Effect of self-management interventions on complications of atrial fibrillation: A clinical trial.

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Abstract

Background: Atrial Fibrillation (AF), the most common chronic cardiac dysrhythmia, is an important cause of morbidity and mortality. Various studies have shown that self-management plays a key role in prevention of complications, improving life style and medical care cost reduction in chronic diseases. Therefore it is quite necessary to strengthen the patients with chronic diseases to apply self-management behaviors. Thus, present study aimed to evaluate the effects of self-management interventions on life-style and disease complications in patients with AF.

Methods: Total of 72 patients were randomly allocated to intervention (36 cases) and control (36 cases) groups. To provide better training, the intervention group was then divided into 2 subgroup of 18 cases. Educational intervention took 3 weeks including 60 minutes sessions (2 sessions each week). After this period of time, patients were given educational handbook. Follow up intervention included 3 times telephone follow ups (after the 4th, 8th and 12th week of study). Cases in control group received usual care. All data were collected using demographic questionnaire, Walker life style questionnaire and complication check list. Data collection was done at three points (before the intervention, after first and third month of intervention). The collected data were analyzed using the SPSS statistical software package version 21. Chi-square test, Fisher's exact test, and t- independent test were used.

Results: In terms of demographic and clinical characteristics, no significant difference was found between two groups. Results revealed a significant increase in life style score after first and third month of study (P<0.001). Rate of re-admissions due to AF and bleedings due to anticoagulants did not show significant differences after the first month in both groups. But it had increased significantly after third month of study in control group (P<0.05). There was no significant increase in cerebral embolic complications in both groups (P>0.05).

Conclusion: Findings showed that self-management interventions can be applied to improve life style and reduce complications in patients with AF. However more studies are required to evaluate effects of these interventions on AF cerebral embolic complications in longer periods of time.

Keywords: Atrial fibrillation, Arrhythmias, Cardiac, Self care.

Introduction

Atrial fibrillation (AF) as the most common cardiac arrhythmia in 1-1.5% of general population [1]. The prevalence rate of AF is 0.5% in individuals aged 40-50 years old to 15% in 80 years old with higher risk of morbidities in men than in women [2,3]. It is associated with a five-fold greater risk of thromboembolism and stroke and other complications including neurologic injury, organ failure, and emergency department (ED) re-admissions [1,2]. The increased health care costs of AF is due to its treatment, hospital admissions, and long-term nursing home care [1,2]. AF risk factors are diverse and include coronary heart diseases, cardiac failure, cardiomyopathy, hyperthyroidism, diabetes, alcohol usage,

hypoxia, and etc. [4]. AF is manifested by various symptoms such as vertigo, tachycardia, shortness of breath, fatigue, chest pain, and syncope [4,5]. Clinical symptoms relief and risk of complications reduction is considered as the current management of AF [4,6]. Diagnostic criteria of AF include physical exam, electrocardiogram, chest radiograph, transthoracic echocardiogram, blood tests [5].

Most recommended treatment for AF is anticoagulant drugs, along with rate and rhythm control of patients [4]. Evidence showed that educational and behavioral interventions can improve patient outcomes such as quality of life (QOL), reduced pain, and decline in complications [7-9]. To date, number of studies has utilized self-management skills; which

refers to the personal's capability to manage the symptoms of disease, improve life style, and decrease medical care costs. Several guidelines recommended the educational aspects of self-management in AF treatment [7,8,10]. The role of self-management in significant reduction of thromboembolism and mortality causes has been shown by Cochrane reviews [11]. A qualitative study has been focused on psycho educational programs to apply self-management behaviors in patients with AF [12]. The major recommendations for the management of AF in adults have been provided through the several algorithms and clinical highlights such as personalized package of care and different interventions to prevent stroke have been suggested [13,14].

To our best knowledge, information obtained from studies can guide upcoming researches and provide well-being procedures for effective self-management interventions of AF [1,3,4]. Therefore it is required to improve and recover the life condition of patients with chronic diseases including AF. Thus, present descriptive study aimed to evaluate critical gaps in educational programs and self-management interventions of QOL in patients with AF.

