Self-Care Training and Information Support of Patients With Mechanical Heart Valve on International Normalized Ratio and the Bleeding Complications

Shirdel Zandi
Hamadan University of Medical Sciences School of Paramedicine

Behzad Imani (✉ behzadiman@yahoo.com)
Hamadan University of Medical Sciences Medical School  https://orcid.org/0000-0002-1544-8196

G Holamreza Safarpor
Hamadan University of Medical Sciences Medical School

Research

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Abstract

Background

Patients with mechanical heart valve due to the possibility of coagulation complications require lifelong use of anticoagulants and International Normalized Ratio (INR) control. But if not taken care of properly, anticoagulant therapy itself can put people at risk for bleeding and be life-threatening.

Objectives

The aim of this study was to determine the effect of Self-care training and information support of patients with mechanical heart valve on INR and the bleeding complications.

Design

A randomized double-blind controlled trial.

Settings and Methods

Participants were recruited via convenience sampling from Farshchian hospital in Hamadan, Iran; and were randomly divided into two groups control (n=80) and intervention (n=80). Participants in the control group received only routine training; in addition, the intervention group received 6 sessions of self-care training and 6 months of information support. Monthly the level of INR and incidence of bleeding were determined. Data were analyzed using independent t-test and chi-square in spss16 software at a significance level of 0.05.

Results

During 6 months of follow-up, except for the third month, the frequency of INR levels in therapeutic target range (2.5-3.5) in the intervention group was significantly higher than the control group (p<0.05). Also in the intervention group, the incidence of bleeding complications was relatively less than the control group, but this difference was not statistically significant (p>0.05).

Conclusion

Proper self-care training and information support in patients with mechanical heart valve replacement have positive results. By doing self-care, the level of a therapeutic target range of INR maintained and the incidence of bleeding complications can be reduced.

1. Introduction

While heart valve replacement as a surgical technique improves survival in the presence of heart valve regurgitation disorders and valve stenosis, it can lead to complications such as prosthetic valve thrombosis or systemic embolism (Tiede et al., 1998, Hirsh et al., 2001). Due to the high prevalence and
risks of these complications, anticoagulant regimens are considered for these patients after surgery, and patients must adhere to this lifesaving drug regimen (Ageno et al., 2012, Members et al., 2012). The purpose of oral anticoagulation (OAC) therapy is to induce a controlled depression of blood coagulability in order to reduce the risk of thromboembolic complications. Vitamin K antagonists (VKAs) such as warfarin are currently considered standard drugs for OAC in these patients (Nishimura et al., 2017). The required VKAs dosage titrated based on the International Normalized Ratio (INR) (Aikins et al., 2020). If the drug is taken correctly and the INR level is maintained in the therapeutic target range, anticoagulation treatments can prevent serious complications such as bleeding and embolism, thereby increasing postoperative survival rates and the quality of life among patients (Kido and Ball, 2019, Eikelboom et al., 2011). However, due to the limited range of treatment, this drug can be considered a complication factor for patients (Zhang et al., 2017). Thus, if the INR is higher than the target treatment range, the patient is prone to bleeding, and in cases below this range, the incidence of thromboembolic events is strengthened (Gibler et al., 2019).

It has been found that several factors such as socioeconomic factors, diet, concomitant medication, underlying disease, knowledge, activity, etc. affect the effects of warfarin and the occurrence of side effects in consumers (Pourafkari et al., 2018, Talboom-Kamp et al., 2017, Di Minno et al., 2017). Accordingly, heart valve replacement patients need to be sufficiently aware of the factors that can affect the individual and take care of themselves against the influential factors. In fact, self-care is a very important behavior in patients with heart failure that can improve treatment outcomes and, in turn, reduce the need for readmission and treatment costs (Boyde et al., 2018, Boyde et al., 2017, Bartos, 2016). Accordingly, the present study aimed to determine the effect of self-care training and information support of patients with mechanical heart valve on INR and the bleeding complications.

2. Method

2.1. Study design

The study was designed as a double-blind randomized controlled trial to determine the effect of self-care training and information support of patients with mechanical heart valve on INR and the bleeding complications. In this study, design and data reporting were performed based on updated guidelines the Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010).

2.2. Participants and Randomization, and blinding

Participants were recruited via convenience sampling. Sampling was performed from August 2019 to September 2020 in Farshchian hospital in Hamadan, Iran. Among the patients who had referred for heart valve replacement during this period, 160 people were selected based on inclusion and exclusion criteria and were randomly divided into control and intervention groups with a ratio of 1: 1.
Inclusion criteria for patients were as follows: 1) Having mechanical heart valve prostheses in any position; 2) at least 18 years of age; 3) ability to effectively communicate; 4) receiving only oral warfarin for anticoagulation therapy; and 5) without drug and alcohol abuse; and 6) telephone communication available. The exclusion criteria were as follows: 1) patient with biological prostheses; 2) simultaneous coronary artery bypass grafting (CABG) surgery; 3) medical history of coagulation disorders; and 4) known ulcerous disease with bleeding tendency.

