The effect of aerobic physical rehabilitation on the quality of life in patients with chronic atrial fibrillation; A randomized controlled clinical trial study

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Original Article

Abstract

BACKGROUND: Management of atrial fibrillation (AF), besides prevention of stroke, mainly stresses symptom control and improvement of quality of life (QOL). In patients with permanent AF, exercising may improve QOL, rhythm, and symptoms. The purpose of this study was to determine the impact of aerobic physical rehabilitation on the QOL of patients suffering from AF and admitted to a coronary care unit (CCU).

METHODS: This randomized controlled clinical trial study was conducted on 50 patients who were hospitalized with chronic AF in the CCU of Montazeri Hospital, Najafabad, Iran, and had the inclusion criteria. The participants were selected using convenience sampling method, and were randomly divided into experimental (n = 25) and control (n = 25) groups. The experimental group received a rehabilitation program in the form of an educational package and scheduled physical activity of aerobics for 8 weeks, and the control group received CCU routine care. The researcher measured the patients' QOL before and after the intervention using the 36-Item Short Form Health Survey (SF-36).

RESULTS: There was no significant difference in the mean score of total QOL between the control and experimental groups before the intervention (P > 0.050). However, the comparison of the mean score of total QOL after the intervention showed a significant increase in the experimental group (P < 0.050).

CONCLUSION: Aerobic rehabilitation activities are effective on the QOL of patients with chronic AF.

Keywords: Aerobic Exercise, Rehabilitation, Quality of Life, Atrial Fibrillation, Coronary Care Units

Introduction

Atrial fibrillation (AF) is the most common form of sustained arrhythmia; this indicates an epidemic and growing disease.[1] It is predicted that its prevalence will reach 12.1 million people in 2030 compared to 5.2 million people in 2010, which is mainly due to aging.[2] Its prevalence is 0.3% per year in the United States, and it is, economically, a costly disease.[3] AF is an arrhythmia often independently connected with increased morbidity and mortality. This disease is associated with complications such as ischemic stroke, systemic thromboembolism, heart failure, and increase in hospitalization. Although AF can occur without symptoms, two-thirds of patients experience its symptoms. Management of AF, besides prevention of stroke, mainly stresses symptom control and improvement of quality of life (QOL). This disease has symptoms such as palpitations, shortness of breath, and fatigue.[4]

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Studies conducted on Health-related Quality of Life (HRQoL) in chronic diseases indicate adverse effects on the physical, psychological, and social performance of the patients. Thus, measuring QOL has become important in the treatment of heart diseases.[5]

Most atherosclerotic cardiovascular disease (ASCVD) factors are also connected with AF. Although most guidelines have confirmed these risk factors, no suggestions have been provided in this regard based on diet, exercise, changes in QOL, and initial and secondary preventions.[6] Based on the international guidelines, many patients with AF are advised to increase their physical activity because of their illness.[7,8] Exercise could be an important supplement and, in some cases, an appropriate substitute for drugs or an invasive technique, and is associated with much fewer risks and complications.[9] As a preventive treatment, exercise should be recommended daily, as is done for a pill. In 2013, the American Heart Association made a scientific statement concerning standards of exercise for testing and education. Sports and physical rehabilitation improve risk factors for ASCVD, and have anti-adrenergic, anti-inflammatory, anti-ischemic, anti-arrhythmic, and anti-thrombosis effects.[10] In patients with permanent AF, QOL, rhythm, and symptoms improved after exercise.[11] Moreover, studies have shown that a moderate level of exercise is useful for patients with AF, and plays a protective role for them.[12,13] Changes in lifestyle and the correction of risk factors reduce AF and its recurrence after lactation, and exercise should be included in the management of AF.[14] Aerobic Interval Training (AIT) is an effective and distinctly controlled method. This method has the potency to be done with higher activity, and induce more biological effects compared to regular exercise.[15,16]

During the years of working in a coronary care unit (CCU), the researcher has seen that patients and their families do not have sufficient information and knowledge on the disease, rehabilitation measures, and cardiac rehabilitation. Moreover, sometimes, due to a misconception of heart problems, they are unable to return to normal work and life. Furthermore, considering the insufficiency of existing knowledge, lack of studies in this field, and the different and contradictory results of various studies on the effect of cardiac rehabilitation on the QOL of patients with AF, the present study was planned and conducted. With the aim to assess the effect of cardiac rehabilitation on the QOL in these patients, we compared the scores of QOL in pre- and post-intervention in both the intervention and control groups, as well as between the groups. Our hypothesis was that cardiac rehabilitation can improve the QOL in these patients.

