THE EFFECT OF A NURSE-LED PATIENT EDUCATION PROGRAM FOR ORAL ANTICOAGULANT THERAPY ON THE INCIDENCE OF THROMBOEMBOLIC AND HEMORRHAGIC EPISODES AFTER SURGICAL HEART VALVE REPLACEMENT

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ABSTRACT Introduction: Although, the effects of patient education on the effective anticoagulant management, among patients undergoing heart valve replacement with a mechanical prosthesis, have been reported, the evidence of this association remains inconclusive. **Aim:** To investigate the effect of a nurse-led patient education program for oral anticoagulant therapy on the incidence of thromboembolic and hemorrhagic episodes after surgical heart valve replacement. **Methods:** A quasi-experimental study was conducted. Patients were allocated to a) a control group (n=100), including those who received the usual education on oral anticoagulants, and b) an intervention group (n=100), with those who attended a nurse-led education program, postoperatively, including verbal courses and written material through an education booklet. We investigated the incidence of hemorrhagic and thromboembolic episodes three months after patients' hospital discharge. Patients' socio-demographic and clinical characteristics were obtained using a structured short questionnaire and through the medical and nursing patient records review. Patients' follow-up data were collected via phone interviews. **Results:** The baseline characteristics were similar for both groups. Patients who received nurse-led education on oral anticoagulant therapy had a significantly lower 3-month incidence of hemorrhagic episodes compared with controls (1% vs. 14%, $p<0.001$). However, we found insignificant differences in the 3-month incidence of thromboembolic events between the two groups. **Conclusion:** The implementation of a nurse-led education program on oral anticoagulants management failed to show effectiveness on the 3-month incidence of thromboembolic episodes. However, this educational intervention seems to be superior to the general patient education, leading to the significantly lower occurrence of hemorrhagic episodes.

KEYWORDS: Anticoagulants, complications, heart valve replacement, patient education, patient outcomes

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Introduction

Replacement of a heart valve with a mechanical prosthesis indicates life-long oral anticoagulant treatment. [1] The ineffective patients' management of their oral anticoagulants is a primary predictor of increased morbidity and mortality rates, making the managing of oral anticoagulants a crucial issue both for the clinicians and the patients. Indeed, oral anticoagulants are among the leading causes of hospitalizations for adverse medication reactions. [1]

As highlighted by many studies patient education on oral anticoagulant therapy is an effective option for reducing the occurrence of complications after heart valve replacement surgery. [2,3] However, other studies [4,5] failed to document this relationship, and the evidence of this effectiveness remains inconclusive. Additionally, the effect of a nurse-led patient education on the effective oral anticoagulant therapy management among heart valve replacement patients has little been studied worldwide.

The aim of the present study was to investigate the effect of a nurse-led patient education program for oral anticoagulant therapy on the incidence of thromboembolic and hemorrhagic episodes after surgical heart valve replacement. Our study intends to add new data to the patient education, on oral anticoagulants, the body of knowledge.

Materials and methods:

Study design and participants

A prospective, quasi-experimental study was conducted. The type of patient education (nurse-led or the usual) was the independent variable of our study. On the other hand, the thromboembolic and hemorrhagic episodes during the first three months after patient discharge were the examining outcomes (dependent variables) of the present study. We considered as thromboembolic events the following disorders: pulmonary embolism, stroke, deep vein thrombosis, myocardial infarction and prosthetic valve thrombosis. Also, we defined as hemorrhagic events the following disorders: hematoma, extensive bruising, epistaxis, rhinorrhagia, hematuria, hemoptysis, haemarthrosis, proctorrhagia, gastrointestinal, cerebral, ocular, uterine, gum and retroperitoneal bleeding.

The inclusion criteria of the study were a-priori defined as follows: a) age $\geq$ of 18 years old, b) placement of a mechanical valve through an open-heart surgery, c) prescribing of oral anticoagulant therapy with acenocoumarol postoperatively, d) knowledge of the Greek language, e) ability to verbal communication and reading, and f) willingness to participate in the study. Patients with a previous surgical heart valve replacement, those who received oral anticoagulants preoperatively, including all vitamin K antagonists, and those with previous stroke, coagulopathy, and psychiatric disorder were excluded. Additionally, we excluded patients who died in the hospital or during our study follow-up.

During a 21-month period, from March 2013 to November 2014, 273 patients were undergone to surgical heart valve replacement in a tertiary general hospital of Athens – Greece and were eligible for enrollment in the present study. Based on the above mentioning inclusion and exclusion criteria, 200 patients (participation rate 73.3%) constituted our final study sample (Figure 1).

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Patients were randomly assigned, based on their hospital admission (the odd numbers into control group and the even into intervention group), by one of the investigators, the same each time, too: a) a control group (n=100), consisted of patients who received the usual patient education on oral anticoagulant therapy, based on the hospital protocol, and b) an intervention group (n=100), with those who received education on oral anticoagulants through a nurse-led education program.