At the beginning of the study, via the randomization method on Cards or envelops shuffling (MOHAMMADI and Janani, 2016) eligible participants were assigned to one of the two control and intervention groups. The random allocation sequence was managed by an independent statistician blinded to the sampling, interventions, and evaluation of participants.

This study was a double-blind trial. In this study, participants and outcome assessors were kept blind to the division of individuals into study groups. Participants were not informed whether they only received routine hospital counseling or home care training. The outcome assessor and data analyst did not know the grouping of participants.

2.3. Ethical considerations

Before any intervention, patients were informed of the purpose of the study, and patients were required to sign an informed consent form to begin work. Patients were informed that they were free to leave the study at any time and for any reason without the need for any explanation. Patients were also promised that personal information would remain confidential and that the results of the study would be published collectively or without personal information.

2.4. Usual care (control) group

Patients in the control group before and after surgery received only routine hospital training, which pre-surgery training including shaving and washing the surgical site with antiseptic detergents and encouraging spirometry. Post-surgery training also included movement training, nutrition counseling, medication counseling, Prothrombin Time (PT) and INR tests, and timely visits to the treating physician at specified times. Also, an educational pamphlet was routinely given to the patient for study at home, and the telephone number of the patient education unit was provided to the patient and his / her companion so that they could contact the medical center if necessary. Also, an educational pamphlet was routinely given to the patient for study at home, and the telephone number of the patient education unit was provided to the patient and his / her companion so that they could contact the medical center if necessary. Also, an educational pamphlet was routinely given to the patient for study at home, and the telephone number of the patient education unit was provided to the patient and his / her companion so that they could contact the medical center if necessary.

2.5. Intervention group
The intervention group, in addition to receiving all the training and routine hospital programs, participated in two one-hour training sessions before surgery and in four one-hour training sessions after surgery. In these sessions, content was provided on self-care training for patients receiving mechanical heart valves. Before surgery, the first session was held on the day of admission to the hospital and the second session was held on the day before the patient was admitted to the operating room. After surgery, the first session was held three days after surgery, the second session the day before discharge, and the third and fourth sessions the first and second weeks after discharge, respectively. These patients received information support from the research team during a 6-month follow-up program.

2.5.1 Educational content

In this study, educational content were prepared based on performing a self-care educational needs assessment of heart valve replacement patients. For this purpose, at the beginning of the study, a qualitative interview was conducted with several, heart valve replacement patients (patients who were in the surgical queue and also patients who had previously undergone this surgery) and was asked questions about their educational needs; Finally, by performing qualitative content analysis of the interviews, the educational needs of these patients were determined. In order to meet the educational needs of these patients, an educational package was prepared based on the opinion of nursing specialists, cardiac surgeons, nutritionists and rehabilitation specialists. To determine the content validity, training package was provided to 8 relevant experts and they were asked to express their opinions of the educational content and to comment if the content needs to be modified and edited. Finally, based on the opinion of experts, the amount of the Content Validity Ratio (CVR) was calculated to be 0.75. (Table 1)
| Main themes              | Sub-themes                                                                 |
|-------------------------|---------------------------------------------------------------------------|
| • Pre-operative errors  | • Neglect in identifying and admitting the patient for surgery            |
|                         | • Lack of commitment on the part of staff in preparing patients for surgery |
|                         | • Inattention of personnel in observing the aspetic and sterile principles |
| • Intraoperative errors | • Improper surgery                                                        |
|                         | • Leaving the foreign object in the operating position                    |
|                         | • Failure to follow the correct principles of positioning                 |
| • Post-operative errors | • Patients fall from the bed                                              |
|                         | • Incorrect registration of surgical samples                              |
| • Anesthesia-related    | • Incorrect injection of similar drugs                                    |
| errors                  | • Wrong blood transfusion                                                 |
|                         | • Ignoring the patient's monitoring during anesthesia                      |
| • Equipment-related     | • Insecurity of stretchers and surgical beds                              |
| errors                  | • Lack and depreciation of devices and equipment and not replacing them   |

### 2.5.2 Information Support Program

To provide information support to the patients in the intervention group, once every two weeks, one of the members of the research team, as the person in charge of education, contacted the patients and provided the necessary information support in the field of self-care. He was also present at the hospital during the follow-up period and communicated with each of the patients in the intervention group who referred to the treating physician to present their INR test results, and discussed their self-care measures. And if the person was faced with a new case that required training and counseling, sufficient information would be provided.