Materials and Methods

This randomized controlled clinical trial study with parallel design included two groups and was conducted in two stages with a pretest-posttest design.

The population consisted of patients, diagnosed with chronic AF and admitted to the CCU of Shahid Mohammad Montazeri Hospital, Najafabad, affiliated to Isfahan University of Medical Sciences, Iran. The sample size was calculated using the sample size calculation formula based[17] on confidence index (Z_1) of 1.96, test power (Z_2) of 0.84, and the margin of error (d) of 0.8. Subjects were selected through convenience sampling and were assigned to study and control groups based on the random numbers table. That number was chosen by using the random number table by closing the eyes by placing a finger on one of the numbers. The direction of movement was predetermined and horizontally to the right, then upwards, and then to the left of the table; each number in the group A or test group was placed and each pair number was entered in group B or control.

The inclusion criteria of the study were age of 30-75 years, stable physical condition, anticoagulants use, lack of pregnancy and breastfeeding, willingness to participate in the study (patient and his/her family), AF with a ventricular response below 100, and lack of presence of angina and valvular diseases. The exclusion criteria were severe resistant hypertension, severe and moderate lung disease, re-admittance after discharge in the past month, the inability to enforce or comply with the study protocol, AF with a rapid ventricular response above 100, coagulation disorders, and AF with a pacemaker or implantable cardioverter defibrillator (ICD). Patients, who had the study inclusion criteria, participated in the research, and in case of their unwillingness to cooperate at any stage of the research and any change in any of the conditions of inclusion at any stage they were excluded. Finally, the study was conducted on 50 patients admitted to the CCU with a diagnosis of chronic AF.

Data collection methods used were observation (arrhythmia, HR) and interviews, and the tools used were the patients' medical records and a questionnaire. The questionnaire consisted of two parts. The first section included a demographic

questionnaire, which had two parts, namely personal information and health and medical characteristics of patients associated with AF. The second section was the 36-Item Short Form Health Survey (SF-36). The questionnaire was completed before and after the intervention for both groups.

To assess QOL, the SF-36 was used which is a standard questionnaire the reliability of which has been approved by Montazeri et al. (Cronbach's alpha = 0.7).[18] This questionnaire consists of two parts, general physical health and mental health. This questionnaire was developed by Ware and Sherbourne, consists of 36 items, and measures 8 domains.[19] These domains include physical function, physical limitation due to physical problems, emotional limitation due to mental problems, vitality, mental health, social function, body pain, and general health. The total score in this questionnaire ranges from 0 to 100, where higher scores show a better QOL. As it was mentioned before, the questionnaire was completed before the intervention (upon admission to the CCU) and at the end of the intervention by the subjects. The average scores of each individual before and after the intervention were compared.

The study was done from 22.10.2016 to 5.6.2017. In the first stage, the participants became acquainted with the nature and manner of the study and gave their written consent for participation, and then, the pretest was administered by having them answer the SF-36.

The experimental group underwent a rehabilitation program in the form of a training package consisting of the aerobic scheduled physical activity in two four-week periods. Aerobic exercises, designed in consultation with a few trained practitioners in this field, physiotherapist, and patient's physician, were conducted 2 sessions a week with light to moderate intensity based on the decision of cardiologist. Each session lasted 60 minutes and consisted of 10 minutes of warm up, 40 minutes of treadmill movements, and 10 minutes of relaxation and cooling. In first 4-week period, the rehabilitation program consisted of exercises with intensity of 40-50 percent of maximum oxygen consumption or heart rate, and maximum metabolic equivalent (MET) of 3.0-5.9; in second 4-week period, the same program was done with intensity of 70-80 percent of maximum oxygen consumption or heart rate, and maximum MET of 8.9. This aerobic physical rehabilitation program was conducted for patients in groups of 5 to 7 individuals. It is noteworthy that there was no coercion to continue the activity during the sessions, and in the event of fatigue and shortness of breath, according to the Borg Scale, the participant would not continue the training.

