Evaluation of the effect of adherence to treatment regimen program on quality of life in atrial fibrillation patients hospitalized in Shahid Chamran Hospital in Isfahan in 2017

Evaluación del efecto de la adherencia al régimen de tratamiento sobre la calidad de vida en pacientes con fibrilación auricular hospitalizados en el Hospital Shahid Chamran en Isfahan en 2017

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Abstract

Background and objective: Atrial fibrillation is the most common cardiac arrhythmia, which is associated with reduced quality of life due to prolonged treatment and its recurrence. One of the key goals in the care of patients with atrial fibrillation is increasing adherence to treatment regimen program and the recommendations provided by the treatment group. Thus, the present study was designed and carried out with the aim of determining the effect of treatment regimen program on quality of life in atrial fibrillation patients hospitalized in Shahid Chamran Hospital in Isfahan in 2017.

Methodology: This clinical trial study was conducted on patients with atrial fibrillation arrhythmia in the Cardiac Care Unit (CCU) and Post CCU Unit and Internal Heart Surgery Unit of Shahid Chamran Hospital in Isfahan. A total of 50 people were randomly selected as sample of study and assigned to two groups of test and control. The test group received two 45-minute sessions of adherence and educational booklet and they were followed-up for one month through phone call. The control group also received one session of usual care training individually with regard to the illness. Demographic data and quality of life data were collected through Atrial Fibrillation Effects on Quality of Life (AFEQT) before intervention, and one and three month after the intervention. Data were analyzed by descriptive and inferential statistics.

Results: There was no significant difference between two groups in terms of quality of life and demographic information before the intervention. However, significant difference was seen between the two groups in terms of quality of life one month and three months after the intervention.

Conclusion: The results suggest the positive effects of adherence to treatment regimen program and follow-up of the patients by experienced nurses on quality of life in these patients one and three months after discharge.

Keywords: Quality of life, adherence to treatment regimen program, atrial fibrillation, nurses.

Resumen

Antecedentes y objetivo: la fibrilación auricular es la arritmia cardíaca más común, que se asocia con una reducción de la calidad de vida debido al tratamiento prolongado y su recurrencia. Uno de los objetivos clave en el cuidado de los pacientes con fibrilación auricular es aumentar la adherencia al régimen de tratamiento y las recomendaciones proporcionadas por el grupo de tratamiento. Por lo tanto, el presente estudio se diseñó y llevó a cabo con el objetivo de determinar el efecto del régimen de tratamiento sobre la calidad de vida en pacientes con fibrilación auricular hospitalizados en el Hospital Shahid Chamran en Isfahan en 2017.

Metodología: este estudio clínico se realizó en pacientes con arritmia por fibrilación auricular en la Unidad de Atención Cardiaca (CCU) y en la Unidad de Post CCU y en la Unidad de Cirugía Interna del Corazón del Hospital Shahid Chamran en Isfahan. Un total de 50 personas se seleccionaron al azar como muestra de estudio y se asignaron a dos grupos de prueba y control. El grupo de prueba recibió dos sesiones de adherencia y un folleto educativo de 45 minutos y fueron seguidos durante un mes a través de una llamada telefónica. El grupo de control también recibió una sesión de entrenamiento de atención habitual individualmente con respecto a la enfermedad. Los datos demográficos y los datos de calidad de vida se recopilaron a través de los efectos de la fibrilación auricular en la calidad de vida (AFEQT) antes de la intervención, y uno y tres meses después de la intervención. Los datos fueron analizados mediante estadística descriptiva e inferencial.

Resultados: no hubo diferencias significativas entre los dos grupos en términos de calidad de vida e información demográfica antes de la intervención. Sin embargo, se ob-

servó una diferencia significativa entre los dos grupos en términos de calidad de vida un mes y tres meses después de la intervención.

Conclusión: los resultados sugieren los efectos positivos de la adherencia al régimen de tratamiento y el seguimiento de los pacientes por parte de enfermeras experimentadas sobre la calidad de vida en estos pacientes uno y tres meses después del alta.

Palabras clave: Calidad de vida, adherencia al régimen de tratamiento, fibrilación auricular, enfermeras.