### 2.6 Instruments

In this study, data collection instrument included three main sections of demographic and clinical information questionnaire, INR test results and bleeding accident checklist.

#### 2.6.1 Demographic and clinical information questionnaire
This questionnaire was used at the beginning of the study and patient baseline information was collected using it. Demographic information included age, height, weight, gender, marital Status, employment, education, residence, and clinical information included body mass index (BMI), hypertension, diabetes, dyslipidemia, smoking habit, alcohol consumption, valve position (Mitral Valve Replacement (MVR), Aortic Valve Replacement (AVR), Tricuspid Valve Replacement (TVR) and Bivalve Replaced (BVR), hospital stay.

2.6.2 INR

Standard blood test was used to determine the INR of patients and the test sheet was considered as a data collection tool. In this study, based on available resources (Whitlock et al., 2012) and the opinion of experts, the INR in the range 2.5 to 3.5 was considered as the therapeutic target range, and measures outside of this range were considered as abnormal rates and need to be corrected.

2.6.3 Bleeding complication

In this study, based on the opinion of experts and previous studies (de Campos, 2014) a checklist was designed to investigate the incidence of bleeding events. Based on which bleeding events were divided into two categories: major hemorrhage complication included macroscopic hematuria, vaginal bleeding, hemoperitoneum, hemopericardium, severe gastrointestinal bleeding, hemorrhagic stroke, retroperitoneal hematoma, and minor hemorrhage complication included subcutaneous bleeding, epistaxis, microscopic hematuria, minor bleeding in stools, mild ocular bleeding, mild hemoptysis, gingival bleeding. To determine the validity of this checklist, the content validity method was used and for this purpose, the checklist was provided to 8 specialists (cardiologist, hematologist, pharmacologist) and they were asked to express their views on the checklist items. And if there is a need to modify or edit, comment. Finally, the CVR value was calculated, which was 0.75.

2.7 Data collection

The investigator was responsible for the collection of data was unaware of the randomization and grouping process. At the beginning of the study and before any intervention, individuals' data were collected using a demographic and clinical information questionnaire. Following the intervention and after the patient was discharged from the hospital for 6 consecutive months, information about the results of the INR test and the incidence of bleeding events were recorded every month.

2.8 Data analysis

Data were analyzed using independent t-test and chi-square in spss16 software at a significance level of 0.05.

3. Results

At the beginning of the study, 160 heart valve replacement patients were included in the study and were randomly divided into control (n = 80) and intervention (n = 80) groups. During the follow-up period, 5
patients died (intervention group, \(n = 2\); control group, \(n = 3\)), 2 patients withdrew from the study process (intervention group, \(n = 1\); control group, \(n = 1\)), and 4 patients was lost to follow up (intervention group, \(n = 3\); control group, \(n = 1\)). Finally, information and data of 149 participant (intervention group, \(n = 74\); control group, \(n = 75\)) were analyzed. (Fig. 1)

3.1. Participant demographics characteristics

Table 2 shows the demographic characteristics of 149 participants by grouping and the two groups are compared. As shown in the table, the two groups in terms of age, height and weight, gender, marital status, occupation, education, and place of residence (city or village) were not significantly different and were homogeneous (\(p > 0.05\)). (Table 2)

3.2 Participant clinical characteristics

Table 3 shows the clinical characteristics of the participants and the two groups are compared. The mean BMI of the two control and intervention groups was 24.92 ± 3.20 and 25.56 ± 4.32 respectively, which were not significantly different between the two groups (\(p = 0.307\)). 37.6% of participants reported high blood pressure, 13.4% diabetes, and 22.8% hyperlipidemia in their clinical history. In this regard, there was no significant difference between the two groups (\(P > 0.05\)). Among the participants, 24.8% reported smoking habit and 10.7% reported a history of alcohol consumption, but the two groups did not differ significantly in this regard (\(p > 0.05\)). 55% of participants had mitral valve replacement (MVR), 27.5% had aortic valve replacement (AVR), 2.7% had tricuspid valve replacement (TVR) and 14.8% had bivalve replaced (BVR), and participants in the two groups did not differ significantly in the valve position replaced (\(P = 0.969\)). Participants in the control and intervention groups were hospitalized for 8.62 ± 2.48 and 9.02 ± 2.39 days, respectively (\(p = 0.318\)). (Table 3)

3.3 Intergroup comparison of INR levels during 6 months after surgery

The table 4 compares the level of INR in the participants. As shown in the table, in the first, second, fourth, fifth, and sixth months, the frequency of INR levels in the therapeutic target range was significantly higher in patients in the intervention group than in the control group (\(p < 0.05\)). In the third month, although the frequency of INRs levels in the therapeutic target range was higher in the intervention, this difference was not significant (\(P = 0.071\)). (Table 4)