For the control group, the routine care program was implemented that describes physical rehabilitation as verbal conversation and is more often the response to the patient's questions about the educational and training pamphlet. During this, the control group subjects did not participate in any organized sports programs. For this group, 3 sessions of training were held at the beginning of the course, and on the fourth and eighth weeks. In both groups, to assess the secondary outcome of the intervention that was the effect of cardiac rehabilitation on ejection fraction (EF) of left ventricle in patients with AF, echocardiography was carried out at the time of admission and after the intervention. After completing the exercises, a posttest was performed through both groups answering the questionnaires. The SF-36 was completed once more.

The Kolmogorov-Smirnov test was used to test the distribution of variables. It showed that the distribution of quantitative variables follows a normal distribution. Between-group comparisons were done by conducting the independent sample t-test (for quantitative variables), and paired t-test was used to compare the mean of each of the quantitative variables between before and after the intervention in each group. Discontinuous variables were analyzed using the chi-square test and Fisher's exact test. Continuous variables were presented as mean ± standard deviation (SD) and categorical variables as number and percentage. T-test was used for continuous data analysis and chi-square test for categorical data analysis. All P values of less than 0.05 were considered statically significant. Data were analyzed using SPSS software (version 18, SPSS Inc., Chicago, IL, USA).

The Ethics Committee of Isfahan University of Medical Sciences approved this study with the code IR.mui.rec.1395.3052. Then, the researcher presented the introduction letter from his university to the study group and the subjects, and received written consent forms from all the subjects of the research community for participation in the study. They were all ensured that all information obtained would be kept confidential, and they would be provided with the research results if they wished to have them. The study was registered in the Iranian Registry of Clinical Trials (IRCT) (IRCT2016122727073N2).
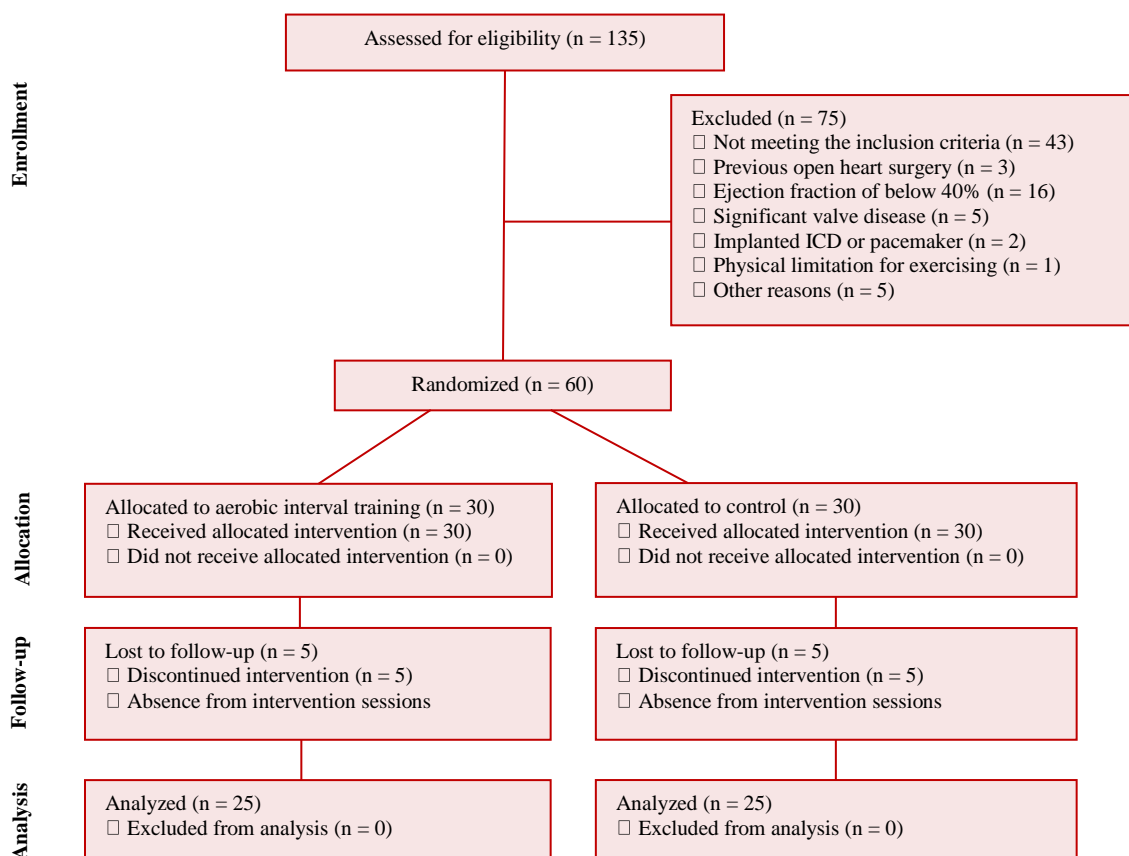
Figure 1. CONSORT diagram of the study