Materials and Methods

Study design and setting

In the present clinical trial, adult patients with AF who referred to Fasa Vali-Asr Hospital, Fasa, Iran, were included in the study. This study was approved by the Ethics Committee of Shiraz University of Medical Sciences and registered on Iranian Registry of Clinical Trials (No. IRCT2015082023606N3). All participants gave informed consent and filled the forms before being included in study. They were randomly allocated to control and intervention groups by a person other than the researchers.

Ethical considerations

In order to comply with the ethical issues the following actions were applied:

• All recommendations of Helsinki protocol and privacy of patient information has been considered.
• An introduction letter from the School of Nursing and Midwifery has been received
• A premition has been received from the hospital administrators (Fasa Vali-Asr Hospital)
• A written consent has been received from the patients
• All patients were free to participate in the study
• Educational booklets has been delivered to the control group at the end of the study
• All hospital administrators and their colleagues has been appreciated at the end of the study
• Transportation cost has been paid to all participants

Participants and inclusion criteria

Simple sampling method was used. Total of 72 patients with recently diagnosed with resistant or recurrent AF approved by cardiologist team and admitted to C.C.U, post C.C.U and emergency department (ED) with 18 years or greater, ability to communicate and understand Persian language were included. Participants who were unwillingness to continue the study or to fill informed consent forms and had medical problems such as cancer, stroke, renal or heart failure were excluded from the study. Patients were randomly allocated to 2 groups: intervention (36 cases) and control (36 cases) using block randomization. To provide better educational sessions, the intervention group was then divided into 2 subgroup of 18 cases. In addition, those who were absent more than 2 times in educational sessions were excluded from the study.

Instrument

Demographic information questionnaire: According to the review of literature, this questionnaire was prepared and developed by experts. It was then filled by interviewers and contained information about the patient's age, gender, marital status, education, occupation, place of residence, diseases, medications, duration for atrial fibrillation and frequency of hospitalizations due to this complication, smoking, alcohol and narcotic drugs abuse.

Life style questionnaire: The second version of health-promoting lifestyle questionnaire [15] were used to measure health promoting behaviors. This questionnaire consists of 52 items including nutrition, physical activity, and responsibility for health, stress management, interpersonal relationships and spiritual growth. Four spectrum of Likerti-point response (never, sometimes, often and routinely) was asked to the respondents. The overall score of lifestyle health promotion and behavior aspects using the average of 52 items for each sub-category was calculated individually based on the relevant items. In this study, the mean score of lifestyle was compared before and after the intervention. It is widely used in other researches and its validity and reliability have been reported in various populations. It is now available in different languages.

Cronbach's alpha coefficient was evaluated and the presenting values for the entire tool were 0.82 and for the subcategories were in the range of 0.54-0.91. All items showed significant correlation (up to 0.34). Findings of retest showed the stability of life style questionnaire and its subcategories. Confirmatory factor analysis of six-factor model represented an acceptable qualification. Assessment of latent structures in measurement model reduced items to 49 out of 52 [16].

Checklist of AF complications and its treatment: The Checklist have been prepared by cardiology specialists during the literature review process. This form was completed according to complications of AF and under the supervision of specialists. It was included the number of cases which were hospitalized due to recurrence or exacerbation of AF, symptoms of bleeding and cerebral embolism during the evaluation period.

Intervention

Taking into ethical considerations and gaining the permission from the relevant authorities the steps below were followed:

- Cases were chosen based on inclusion criteria.
- The sampling process was carried out during April and May 2015.
- After obtaining the written informed consent, demographic and lifestyle questionnaires were filled by the patients and checklist of AF complications was also filled by the researcher according to patient's statement and their medical records.
- Cases who had AF complications or not during 3 months before the intervention were examined.

