Original Article

Effect of Self-Management Program on Self-efficacy and Medication Adherence in Patients with Mechanical Heart Valve: a Randomized Clinical Trial

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ABSTRACT

Introduction: Patients with mechanical heart valve need anticoagulant therapy to prevent thrombotic events. The treatment interacts with some foods and drugs. The aim was to evaluate the effect of self- management program on self-efficacy and medication adherence in patients with mechanical heart valve.
Methods: This was a randomized controlled trial. eighty eligible patients, with the ability to read and speak in Farsi, aged between 15 to 60, were included in the study from the cardiac surgery clinic in Imam Khomeini hospital affiliated to Tehran University of Medical Sciences (Tehran, Iran) and randomly allocated to intervention and control groups. The participants had no history of psychiatric disorders, had undergone valve replacement surgery at least one year before the study, and were being treated with Warfarin. The intervention was a combination of 2 one- hour self-management education via small groups with 3 to 5 members, self-management educational booklets, and weekly call follow- ups for 8 weeks about 10- 15 minutes. The control group received no intervention. Self- efficacy was the primary outcome and medication adherence, Prothrombin Time (PT), and International Normalized Ratio (INR) were secondary outcomes. Data were analyzed using SPSS13.
Results: Although the mean of self-efficacy and medication adherence, PT, and INR values were not different between the two groups at baseline, they improved significantly following the program.
Conclusion: Self-management program had a positive effect on self-efficacy and medication adherence of patients with mechanical heart valve.

Introduction

Valvular heart disease (VHD) is prevalent in developed and developing countries with etiology of degenerative[1] and rheumatic valvular disease by Staphylococci (Group A).[1,2] In the United States, VHD accounts for 10% to 20%[3] and in Iran, it comprised 7.2% of all cardiac surgeries.[4]

From reported complications, thrombosis, thrombo-embolism, and anticoagulant- related complications account for 75% of all complications[5] which usually occur six months after surgery and necessitates the post operation follow- ups[5] Moreover, they are the leading causes of morbidity and mortality[6] imposing a psychological burden and a negative effect on the quality of life.[5]

Although the long term durability is the main advantage of mechanical heart valves, there is need for Vitamin K antagonists (VKAs) with inherent risk of thromboembolism and bleeding events in contrast.[7]

Warfarin and other VKAs interact with some foods and drugs, which makes the management of oral anticoagulant therapy challenging for both patients and health care providers.[8] Therefore, the management of oral anticoagulant therapy is a key issue among patients with mechanical heart valve[7] and the therapy should be individualized by focusing on patient education and monitoring[9] in order to reduce the risk of bleeding and Thromboembolism events.[9,10] One of the strategies is self-management program that empowers patients to monitor and adjust treatment at home.[11] Previous studies have shown that self- management program improves the INR control, quality of life,[12] self-efficacy,[13] medication adherence, and adjustment of treatment[14] and leads to lower risk of all- cause mortality rate,[15,16] and thromboembolism and major bleeding.[15]

Although most patients with a mechanical heart valve may benefit from self-management program,[7] Iranian patients with mechanical heart valve have a permanent fear and concern about INR fluctuation, its regulation, and correct use of VKAs during their treatment.[17] On the other hand, insufficient support can make life difficult for them.[18] Thus, because the self-management program appears at least better than the routine care,[11] and there is crucial need for further randomized controlled trials to assess the efficacy of self-management program in order to consider it as the standard care,[15] and in view of lack of this program in our health care setting so as to overcome the patients` fear and concerns and improve clinical outcomes, the aim of this study was to evaluate the effect of self- management program on self-efficacy and medication adherence of patients with mechanical heart valves.

Materials and methods

This was a parallel randomized controlled trial that has been approved by the institutional review board (IRB) of Tehran University Medical Sciences (TUMS) (No:

130/1225/93/d), and IRCT code IRCT201406154443N13. With Helsinki ethical principles for human research considered during the study period.

The participants were patients aged between 15 to 60 years, who had undergone valve replacement surgery at least one year before the study and were being treated with Warfarin, with the ability to read and speak Farsi, no history of psychiatric disorders. The patients who experienced the drug side effects during the study period, were discharged before completing the two-educational sessions, did not answer the phone calls during the call follow- ups, or were not willing to continue the study were all excluded from the study.