Results

From 135 patients, 60 individuals with inclusion criteria were entered the study.

Of the 60 participants, 50 individuals completed the study; 10 patients (5 from each group) were excluded from the study due to absence in cessions (Figure 1).

The results of this study indicated no significant differences between the control and experimental groups in terms of demographic variables, cardiac risk factors, AF duration, warfarin consumption (mg), signs of AF, quantitative variables of blood pressure, quantitative variables of heart rate, and consumed drugs (P > 0.050) (Tables 1 and 2).

The mean score of QOL in the experimental group before the intervention was 53.2 ± 3.2. After the intervention, the overall mean of QOL was 72.62 ± 2.50. Paired t-test showed that in the experimental group, the mean scores of overall QOL and its domains, except mental health, statistically increased after the intervention (P < 0.050) (Table 3).

Table 1. The mean of some demographic and clinical characteristics variables in the two groups

Variable	Experimental group (n = 25)	Control group (n = 25)	P
	Mean ± SD	Mean ± SD	
Age (year)	57.2 ± 7.4	59.9 ± 7.5	0.200
Weight (kg)	78.1 ± 13.0	75.4 ± 8.3	0.380
Height (cm)	165.9 ± 8.6	165.4 ± 7.9	0.840
Abdominal circumference (cm)	96.7 ± 8.3	95.7 ± 6.3	0.650
BMI (kg/m^2)	28.4 ± 4.6	27.6 ± 2.7	0.440
Atrial fibrillation duration (year)	2.2 ± 1.3	2.6 ± 2.0	0.420
PT	23.0 ± 5.6	24.7 ± 2.7	0.180
INR	1.9 ± 0.5	1.9 ± 0.3	0.630
EF	54.0 ± 6.3	50.9 ± 7.3	0.110

BMI: Body mass index; PT: Prothrombin time; INR: International normalized ratio; EF: Ejection fraction; SD: Standard deviation

Table 2. Frequency of some clinical characteristics and past medical history variables in the two groups

Variable	Experimental group (n = 25) n (%)	Control group (n = 25) n (%)	P
Sex (male)	10 (40)	13 (52)	0.400
Medical history			
Hyperlipidemia	5 (20)	8 (32)	0.330
Hypertension	19 (76)	20 (80)	0.730
Diabetes	3 (12)	5 (20)	0.350*
Smoking	2 (8)	4 (16)	0.330*
Overweight*	13 (52)	12 (48)	0.780
Clinical symptoms			
Dyspnea	16 (64)	18 (72)	0.540
Palpitation	16 (84)	20 (80)	0.210
Dizziness	9 (36)	11 (44)	0.560
Weakness	11 (44)	10 (40)	0.770
No symptoms	2 (8)	3 (12)	0.500*
Medication at baseline			
Antiplatelet	12 (48)	8 (32)	0.250
Flecainide	1 (4)	0 (0)	0.500*
Amiodarone	2 (8)	3 (12)	0.500*
Sotalol	0 (0)	0 (0)	> 0.990
Digoxin	5 (20)	7 (28)	0.510
Calcium Blocks	7 (28)	3 (12)	0.160
β-Blockers	9 (36)	6 (24)	0.350
ACE I-ARB	14 (56)	16 (64)	0.560
α-Blocking agents	7 (28)	9 (36)	0.540
Statin	7 (28)	9 (36)	0.500
Warfarin	24 (96)	25 (100)	0.500*