Introduction

Nowadays, cardiovascular diseases are the most important cause of death in the world. Based on American Heart Association in 2010, the general death caused by cardiovascular disease was 235 per 100000 people[1]. In Iran, the first and most common cause of death at all ages and in both genders is cardiovascular disease. Shabani et al reported that cardiovascular diseases account for 46% of all deaths in Iran[2]. One of the most common heart disorders is arrhythmia and atrial fibrillation is considered the most common heart arrhythmia. Approximately 2.3 million Americans suffer from this disease[3]. The prevalence of this disorder is less than 0.1% in people aged below 45 years and 9% in people aged over 80 years. In other words, the prevalence of the disease is directly related to age[4]. Based on the American Society of Cardiovascular Guideline, the risk factors for atrial fibrillation in 2016 included heart failure, valvular disease, hypertension, obesity, and smoking[5]. This disorder control is crucial due to symptoms and complications such as hemodynamic disorder, palpitation, chest pain, shortness of breath, fatigue, dizziness, thromboembolism, increased heart and brain infarctions, and longer hospitalization and recovery period[6].

Treatment strategies in these patients include the use of anticoagulants, heart rhythm and beat controllers, catheterization, the use of pacemaker, and cardioversion[7], which alleviate the symptoms and improves the quality of life in these patients[8]. Patients with atrial fibrillation are at increased risk of recurring fibrillation and are always affected by the disease. For this reason, they should undergo long-term treatment, which may reduce the likelihood of recurrence of fibrillation[9]. Adherence to treatment regimen program in these patients is very important in preventing progression of the disease and recurrence of the attacks[10]. Non-treatment of symptoms puts the individual at risk of recurring fibrillation attack. Several studies report that using appropriate regimen is crucial in these patients since it prevents recurrence of attacks[11]. Adherence to treatment regimen program in patients means the skills used to reduce stress, observe the proper diet, doing proper physical activities and proper use of prescribed drugs in order to promote appropriate health behaviors in the target population[12]. In general, the promotion of health-related behaviors will result in maintaining the performance, strengthening the people autonomy, increasing their quality of life, and reducing health care costs[13], since the results of studies show that 53% of the reasons for people death are associated with their life style and non-healthy behaviors[14]

Given the long process of treatment, the patients need to be followed-up with the aim of establishing a continuous and dynamic care relationship, which improves the quality of life of patients and reduces the complications of the disease and promotes the health[15].

There are different self-control and training methods in order to help patients to adapt to lifestyle changes and can improve their health and prevent recurrence of complications. By informing the patients, they can help the patients follow the appropriate treatment regimen program and reduce the recurrence of the attacks. Non-adherence to treatment regimen program leads to harmful consequences for patients, treatment staff and healthcare system. Based on the World Health Organization, almost 50% of patients do not adhere to treatment regimen programs[16]. Evidence suggests that non-adherence to treatment leads to inadequate control of the disease and puts the patients at a greater risk of adverse effects[17]. The costs related to direct and indirect consequences of non-adherence to treatment, including hospitalization and disease progression, imposes high burden on the health system[18]. The costs imposed on the healthcare system for treatment of atrial fibrillation is about 6.2 billion euros in Europe and 6.65 billion dollars in the United States[19]. These costs are spent to treat the atrial fibrillation complications includes stroke, heart failure and hospitalization[20].

In a study conducted by Kimmel et al with the aim of evaluating the effect of adherence to the treatment regimen program on the control of anticoagulant drugs, results showed that patients who had problems in maintaining adherence to the regimen had significant problems ranging from thrombosis to bleeding in coagulation factors[21]. Another study conducted by Lip et al (2015) showed the importance of emphasizing the use of guidelines to prevent stroke in patients with atrial fibrillation[22]. In a study conducted by Hessel et al in 2011, the results showed that the intensity of heart rate control had no impact on the quality of life of these patients, but symptoms, gender, age, and severity of the disease affect the quality of life of these patients[23]. Another study conducted by Lakkireddy et al in 2013 showed that yoga in atrial fibrillation patients improved the disease symptoms, arrhythmias, heart rate, hypertension, anxiety and depression, and different domains of quality of life[24]. Moreover, there is a correlation between the adherence to treatment and the quality of their life. In this regard, the World Health Organization defines the quality of life as people perception of the status of life in the form of culture and values governing the community in line with the goals, standards, expectations, and interests of the individual[25]. Thus, atrial fibrillation is