Therefore, 80 eligible patients with mechanical heart valves were included in the study from the cardiac surgery clinic in Imam Khomeini hospital affiliated to TUMS in 2014.

In this trial, the intervention consisted of self-management education, and weekly call follow- ups for 8 continuous weeks, each lasting from 10 to 15 minutes. In order to provide self-management education, the patients were divided into groups of 5 to 7 members and received 2 one-hour self-management education sessions at 2 to 3-day intervals. Self-management education and booklets were about the nature of the disease, medication management, drugs' side effects, and actions needed to be taken to prevent drug side effects, food and drug interactions, having Warfarin card, prevention of actions that lead to complications, physical activity and stress and anxiety reduction methods. The content validity of the educational booklet was evaluated by three nursing and midwifery faculty members of TUMS. While the patients in the control group received no intervention.

The outcomes of this trial were self-efficacy as a primary outcome, and medication adherence, prothrombin time (PT) and international normalized ratio (INR) were the secondary outcomes. In order to including 31 items with five- point Likert from extremely high to extremely low, with the higher scores indicating the higher self-efficacy behavior.[19,20] The questionnaire was translated into Farsi by forward- backwards translation method and its content validity was approved evaluate the patient`s self-efficacy, a researcher-constructed self-efficacy questionnaire was used by 10 faculty members in the school of nursing and midwifery affiliated to TUMS. It had an acceptable reliability coefficient, too (Cronbach's alpha= 0.82). The patients were asked to complete the questionnaire themselves at baseline and at the end of the study. Medication adherence was another study outcome which was evaluated by a medication adherence   questionnaire[21,22] consisting of 22 items with five- point Likert from always to never, where the higher scores were considered as higher medication adherence. 10 nursing and midwifery faculty members approved the content validity and Table 1 shows the demographic and clinical characteristics of the patients in the intervention and control groups. According to this table, no Significant difference for clinical and demographic data were found between the two groups at baseline (P>0.05) (Table 1).

 Comparison of the mean and standard deviation of the

Cronbach's alpha was 0.85. The medication adherence questionnaire was completed by patient`s self- report at baseline and at the end of the study. In addition, PT and INR were measured by BIOLABO kit (France) with therapeutic range of INR between 2 and 3.5 at baseline and at the end of the study.

Demographic and clinical variables including age, sex, education level, job, income, insurance, smoking, family history of cardiovascular diseases (CVDs), consumption of other medications, and post-operation duration were among the study variables which were recorded at baseline for each patients based on their self-report and clinical records.

The collected data were analyzed using SPSS (version 13.0, Chicago, IL, USA). We described demographic and clinical data by descriptive statistics such as frequency, partial frequency percentage, the mean and standard deviation Mean (SD). In order to compare the means between the intervention and control groups, independent- samples t- test and chi- squared test were used to compare the frequency between the two groups. The significance level of statistical tests was less than 0.05.

Results

In this trial, 88 eligible patients were recruited during the enrolment phase and data related to 80 patients were analyzed. The total attrition rate was 10% as it was expected a priori. The most common causes of exclusion from the study were "not answering the call- follow-ups" and "no willingness to continue the study" during the follow- up period. The study process from the enrollment to analysis has been shown in CONSORT 2010 flow diagram (Figure 1).
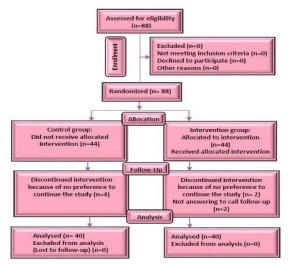

Figure 1. Flowchart of study

study outcomes between the intervention and control Groups has been shown in Table 2. According to table 2, although the mean and standard deviation of self-efficacy, medication adherence, and PT and INR were not significantly different between the two groups at baseline (P> 0.05), they improved significantly in the intervention

Table 1. Demographic and clinical characteristics of patients in the intervention and control groups (n=40)