Overweight: Body mass index (BMI) > 25 kg/m^2
ACE-Is: Angiotensin converting enzyme inhibitors; ARBs: Angiotensin receptor blockers
* Fisher's exact test; Other items: Chi-square test

The mean score of the QOL in the control group before the intervention was 51.9 ± 2.8. After the study, the overall mean score of QOL was 52.9 ± 2.7. Paired t-test showed that in the control group, the mean score of overall QOL and its domains did not have significant changes after the intervention compared to before it (P > 0.050) (Table 3).

Table 3. The mean of total quality of life score and its domains before and after the intervention in the two groups

Aspects of quality of life	Group	Before the intervention Mean ± SD	After the intervention Mean ± SD	P*	Mean differences Mean ± SD	P**
Physical function	Experimental	62.5 ± 4.10	88.9 ± 1.7	< 0.001	26.4 ± 3.1	< 0.001
	Control	61.2 ± 4.30	59.7 ± 4.3	0.450	-1.5 ± 1.9	
Limitation due to physical problems	Experimental	40.4 ± 5.90	66.0 ± 6.3	< 0.001	25.6 ± 3.9	< 0.001
	Control	37.0 ± 6.50	35.0 ± 7.1	0.630	-2.0 ± 4.1	
Limitation due to mental problems	Experimental	39.5 ± 6.60	76.0 ± 7.1	< 0.001	36.5 ± 5.9	< 0.001
	Control	36.0 ± 7.90	36.0 ± 8.1	> 0.990	0 ± 0	
Vitality	Experimental	60.4 ± 3.40	67.4 ± 3.2	0.020	7.0 ± 2.8	0.040
	Control	57.2 ± 3.70	56.4 ± 3.3	0.760	-0.8 ± 2.6	
Mental health	Experimental	58.1 ± 4.70	62.1 ± 4.2	0.340	4.0 ± 1.4	0.490
	Control	57.9 ± 3.90	58.4 ± 3.2	0.870	0.5 ± 2.9	
Social health	Experimental	62.5 ± 4.02	80.5 ± 3.5	< 0.001	18.0 ± 3.2	< 0.001
	Control	60.8 ± 2.90	62.5 ± 3.5	0.580	1.7 ± 3.1	
Body pain	Experimental	62.0 ± 4.40	78.8 ± 2.8	0.001	16.8 ± 4.4	0.008
	Control	60.5 ± 3.70	61.0 ± 3.7	0.900	0.5 ± 3.9	
Overall health	Experimental	43.4 ± 3.80	55.9 ± 4.4	0.006	12.5 ± 4.2	0.010
	Control	44.8 ± 2.90	44.0 ± 2.4	0.780	-0.8 ± 2.8	
Total quality of life score	Experimental	53.2 ± 3.20	72.6 ± 2.5	< 0.001	19.4 ± 1.8	< 0.001
	Control	51.9 ± 2.80	52.2 ± 2.7	0.800	0.3 ± 1.4	

* Paired samples t-test; ** Independent samples t-test; SD: Standard deviation

The comparison of the mean changes in the overall QOL score and its domains after and before the intervention in the two groups is presented in table 3. Independent t-test showed that after the intervention, the mean total score of QOL and its domains in the experimental group, except mental health, were significantly more compared to control group (P < 0.050). However, the mean value of mental health score changes did not differ significantly between the two groups (P > 0.050).