3.4 Intergroup comparison of the prevalence of bleeding during 6 months after surgery

The table 5 compares the prevalence of minor and major bleeding in the two groups over a 6-month follow-up. As shown in the table, during the 6 months of follow-up, the frequency of both types of bleeding (minor and major) in the intervention group was lower than the control group, but this difference was not statistically significant (\(p > 0.05\)).
4. Discussion

In this study during a 6-month follow-up program, to determine the effect of self-care training and information support of heart valve replacement patients on INR and bleeding complications, the INR level data and bleeding complications of 149 participants in two groups of control and intervention compared. This is the first study of training self-care and information support to mechanical heart valve patients that directly investigated the effects of this method of care on INR levels and the incidence of bleeding complications during a clinical trial. One of the strengths of this study is that at the beginning of the study to determine the topics of self-care education of patients in the target group, the training needs assessment was performed and finally the training package was used which was specific to patients with mechanical valve replacement. In this way, patients were introduced to care measures that had a positive effect on patients’ recovery process.

The results of this study showed that patients will experience the effectiveness of self-care if they become familiar with the basic and scientific methods of self-care and follow up in the form of a support program and receive the necessary information that is specific to each patient.

One of the benefits of self-care for heart valve replacement patients, which can be deduced from the results of this study it was that in the group that receiving self-care training and information support interventions, significantly the frequency of the therapeutic target range of INR was higher than the control group. This finding is consistent with the results of educational studies that have examined the effect of self-management education (Soliman Hamad et al., 2009, Eitz et al., 2008, Thompson et al., 2013).

Another benefit of self-care that the results of this study show are the reduction in the incidence of bleeding complications. So that, in this study, it was shown that bleeding complications in the intervention group who received self-care educational and supportive interventions were less prevalence than the control group, but this difference was not statistically significant. This finding is consistent with the results of other studies that have examined the effect of self-management training interventions on the incidence of bleeding complications and have shown that self-management can reduce the prevalence of bleeding complications (Christensen et al., 2016, Christensen et al., 2003, Mair et al., 2012).

Complications of bleeding are less prevalence in these patients (Rubboli et al., 2011), therefore, to show a statistically significant difference between the two groups in terms of the prevalence of bleeding, it is necessary to perform interventions on a large sample size of participants. Accordingly, in the present study, despite the lower incidence of bleeding in the intervention group, due to the small sample size, a significant difference between the two groups in terms of bleeding has not been proven.

Study limitations

There are some limitations to our study. The first is the small sample size, because the bleeding variable is less prevalence in the study population and in order to determine the effect of interventions, it is
necessary to take a large sample size. Another limitation of the present study is the short follow-up period (6 months), despite this limitation, it is not possible to evaluate the mid and long-term results of the interventions. Accordingly, it is suggested that more extensive studies be conducted in this field with larger sample size and follow-up time.

5. Conclusion

The results of this study showed that self-care training and information support of heart valve replacement patients during the postoperative period have positive effects on the patients' clinical condition. Based on the results, patients who have received proper self-care training and receive support information from medical staff during the postoperative period are more likely to experience the therapeutic target range of INR. It can also be concluded that proper self-care can reduce the incidence of bleeding complications in patients with mechanical heart valve. Therefore proper self-care training can led to improve patients condition and experience a safe anticoagulant regimen.

Abbreviations

INR: International Normalized Ratio; OAC: oral anticoagulation; VKAs: Vitamin K antagonists; CONSORT: Consolidated Standards of Reporting Trials; CABG: Coronary Artery Bypass Grafting; PT: Prothrombin Time; CVR: Content Validity Ratio; BMI: body mass index; MVR: Mitral Valve Replacement; AVR: Aortic Valve Replacement; TVR: Tricuspid Valve Replacement; BVR: Bivalve Replaced; ITT: In Therapeutic Target; OTT: Out of therapeutic target; MajH: Major hemorrhage; MinH: Minor hemorrhage.

Declarations

Conflict of interest
The authors declare no conflicts of interest.

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Ethical approval
This study is the result of a student thesis that has been registered in Hamadan University of Medical Sciences of Iran with the ethical code IR.UMSHA.REC.1398.403.

Consent for publication
Not applicable

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Author contributors

ShZ designed the study, collected the data, and provide the first draft of manuscript. BI designed the study and revised the manuscript. GhS participated in design of the study, the data collection, and revised the manuscript. All authors read and approved the final manuscript.

Availability of data and materials

Please contact author for data requests

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### Tables

Tables 2, 3, 4 and 5 are not available with this version