one of the most common heart arrhythmias and one of the important challenges in treatment of this disease is adherence to treatment regimen program. Moreover, high costs are imposed on the healthcare system by frequent hospitalization of patients. Few studies have been conducted on atrial fibrillation patients in Iran and foreign countries and contradictory results have been reported by these studies. Given what was stated above, the researcher decided to investigate the effect of a program of adherence to treatment regimen program on quality of life of atrial fibrillation patients hospitalized in Shahid Chamran Hospital in Isfahan in 2017.

Materials and methods

The present study was a clinical trial with two-group and three-stage design. It was conducted on atrial fibrillation arrhythmia patients hospitalized in the Cardiac Care Unit (CCU) and Post CCU Unit and Internal Heart Surgery Unit of Shahid Chamran Hospital in Isfahan in 2018. The sample size was calculated to be 25 people in test group and 25 people in control group based on the 95% confidence level and the test power of 80%. They were selected from patients with atrial fibrillation who met the inclusion criteria of the study. They were randomly assigned to the control and test groups using the odd and even numbers card. The research inclusion criteria included age range of 35-70 years, hospitalized for the first time in a hospital with medical diagnosis and registration of atrial fibrillation in the medical record, lack of limiting motor disorders and non-participation in intervention programs similar to adherence to treatment regimen program, having the reading and writing literacy and the ability to speak Farsi and the willingness to participate in the study.

After obtaining informed written consent from the samples and receiving the ethics code from the Isfahan University of Medical Sciences, the researcher provided the usual care with regard to the disease for control group samples in a 30-minute face to face session. The test group also received two 45-minute sessions of adherence and educational booklet and they were followed-up for one month through phone call. Adherence to treatment regimen program intervention included two educational and support sections. In the educational section, the researcher provided the educational content derived from the sources and in accordance with the components of the AFEQT questionnaire, approved by the cardiologist, as a combination of individual training and practice in two consecutive 45-minute sessions on the second and third days of hospitalization during 8-12 am on the patient's bedside. It included information on the type of arrhythmia, the methods of treatment, the drugs used and its complications, the level of activity, the method of coping with mental problems, the importance of performing coagulation tests, the type nutrition. They were provided in the face to face manner and by using the images of educational booklet.

In the supportive section, the researcher provided the content of topics discussed in the sessions, question and answer and the disease control and management power to the control group samples in a weekly phone call between the hours 8 am and 8 pm. The duration of each phone call was 10 minutes based on the patient's need. No intervention was provided for this group during these 8 weeks. Finally, 12 weeks after the beginning of the intervention, the questionnaire was completed by a researcher assistant in the test and control groups. In the case of physical and psychological problems resulting in disability, death of the patient and lack of willingness to continue the study, the person was excluded from the study.

The data collection tool included a two-part questionnaire. The first part consists of demographic characteristics and disease information. The second part consists of a questionnaire on the effects of atrial fibrillation on quality of life (AFEQT). It is a standard questionnaire confirmed by the AFEQT Core team in North America using Cronbach Alpha (0.9). To confirm the validity of this questionnaire, the researcher used the content validity and the opinions of eight faculty members of the Faculty of Nursing and Midwifery and two cardiologists were applied on the questionnaire. Then, Cronbach's alpha coefficient was used to determine the reliability of this questionnaire, so that the questionnaire was provided to ten patients with atrial fibrillation who met the inclusion criteria of the study after applying the necessary modifications in it. It was confirmed with Cronbach's alpha was 0.87. The questionnaire includes 20 questions scored on a 7-point Likert scale in three domains of symptoms and symptoms, activity, treatment concerns. The minimum score was zero and the maximum score was 100. A separate score was calculated for each domain. The higher scores mean the higher quality of life. The questionnaire was completed in three stages by a researcher assistant. Before the intervention, it was completed through questioning in face to face and one and three months after the intervention, it was completed by phone call and questioning. The collected data were analyzed using SPSS21 software. In analyzing the data, independent t-test, Mann-Whitney, Chi-Square, Fisher, covariance and LSD post hoc tests were used