Based on our findings, in experimental group, the mean EF was 54.0 ± 6.3 percent before the intervention; which changed to 57.1 ± 5.6 percent after it. Paired t-test showed that EF significantly increased in this group (P < 0.050). But in control group, the mean EF was 50.9 ± 7.3 and 50.8 ± 7.5 percent before and after the intervention, respectively, which showed no significant difference (P > 0.050). Moreover, the mean EF was not significantly different between the two groups before the intervention (P < 0.050).

Discussion

The existence of no differences between demographic variables and QOL before the intervention in the two groups suggests appropriate homogeneity between the groups. A statistically significant difference was not observed in QOL the end of the intervention in the control group. However, in the test group, improvement was evident in all aspects of QOL, excepting mental health. According to the findings, the QOL of patients with AF improved significantly (P < 0.050) after rehabilitation, which was consistent with the results of Malmo et al. in Norway.[17] They indicated that aerobics reduces AF load and improves QOL at physical and mental health levels. However, in their study, all aspects of QOL had increased in the experimental group, except for the level of mental health and euphoria that was higher in the control group.[19] Moreover, the result of another review by Santos-Lozano et al. in the United States indicated that sports interventions in patients with AF increase VO$_2$ peak and QOL in these patients.[20] Another study by Conraads et al. Conducted in Belgium showed that 12 weeks of aerobic exercise had a significant effect on VO$_2$ peak, QOL, and some of the risk factors for cardiovascular diseases (P < 0.001).[21] Moreover, the clinical trial paper by Osbak et al. in Denmark showed that muscle strength, exercise capacity, and QOL increase with exercise in people with AF.[22] In another study in Canada, Giacomantonio et al. showed that

moderate physical activity can improve the capacity for daily living activities, and overall QOL in people with AF.[23] Furthermore, in a meta-analysis conducted in Texas in 2016 on atherosclerosis and AF, Mohanty et al. showed that an average amount of physical activity reduced the risk of AF and increased QOL in both women and men.[24]

In this regard, contradictory results have also been reported in studies. An example is a review study conducted by Risom et al. in Denmark on cardiac rehabilitation for adults with AF. Given the small number of patients and the random results, they could not examine the actual impact of exercise-based cardiovascular rehabilitation on mortality or complications and their findings suggested no clinically relevant effect on QOL, but an increase in physical capacity as a result of exercise.[25] This study was inconsistent with the present study findings due to the small number of patients and randomized results. Moreover, Dakei et al. conducted a study in Kermanshah, Iran, entitled "The Effect of Two Resistance and Aerobic Protocols on Performance Capacity and Quality of Life in Male Patients after Myocardial infarction".[26] Their results showed that in terms of QOL, no significant difference existed between the 3 groups of resistance, endurance, and control over time. This may be due to the low volume of samples (24 men in 3 groups of 8 individuals).[26]

The results of most of the above studies are in line with the present study, indicating that aerobic rehabilitation can improve the QOL of patients with AF. The learning of cardiac rehabilitation by nurses is easy as they pass academic education at universities, and the implementation of these activities in the clinic does not have high costs. Thus, training these activities to the nurses working in cardiovascular departments can improve the QOL of patients and their physical and mental health indices. Moreover, it is possible to improve patients' QOL by educating patients about the principles of rehabilitation and the gradual progression of activities. Moreover, by doing so, complications caused by lack of awareness and the patient's non-observance of appropriate activities at the time of recovery can be prevented after discharge, resulting in a reduction in frequent hospitalization and related costs. Nevertheless, performing these rehabilitation activities requires the training of patients and monitoring of the correct functioning of rehabilitation activities.

Of the limitation of this study was the individual differences in patients that could be effective on the

QOL of individuals, which the researcher could not control. In addition, the results are only generalizable to those who refer to the CCU.

Finally, the researchers recommend that a similar study be conducted with more participants and for a longer duration.

Conclusion

The results of this study, as well as other studies conducted in the field of rehabilitation of patients with AF, suggest the improvement of QOL through the performance of cardiac rehabilitation intervention. Thus, given the increase in the aging population, the increase in the rate of AF, and the role of nurses in promoting health and empowerment of patients with the help of these programs, it is necessary to pay more attention to the rehabilitation of these patients.

Acknowledgments

Conflict of Interests

Authors have no conflict of interests.

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