the chosen key time points depended on subjective decisions of an attending physician (date of transfer from the intensive care unit, discharge). Overall, due to a large number of exclusion criteria (84% of patients were excluded from participation), the patients under study were not similar to those undergoing conventional surgery in real-life settings. Therefore, it may not be worthwhile to use the obtained results in routine practice.

Conclusion

The results of our trial have not confirmed the effectiveness of posterior pericardiotomy to prevent postoperative atrial fibrillation and pericardial effusion after isolated primary aortic valve replacement in low risk patients during the in-hospital period. However, further investigations are required.

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The trial was carried out within the framework of thesis research in accordance with the research plan of Kuban State Medical University and had no other financing than that allocated for post-graduate scholarships.

Conflict of interest

The authors declare no conflict of interest.

Author contributions

Conception and study design: V.I. Kaleda, K.O. Barbuhatti.

Data collection and analysis: V.I. Kaleda, S.Yu. Boldyrev, S.A. Belash, I.I. Yakuba, S.S. Babeshko, I.A. Belan.

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Final approval of the version to be published: V.I. Kaleda, S.Yu. Boldyrev, S.A. Belash, I.I. Yakuba, S.S. Babeshko, I.A. Belan, K.O. Barbuhatti.

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