Results

The results showed that in the test group, 44% of the patients were male and 56% were female, and in the control group, 48% of the patients were male and 52% were female. The highest percentage of samples in both groups was self-employed. In both groups, 60% of the samples were married. In the

test group, 56% had education lower than diploma, and in the control group, 48% had education lower than diploma. The highest number of samples in both groups was in the age group of 51-55 years and the most of the risk factor in the test group were hypertension (36%), and in the control group, it was smoking (40%). The most common cause of hospitalization was hypertension (28%) in the test group and heart failure (28%) in the control group. The duration of the disease was 1-3 months (32%) in the test group and 3-6 months (40%) in the control group.

Independent t-test showed that the mean of total score of quality of life and its dimensions before intervention was not significant between the two groups (P>0.05). However, the covariance analysis showed that the mean of total score of quality of life, and the dimensions of signs and symptoms and physical activity one month after the intervention in the test group was significantly more than that of the control group (P<0.05). However, the mean score of quality of life in the dimensions of treatment problems and satisfaction one month after intervention showed no significant difference between two groups (P>0.05). Covariance analysis showed that the mean of total score of quality of life and all its dimensions were significantly higher in the test group three months after intervention than that in the control group (P<0.05) (Table 2).

Table 1. comparing the disease-related demographic information of test and control groups

variable		Test group		Control group		test	χ2	P
		n	%	n	%			
Patient's gender	male female	11 14	44 56	12 13	48 52	Chi-square	0.08	0.78
job	employee Self-employed Retired housewives others	5 10 6 3 1	20 40 24 12 4	4 8 6 7 0	16 32 24 28 0		3.37	0.50
Marital status	single married divorced spouse deceased	2 15 3 5	8 60 12 20	2 15 2 6	8 60 8 24		0.29	0.96
Risk factors	Hypertension High blood fat High blood glucose Smoking others	9 6 3 5 2	36 24 12 20 8	6 5 3 10 1	24 20 12 40 4		2.73	0.60
Cause of hospitalization	Heart failure Hypertension heart attackischemic disease others	4 7 5 3 4 2	16 28 20 12 16 8	7 5 4 3 5 1	28 20 16 12 20 4		1.73	0.89
Age range (year)	40-35 45-41 50-46 55-51 60-56 65-61 Over 65	1 2 3 7 5 3 4	4 8 12 28 20 12 16	2 3 4 5 4 3 4	8 12 16 20 16 12 16	Mann-Whitney	Z 0.54	0.59
Level of education	Under diploma diploma academic	14 9 2	56 36 8	12 10 3	48 40 12		0.62	0.54
Disease duration	1-3 month 3-6 month 6-12 month 1-2 year 2-5 year 5-10 year 10-15 year Over 15 years	8 3 5 1 2 2 1 3	32 12 20 4 8 8 4 12	4 10 3 2 3 2 0 1	16 40 12 8 12 8 0 4		0.22	0.83

Table 2. comparison of the total score average of the life quality and its dimensions in the control and experiment groups before the intervention, one month and three months after the intervention

Quality of life dimensions		Test group		Control group		test	
		mean	SD	mean	SD	t	p
Total score	Before intervention	60.54	86.7	87.55	71.6	61.0	54.0
	One month after intervention	60.61	85.5	87.58	43.6	F 81.14	001.0>
	Three months after intervention	93.71	81.5	30.63	53.6	22.29	001.0>
Signs and symptoms	Before intervention	33.38	78.14	83.38	07.12	t 13.0	90.0
	One month after intervention	17.52	14.14	33.44	78.11	F 92.8	004.0
	Three months after intervention	50.60	76.16	49	04.14	41.12	001.0
Physical activity	Before intervention	83.58	96.15	83.60	84.10	t 52.0	61.0
	One month after intervention	67.63	40.12	58.62	25.9	F 97.4	03.0
	Three months after intervention	91.72	61.7	50.65	78.8	02.23	001.0>
Treatment problems	Before intervention	33.55	05.14	33.56	19.18	t 22.0	83.0
	One month after intervention	59	76.12	67.57	32.17	F 73.3	06.0
	Three months after intervention	44.72	71.8	78.64	55.16	14.7	01.0
satisfaction	Before intervention	68	32.13	67.68	89.17	t 15.0	88.0
	One month after intervention	80	77.15	67.76	78.21	F 94.0	34.0
	Three months after intervention	33.89	42.11	67.78	14.20	52.7	009.0