Cases (n=36) were divided into 2 subgroups with 18 subjects in each group. Interventions were performed on 2 parts during the twelve weeks (from mid-June to mid-September 2015). In first part, educational intervention was conducted during three weeks (one-hour sessions in three weeks) based on the study of literature. Training was composed of various aspects of treatment and disease including pathophysiology of disease, AF characteristics (causes, consequences, and complications), treatment, programs, symptom control, challenges in psychosocial management of AF, and skills for self-management of chronic diseases such as problem solving, decision making, benefit from the resources, and networking collaboration between patients. At the end of this period patients were received educational handbook.

Second part, telephone follow up, included three times follow ups at the end of the fourth, eighth and twelfth weeks of intervention. This part aimed to evaluate quantity of applied educations by patients, answer their questions and motivate them to participate in self-management activities. Cases in control group received usual cares and training program. All data were collected using demographic questionnaire, Walker life style questionnaire and complication check list. Data collection was done at three points (before intervention as the baseline data, after first month and third month of intervention period).

Statistical analysis

The collected data were analyzed using the SPSS statistical software package version 21 (SPSS Inc, Chicago, IL, USA). In terms of demographic characteristics, the comparisons of two groups were performed using chi-square test, Fisher's exact test, and t- independent test. Changes in qualitative and quantitative clinical characteristics between two groups were analyzed using chi-square test, and t-independent test. Independent t-test and post-test analysis of variance was used to compare the differences in lifestyle, number of hospitalizations, cerebral embolic complications, and bleeding risk between two groups. A difference of P<0.05 between groups was considered significant.

Results

Demographic characteristics of patients

A total of 88 patients diagnosed with AF, of which 72 were willing to participate in study and fill a consent form. Patients were divided into 2 groups as intervention (36 cases) and control (36 cases). The mean age of patients was 59 ± 13 in both intervention and control group. The comparison of patient's distribution as qualitative and quantitative demographic variables showed that most of the subjects in the intervention (55.6%) and control (63.8%) groups were male. The marital status of most patients is married with 66.6% in the intervention and 63.8 in control group. The education level of most of the patients was high school diploma with the percentage of 86.2% and 88.8 in intervention and control group, respectively. In terms of demographic characteristics of patients, there is no difference between intervention and control group (P>0.05).

Clinical characteristics of the patients

Variables that were evaluated as clinical features of patients include history of disease and treatment such as hypertension, heart failure and attack, diabetes, transient brain stroke, renal and liver failure, coagulation problems, depression and treatment with warfarin, aspirin, methoral, gabapentin, penthoral, atorvastatin, nitroglycerin and digoxin. History of disease in both group (intervention and control) was compared. Most of the patients had hypertension, heart attack with 22.2% in intervention and 16.6% in control group. Warfarin, aspirin and digoxin had been consumed as a common treatment by most of the patients in both groups. The mean period of time after diagnosis of AF (month) was 11.5 ± 8.9 and 4.17 ± 12.2 in intervention and control group, respectively. The mean numbers of hospitalization due to AF was 5.15 ± 0.19 in intervention and 6.21 ± 0.37 in control group. No significant differences was observed between the qualitative and quantitative characteristics of AF in both group (p>0.05).

Smoking, alcohol and drug abuse habits between groups of the study

Smoking habits was found in only 25% and 22.2% of patients in both group of study. Small number of patients consumed alcohol (5.50 *vs.* 4.16) and abused narcotic drugs (8.33 *vs.* 5.55) in intervention and control group, respectively. Any significant correlation was not found between the groups (p>0.05).

Comparison of major characteristics of AF before and after intervention in both groups

According to the T-independent statistical test, there was any difference between the mean score of lifestyle in 2 groups before intervention (p>0.05). The mean score of lifestyle in intervention group was increased during one and 3 months after intervention compared with the control group (Table 1). In addition, comparison of mean score of lifestyle in

intervention groups showed a significant increase between the months of intervention. In terms of the mean score of lifestyle, there was a significant difference between two groups over time (p<0.001).

The number of patients with recurrence or exacerbation type of AF who were in the intervention group showed a slight increase after 3 months of intervention than 3 months before the intervention (Table 2). In addition, the number of cases in control group increased over time which was statistically significant (p<0.05). There is no significant correlation between the cerebral embolic complications of AF in 2 groups after one and 3 months of intervention (p>0.05).

