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ORIGINAL ARTICLE

Quality of Life after Surgical Ablation of Persistent Atrial Fibrillation: A Prospective Evaluation

Alexander Chernyavskiy, MD [a], Yulia Kareva, PhD [a*], Inessa Pak, PhD [a], Sardor Rakhmonov [a], Evgeny Pokushalov, MD [b], Alexander Romanov, MD [b]

[a]Department of Surgery, Aorta, Coronary and Peripheral Arteries, Novosibirsk Research Institute of Circulation Pathology, Novosibirsk, Russia
[b]Department of Rhythm Disorders of the Heart, Novosibirsk Research Institute of Circulation Pathology, Novosibirsk, Russia

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Aim To compare the quality of life (QoL) of patients with persistent atrial fibrillation (AF) and ischaemic heart disease after modified mini-maze (MM) procedure or pulmonary vein isolation (PVI) using radiofrequency ablation (RFA) with patients in the control group (coronary artery bypass graft [CABG]) alone.

Methods In this prospective randomised study, we included 95 patients with persistent AF and coronary heart disease who underwent open-heart surgery combined with intraoperative irrigated RFA (irrRFA). Patients were randomly assigned to three groups: CABG and PVI using irrRA (CABG+PVI, n=31), CABG and MM procedure using irrRA (CABG+MM, n=30), and isolated CABG (CABG alone, n=34). All patients received implantable loop recorders (ILRs). Patient QoL was assessed using the Short Form 36 (SF-36) preoperatively, and one and two years post-operatively. The study primary end point was freedom from AF one year after operation, measured by implantable loop recorders (ILRs); secondary endpoint included long-term clinical outcomes.

Results No reoperations or hospital mortalities were recorded. Mean follow-up was 14.4±9.7 months. The percentages of patients free from AF determined by ILR were 80%, 86.2%, and 44.1% in the CABG+PVI, CABG +MM, and in the CABG alone groups, respectively. The QoL significantly improved in CABG+PVI and CABG+MM groups compared with CABG alone group in most domains.

Conclusion Effective elimination of AF during CABG surgery improves QoL in all physical health domains of the SF-36 and the role-emotional functioning domain. Thus, patients with concomitant AF and coronary heart disease may benefit from intraoperative radiofrequency ablation to prevent relapse of the arrhythmia.

Keywords Atrial fibrillation • Quality of life • Intraoperative radiofrequency ablation • Implantable loop recorders.

Introduction

Atrial fibrillation (AF) can be a highly symptomatic arrhythmia. Patients with AF have reported palpitations, dizziness, breathlessness, exercise intolerance, and fatigue [1]. Thus, it is unsurprising that patients with AF report a reduction in their quality of life (QoL) when compared with the age- and sex-matched individuals with sinus rhythm among the general population [2–4]. Atrial fibrillation is a chronic condition that increases the risk of patient mortality and morbidity and often requires life-long treatment, including long-term oral anticoagulation. Therefore, QoL is an important treatment outcome when measuring patients' physical, emotional, and social functioning, as well as their perceived health. The

*Corresponding author at: 630055 Russia, Novosibirsk, Stroiteley str., 9, 46. Tel.: +7 906 995 28 39, Email: julia11108@mail.ru

purpose of this study was to analyse the possible differences in the QoL of the patients according to the type of treatment of AF they underwent, using a QoL-specific questionnaire.

Methods

Study Design

The present study was designed as a prospective, blinded, parallel-group trial assessing the freedom from atrial fibrillation after different methods of surgery for atrial fibrillation. This study was approved by the local Ethics Committee and conducted in compliance with the protocol and in accordance with standard operating procedures over a period from 2008 to 2011. The study's primary endpoint was freedom from AF one year after operation, measured by implantable loop recorders (ILRs); secondary endpoint included long-term clinical outcomes.

The sample size for addressing the primary endpoint was calculated on the basis of differences in freedom from AF in previous study involving patients treated with RFA vs control group [5]. Assuming a 36% improvement with treatment and applying the variance seen in our patients, we anticipated a sample size of 30 per group to show a significant difference ($p<0.05$) at power of 90%.

The procedure of randomisation to CABG and PVI (CABG +PVI), CABG and MM (CABG+MM), and isolated CABG (CABG alone) groups was performed in blocks of 10 with an allocation ratio 1:1 using sequentially numbered, opaque, sealed envelopes. The designated person coordinating the study, who was not involved in filed procedures, was responsible for the preparation of the randomisation list. Patients participating in the study and the investigators evaluating the outcomes were blinded to group assignment.

Following this randomisation procedure, the patients were allocated to one of the following three groups: CABG with radiofrequency pulmonary vein isolation (CABG+PVI, n = 31); CABG with a radiofrequency-modified mini-maze procedure (CABG+MM, n = 30); and isolated CABG (CABG alone, n = 34). The study's primary endpoint was estimated in previous work [6]. In this study we evaluated the secondary endpoint which included QoL.

Inclusion criteria were:

1. Presence of persistent AF. Patients had to have a documented history of persistent AF, as defined by the ACC/AHA/ESC Guidelines [7]: ''episodes of non-self-terminating atrial fibrillation that usually last more than 7 days''.
2. Presence of coronary artery disease with indications for CABG surgery.
3. Men or women who were aged 30 to 75 years (inclusive) on the day of signing the informed consent and were willing to comply with the study requirements.
4. Ability to take the anticoagulant warfarin (Coumadin)

Exclusion criteria were:

1. History of CABG.
2. Need for urgent cardiac surgery (e.g. cardiogenic shock).
3. Pregnancy or desire to be pregnant within 12 months of the study treatment.
4. Rheumatic heart disease.
5. Wolff–Parkinson–White syndrome.
6. Contraindication for anticoagulation therapy.
7. Current diagnosis of active systemic infection.
8. Presence of comorbidities of other systems, which might lead to death within the first three years after surgery.

The baseline assessment included clinical evaluation, study of QoL, standard laboratory tests, 12-lead ECG, transthoracic and transoesophageal echocardiography, and coronary angiography. Baseline characteristics of patient population are seen in Table 1. Operative technique was described in a previous paper [6].

Table 1: Baseline characteristics of patient population.

Short Form 36 (SF-36)

The SF-36 questionnaire evaluates eight health domains: physical functioning, role-physical functioning, bodily pain, general health, vitality, social functioning, role-emotional functioning, and mental health. The scores range from 0 to 100, with higher scores reflecting better functional status and well-being. All patients underwent QoL assessment based on SF-36 domain scores preoperatively and at one and two years postoperatively.

Statistical Analysis

Results are expressed as average ± standard deviation, or as numbers and percentages, as appropriate. Continuous variables were compared by one-way ANOVA. The Mann–Whitney *U*-test was used if normal distribution criteria were not met. Kaplan–Meier analysis with the log-rank test was performed to analyse the AF-free survival rates.

Results

In our study, the mean clinical follow-up time was 14.4±9.7 months. All data were collected in our clinic. During follow-up in the CABG+PVI group, we failed to contact one patient. In the CABG+MM group, one patient was unable to attend the follow-up visit for family reasons.

There were no cases requiring permanent pacemaker implantation for sick sinus syndrome or atrioventricular block because of ablation. No reoperation due to bleeding was required. No complications related to the ablation or monitoring device implantation occurred. No in-hospital mortality was recorded. All patients were discharged in sinus rhythm. No patient was excluded during ILR implantation and follow-up because of sensing problems, and the investigators analysed all data. There were no thromboembolic events during the 24-month follow-up.