Discussion

The results showed that there was no significant difference between the two groups in terms of demographic information (age, gender, job, level of education, marital status). In addition, no significant difference was found between two groups in terms of information related to disease, such as risk factors, duration of disease and the cause of hospitalization. These results confirm the random allocation of samples in two groups. Moreover, the results of this study showed that the mean score of quality of life and its dimensions before intervention was not significantly correlated between the two groups. However, there is a significant difference between two groups in terms of mean of total score of quality of life one and three months after intervention.

In agreement with these results, Shojaei et al (2013) showed that the psychological dimension of quality of life could change under severe conditions, including chronic diseases, feeling disability, fear of death, reduced function and many different conditions. Their results also showed that training during discharge and then phone follow-up can increase the level of hope in patients with heart failure and reduce costs to improve the health of patients[1].

In the present study, adherence to the treatment regimen program improved the quality of life of atrial fibrillation patients. One of the important factors playing a major role in controlling the disease is the patient's adherence to the treatment regimen program. There is a mutual relationship between adherence to treatment regimen program and quality of life of the patients. Receiving the adherence to treatment regimen program program in addition to having a significant effect on the general mean of these people's quality of life compared to that in the control group had also a significant effect on the quality of life of the patients in the intervention group. In a study conducted by Roodsari et al. (2013), results consistent with those of this study were obtained, since their results showed that there is a significant relationship between the health-related quality of life and adherence to treatment regimen program in patients with hypertension[2].

In a study conducted by Guo et al in 2017 to evaluate the effect of mobile technology on better management of atrial fibrillation, knowledge, quality of life, drug adherence, and satisfaction with anticoagulants were measured at the beginning of the study, one and three months later by designing a simple program on Android OS and ios in two groups of atrial fibrillation patients. The results showed that a proper clinical and educational process in the management program of these patients would lead to improvement in the continuous adherence to drug therapy, knowledge level and satisfaction with receiving anticoagulants, as well as quality of life in these patients[32].

In this regard, a study carried out by Tekeh Fallah et al in 2016 showed that distance nursing for three months would improve the quality of life of patients with fibroblasts[26]. These results were consistent with those of our study. One of the reasons for the consistency might be the duration of follow-up which it was similar in two studies (3 months)[33]. However, the researcher used distance education in this study, but the education was provided by the researcher and in face to face manner in the present study[34]. In another study conducted by Lakkireddy et al in 2013, they showed that yoga improved disease symptoms, arrhythmias, heart rate, blood pressure, anxiety, depression, and various domains of quality of life in patients with atrial fibrillation[24]. The results of this study also showed that yoga in the life of patients with atrial fibrillation can be a factor affecting their quality of life.

In addition, in another study conducted by Lip et al (2015), the use of guidelines to prevent stroke in patients with atrial fibrillation was emphasized[22]. Given the results of this study, one of the reasons for the significant difference between the two test and control groups in the present study might be attributed to the implementation of several educational sessions, follow-up after discharge, and presentation of the educational booklet. Adherence to treatment regimen program is a new intervention, which has not been investigated due to its importance in atrial fibrillation. For this reason, few articles were found in this regard. In a study conducted by Esmkhani et al in 2017, the effect of adherence to the treatment regimen program on quality of life in patients with schizophrenia was studied[35]. In this clinical trial, 70 patients with schizophrenia were divided into test and control groups. In the test group, six sessions of lecture and discussion were held for 30-60 minutes per week and the control group received the usual cares[36]. The results showed that the implementation of adherence to treatment regimen program programs improved the quality of life of schizophrenic patients. These results are in line with those of our study[37]. However, in the present study, the quality of life of patients was evaluated one and three months later. However, it was examined immediately after the intervention[37,39].

The results of this study also showed that there was no significant difference between the mean scores of the dimensions of quality of life (signs and symptoms, physical activity, treatment problems, and satisfaction with treatment) in patients with atrial fibrillation in the test and control groups before intervention[38].