Demographic and clinical characteristics	Intervention N (%)	Control N (%)	P
Age (Year)			0.36
15-30	7 (17.5)	4 (10)	
31- 45	14 (35)	11 (27.5)	
46- 60	19 (47.5)	25 (62.5)	
Sex			0.62
Male	14 (35)	23 (57.5)	
Female	26 (65)	17 (42.5)	
Education level			0.86
Elementary school	16 (40)	18 (45)	
High school	12 (30)	12 (30)	
Diploma & Academic	12 (30)	10 (25)	
Job			0.81
Yes	22 (55)	21 (52.5)	
No	18 (45)	19 (47.5)	
Income			0.75
Enough	16 (40)	15 (37.5)	
Not enough	24 (60)	25 (62.5)	
Insurance			0.49
Yes	34 (85)	36 (90)	
No	6 (15)	4 (10)	
Smoking			0.36
Yes	5 (12.5)	8 (20)	
No	35 (87.5)	32 (80)	
Family history of CVDs[€]			0.36
Yes	18 (45)	14 (35)	
No	22 (55)	26 (65)	
Consumption of other medications			0.34
Yes	25 (62.5)	29 (72.5)	
No	15 (37.5)	11 (27.5)	
Post-operation duration (Month)			0.44
< 1	11 (27.5)	7 (17.5)	
2-6	14 (35)	13 (32.5)	
7 – 12	15 (37.5)	20 (50)	

[€]CVDs: Cardiovascular Diseases

Compared with the control group following the program (P<0.05).

Table 2. Comparison of mean and standard deviation of study outcomes between the intervention and control group (n=40)

Study outcomes	Intervention Mean(SD)	Control Mean(SD)	P
Self-efficacy			
Before	93.22(12.05)	96.22(14.99)	0.327
After	118.20(12.94)	100.40(16.01)	0.0001
Medication adherence			
Before	60.02(6.26)	79.60(9.04)	0.813
After	94.97(8.55)	80.80(10.21)	0.0001
PT (Second)			
Before	17.78(2.91)	18.21(3.45)	0.530
After	19.94(3.31)	17.56(4.11)	0.008
INR			
Before	1.89(0.49)	1.95(0.62)	0.640
After	2.29(0.67)	1.94(0.45)	0.019

Discussion

In this trial, the effect of self-management program on self-efficacy and medication adherence of patients with mechanical heart valve was evaluated. According to the result of the present study, the patients` self-efficacy improved significantly following the intervention. Previous studies assessed the effect of the intervention on self- efficacy among patients with multiple sclerosis, care following the intervention, too.[13,19,23,24] In contrast, in Elzen et al., study, although the mean of self-efficacy score increased following the intervention, this difference was not statistically significant which may be due to the aged study population and different disease conditions.[25]

Reduce the health care costs.[26] the positive effect of self-management program on patients` medication adherence has been shown in our study which was consistent with previous studies where the mean of medication adherence was significantly higher in the intervention group in comparison to the control group.[22,27]

Education about anticoagulant self-management can result in the patients' satisfaction, quality of life improvement, anticoagulation control, and reduction in thromboembolic events and mortality.[28-30] in the present study, the mean of PT and INR were significantly higher in the intervention group in comparison to the control group. In Jeon and Park study in 2015, PT and INR were maintained in the therapeutic range, following the intervention among patients with cardiac valve replacement.[13] In addition, educational intervention plays a key role in controlling INR and its maintenance in normal range[31] In contrast, Sedri et al., indicated that PT and INR were not significantly different between the two groups of intervention (interactive and non- interactive short message service) and control[22] which may be due to the type of intervention and follow- up duration.

Conduction of this research project in a tertiary referral hospital that covers all patients with different health care behaviors was the strength of this study. The main limitation of this study was the presence of patients in educational sessions in order to receive the intervention that made patients discontinue the program. Thus, it is recommended the self-management program be provided through internet or by mobile health applications to improve patients` involvement in their care.

Conclusion

Self-management program had a positive effect on self-efficacy and medication adherence of the patients with mechanical heart valves. Therefore, this intervention can be applied by nurses as a part of the discharge plan in order to reduce the outcomes of patients with mechanical heart valve and improve their self-efficacy and medication adherence.

Acknowledgments

Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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