The bleeding caused by oral anticoagulant increased in cases who were in control group, but it was not statistically significant (p>0.05) (Table 2). Bleeding risk of AF caused by oral anticoagulant more increased over time in control group, which was statistically significant (p<0.05). In terms of bleeding caused by oral anticoagulant, there was a meaningful correlation between intervention and control group (p<0.05) (Table 2).

Discussion

Development of QOL is essential for patients with AF. Behavioral interventions have been applied in different settings. Several methods attempted to improve and modify behavior of patients on symptoms of disease. Comprehensive training programs covering disease knowledge, treatment, diet, self-care as patient's abilities need to apply in this area. The main goal of present study was to improve the QOL of patients with AF through the self-management interventions that also educated patients who suffered from lack of sufficient information about their disease. Based on the findings of this study, both intervention and control groups were not significantly different concerning demographic and clinical variables. Therefore, changes in lifestyle, number of hospitalizations, cerebral embolic complications and bleeding induced by oral anticoagulant could be evaluated with more confidence in intervention group. Findings of the lifestyle scores of patients with AF in both groups over time showed that the time has been significant factor for change in total lifestyle scores of participants. The results from the interaction of time/group showed the significant effect of self-management on the intervention group. The mean score of lifestyle showed 5.42 score increase in intervention group overtime than 0.75 in control group. The results of present study are consistent with results of previous study. Physical, mental and social problems followed by cardiovascular diseases such as AF can impact on the patient's lifestyle. Therefore, the lifestyle will be more change with increases in number of problems. Ellsworth et al. suggested that intensive lifestyle change programs had important role in primary prevention in patients with increased risk of clinical cardiovascular disease (CVD) [17]. Mohammadizeidi and colleagues reached the conclusion that patients with cardiovascular disease showed variable lifestyle conditions [18]. In a study performed by Vahedi et al. in 2016, health-

promoting lifestyle of patients with and without diabetes has been compared. Their finding showed that scores of factors such as stress management, physical activity and nutrition were significantly lower in patients with diabetes than without diabetes. They concluded that patients with diabetes need more attention to manage the disease [19]. Data pooled from a systematic review composed of 14 unique randomized clinical trials (RCTs) revealed that multi-factorial lifestyle interventions can improve variable risk factors and fatal cardiovascular events in patients with established Coronary heart disease (CHD) [20]. We found that the average score of lifestyle in patients at baseline were not in desirable level (118.19 *vs.* 137.13 after intervention). Aldana et al. also noted that patients with CHD had not desirable lifestyle scores [21]. They also found that patients who participated in new behavioral programs had greater improvements in CVD risks than patients who participated in traditional cardiac rehabilitation or informal programs [21]. In a RCT carried out on 180 Iranian patients suffering from ischemic heart disease (IHD), the education has been considered as an effective factor on modifying life style of cases [22]. They indicated that development of knowledge about factors such as heart diseases, life style, body mass index, and blood pressure, blood sugar, triglyceride, and cholesterol level could increase life style scores of patients [22]. In another RCT study on lifestyle after myocardial infarction (MI) in Chinese patients, a significant increase observed in illness perception and lifestyle of MI patients after telephone follow-up intervention [23]. It can be concluded from the findings of various studies, the average of lifestyle can be changed in patients with different diseases and self-management programs.

Evaluation of hospitalization number due to recurrence or exacerbation of AF revealed no difference between 2 groups in baseline data and so it could be reassured to compare the findings of this study before and after the intervention. In addition, significant differences did not found between groups in hospitalization number of baseline and one month after intervention. Theses result showed that the intervention could not be caused in differences between two groups in this period of time. The number of hospitalized patients in the control group had increased three months after the intervention compared with intervention group (P<0.001). These findings indicate that self-management can play an important role in improving the symptoms of patients with AF. A systematic review and meta-analysis study performed on optimizing chronic disease management in the community (outpatient) setting (OCDM) by health quality Ontario agency. Their study included interventions that could control and manage chronic diseases at maximum level of desired outcomes in study population [24]. In other study, significant effect of discharge plan upon re-admission on satisfaction with nursing care and self-care ability in patients with coronary artery bypass graft surgery has been shown [25].