This result was expected due to the random allocation of samples and the similar conditions of the two groups. In agreement with findings of the present study, the results of the Osbak et al study in Denmark entitled "The effect of physical education on muscle strength and body composition and its relationship with practical capacity and quality of life of patients with atrial fibrillation" showed that the mean level of quality of life in the two groups was not significantly different before aerobic exercise[46].

However, there was a significant difference between the mean scores of signs and symptoms in patients with atrial fibrillation in the control and test groups one month after the intervention and three months after the intervention ($p < 0.05$). This suggests that follow-ups after discharge can affect the quality of life of the patient. In this regard, in an 8-month study, Wang et al investigated the effect of drug adherence on depression and quality of life in AIDS patients and showed that quality of life in the test group was significantly higher than that of the control group. In this study, phone intervention increased the quality of life scores in the different dimensions in the intervention group, while in the present study, follow-up treatment with in-person sessions and talking with patients increased the quality of life of patients[3,44].

Moreover, in a clinical trial study conducted in Norway by Malmo on aerobic exercise and reduced atrial fibrillation load, exercise training was considered as an important and effective treatment for atrial fibrillation and associated diseases. They evaluated the effects of intermittent aerobic exercise on atrial fibrillation symptoms, cardiovascular health and quality of life in patients with atrial fibrillation, which was associated with significant improvement. In addition, general mean of quality of life and its domains in the test group was improved compared with the control group[45].

There was no significant difference between test and control groups 1 month after intervention, but there was a significant difference between them 3 months after the intervention ($p < 0.05$). This can indicate that adherence to treatment regimen program needs more time to increase the patient's ability. In a study conducted by Shabani et al in Hamadan entitled "The effect of heart rehabilitation program on physical function and quality of life in patients with heart attack", it was shown that there was no significant difference in the quality of life and its domains in the control group before and after the intervention[47]. In addition, in this study, there was no significant difference between the test and control groups in terms of mean scores of concerns as one of the dimensions of quality of life of the patients one month after the intervention and three months after the intervention. However, the study conducted by Kirch et al showed that phone follow-up even after 48 hours and providing guidance to the patient's family could improve the quality of patient care.

This contradiction at follow up time might be due to the difference in the objectives of the present study, which this study focused more on the quality of life[4,43]. In a study conducted in Norway by Malmo about aerobic exercise and reducing atrial fibrillation load, all domains of quality of life in the test group increased, except for the mental health and euphoria that had no significant difference[45]. There was no significant difference between the mean scores of satisfaction of the treatment process in patients with atrial fibrillation in the test and control group one month after the intervention, but there was a significant difference between them three months after the intervention ($p < 0.05$). In this regard, Davis et al conducted a research and showed that phone call for six months had an impact on quality of life and the satisfaction of patients with advanced diseases. This might indicate that increasing the duration of phone follow-up can increase the satisfaction of the patients[5,42]. In general, the results of this study and other studies confirm the positive effect of adherence to treatment regimen program programs in patients with atrial fibrillation. In addition, quality of life is a concept related to the field of nursing and nurses have always tried to improve it [27]. By providing health care and participating in nursing research, they tried to improve the quality of life of patients. In this regard, Scott (2004) showed that patients with severe heart failure experience anxiety and depression and loss of control over life caused by the disease [30]. In general, a few studies conducted in this regard show that quality of life in patients with heart failure is weaker compared to other chronic diseases [28, 41]. Another study conducted by Rodriguez et al (2008) found that the training of patients with heart failure was the base of individual management of the heart failure [29, 40].

Harrison (2002) showed that providing training by a specialist nurse for the samples and visiting them two weeks after discharge and their follow-up for 12 weeks increased the quality of life of the test groups in the physical and mental dimensions and this increase was significant 6 weeks in the test group, which is in line with the results of our study. Stewart et al stated that heart failure treatment by a specialist nurse improved the quality of life of the patients [31].

Conclusions

Thus, it can be concluded that the implementation of an adherence to treatment regimen program based on existing guidelines and follow up of the patients during the hospitalization one and three months after discharge by using experienced nurses is crucial to enhance their knowledge, empower and promote the dimensions of quality of life of the patients. It is important to use this program to improve the quality of life of patients with atrial fibrillation.

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