Assessment of increase in bleeding risk due to several anticoagulant consumption overtime showed a highly significant difference in number of patients with bleeding in the control group (P<0.001). The effectiveness of educational

interventions in the management of anticoagulation treatment in patients with AF assessed by Clarkesmith et al. on 97 patients [26]. They found that educational intervention significantly improved management of warfarin therapy in AF patients overtime [26]. These findings suggest that self-care interventions can be affected on bleeding risk of patients with AF. But the remarkable issue is that when training of patients monitored by telephone follow up, the impact of training will be increased over time. Our findings indicated that there was no meaningful correlation between cerebral embolic complications and intervention overtime in 2 groups of study. Therefore, it seems that longer period of time need to intervene with cerebral embolic complications in AF patients. In terms of cerebral embolic complications, different results were found in other studies. Studies on different chronic dieses such as multiple sclerosis (MS) showed that self-care intervention could be effective on cerebral embolic complications of patients [27-29].

The results of this study showed that the design and implementation of self-care programs could be able to improve significantly lifestyle of patients in intervention group. Thus it may help to manage and control some of the symptoms of AF including hospitalization due to recurrence or exacerbation of AF and bleeding induced by oral anticoagulant. On the other hand, increased knowledge and education on self-care behavior considered as essential factor of patients with AF. It can be concluded that empowerment of patients through self-care education can effect on physical, psychological, and social problems. Therefore nursing units can take major steps to create confidence in the self-care and to improve lifestyle of patients with AF.

Table 1. *Comparison of life style score of AF in both groups.*

Life Style Score	Before Intervention	One Months after Intervention	3 Months after Intervention	P-value		
	Mean ± SD	Mean ± SD	Mean ± SD	Time	Group	Time/ Group
Intervention Group (n=36)	118.19 ± 24.27	123.61 ± 25.28	137.13 ± 26.47	<0.001	<0.001	<0.001
Control Group (n=36)	116.94 ± 24.27	117.69 ± 22.76	117.61 ± 22.64			

Table 2. *Comparison of major complication of AF before and after intervention in both groups.*

Intervention program	Referred cases	Hospitalization rate of recurrent AF			cerebral embolic complications of AF			Bleeding risk of AF		
		Intervention (n=36), No. (%)	Control (n=36), No. (%)	P-value	Intervention (n=36), No. (%)	Control (n=36), No. (%)	P-value	Intervention (n=36), No. (%)	Control (n=36), No. (%)	P-value
Three months Before intervention	No	27 (75)	25 (69.4)	0.89	32 (88.8)	33 (91.6)	>0.05	31 (86.1)	33 (91.6)	0.89
	1-2	8 (22.2)	8 (22.2)		4 (11.1)	2 (5.56)		5 (13.8)	2 (5.55)	
	3-4	1 (2.88)	3 (8.33)		0 (0)	1 (2.78)		0 (0)	1 (2.78)	
	>4	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
One months after intervention	No	27 (75)	24 (69.4)	0.06	31 (86.1)	31 (86.1)	>0.05	31 (86.1)	31 (86.1)	0.10
	1-2	8 (22.2)	9 (25)		5 (13.8)	3 (8.33)		5 (13.8)	3 (13.8)	
	3-4	1 (2.88)	3 (8.33)		0 (0)	2 (5.56)		0 (0)	2 (5.55)	
	>4	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
Three months after intervention	No	26 (72.2)	20 (55.5)	0.04	30 (83.3)	29 (80.5)	>0.05	29 (86.1)	24 (66.6)	0.02
	1-2	9 (25)	7 (19.4)		5 (13.89)	4 (11.1)		5 (13.8)	9 (25)	
	3-4	1 (2.88)	7 (19.4)		1 (2.88)	3 (8.33)		2 (5.55)	3 (8.33)	
	>4	0 (0)	2 (5.55)		0 (0)	0 (0)		0 (0)	0 (0)	

AF: Atrial Fibrillation.

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