Procedure and data collection

Acenocoumarol was the drug that was prescribed as anticoagulant therapy, postoperatively, for all patients in our study. Patients in the control group received, according to the hospital protocol, oral and written standard information by their surgeon about the oral anticoagulant therapy, including drug's name, its indications, dosage, how to take, when to take, when not to take and its side effects. Patients in the intervention group received a nurse-led education program for oral anticoagulant therapy, including a verbal 20-minute course on oral anticoagulants after mechanical heart valve replacement surgery and a patient-education booklet called "What should I know about my anticoagulant therapy following heart valve replacement surgery." This booklet was created by the researchers based on the purpose of the study, the related literature and the opinion of two independent experts on the topic. The verbal educational course was carried out on the 4^{th}, the 5^{th} and the 6^{th} post-intensive care unit (ICU) day and was provided for every patient in an empty room, by the same researcher each time. The education booklet was distributed to patients of the intervention group at the 4^{th} post-ICU day for reading. The information in the education booklet covered the following topics:

1. What are the effects of anticoagulants and who needs anticoagulant therapy?
2. What are the anticoagulant drug?
3. What is acenocoumarol (Sintrom)?
4. What is the dosage for acenocoumarol?
5. What is the international normalized ratio (INR) and what are its normal levels?
6. How often should I get a blood test for INR measurement?
7. When should I take acenocoumarol?
8. How long should I take my anticoagulant therapy?
9. Acenocoumarol and my health status.
10. Acenocoumarol and pregnancy.
11. What are the side effects of acenocoumarol?
12. Dangerous signs and symptoms.
13. Diet.
14. Lifestyle changes for reducing the risk of blood clots (thrombosis)?

The booklet structure and content were explained, analytically, by the researcher. The researcher gave enough time to patients for questions and clarifications.

For data collection purposes we performed structured patient interviews through a short questionnaire on basic sociodemographic and clinical patient data. The questionnaire information included patients' age, gender, height, weight, the patients' income and insurance. Other variables, such as the EuroSCORE values, the INR and the activated partial thromboplastin time (APTT) levels, the cardiac patient history, the comorbidity, the type of surgery, and the emergency or elective character of surgery were obtained after medical and nursing patient records review. During the follow-up period (3 months after patient hospital discharge) data on the occurrence of thromboembolic and hemorrhagic episodes were obtained using phone patient interviewing. We documented the existence of the previously mentioned outcomes only if the patient referred hospitalization that was directly related to the event, or these episodes had been diagnosed by a general practitioner at a primary healthcare center. Aiming to ensure the validity and reliability of the data collection process, data collection was carried out by one of the researchers, the same each time.

Statistical analysis

Quantitative variables were expressed as mean values [± Standard Deviation (SD)], while qualitative variables were expressed as absolute and relative frequencies. For the comparison of proportions, chi-square and Fisher's exact tests were used. Independent samples Student's t-tests were used for the comparison of mean values between the control and intervention group. All reported p values were two-tailed. Statistical significance was set at $p<0.05$ and analyses were conducted using SPSS statistical software (version 19.0).

Ethics

The data collection was conducted after written permission from the ethics committee of the hospital (Permission ID: 13488). Researchers received patients' consent after being informed about the type and purpose of the study. The same researcher informed each potential subject of the aims, methods, anticipated benefits and potential risks of the study one day before the surgery. The potential subject was informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. The investigation was carried out by the ethical standards of the responsible institutional committee for human experimentation and with the Helsinki Declaration of 1975, as revised in 2013. Precautions took place to protect the privacy of research subjects and the confidentially of their personal information, including limiting the amount of personal information to the absolute minimum, assigning an identification number to each subject and attaching the identification number to the actual research information, removing the subject names as soon as data were analyzed and maintaining any identifying information and lists of identification numbers in a safe and locked file. No part of the standard care was omitted.

Results

Patients' baseline sociodemographics and clinical characteristics for each study group are presented in Table 1 and Table 2,3, respectively. The mean (± SD) age for the control and the intervention group was 65.0 (± 11.5) and 65.4 (± 11.3) years old, respectively, and the majority in both study groups were males, overweighed, with primary educational level, monthly income 500-1000 € and living in Athens - Greece.

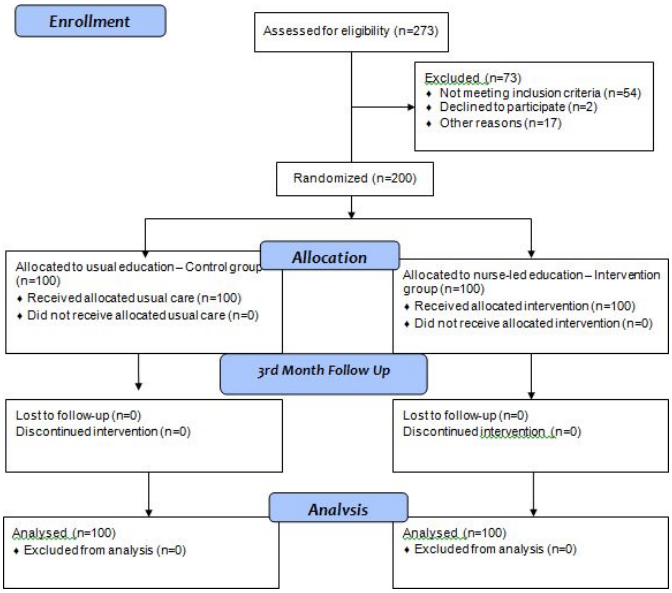

Figure 1: Flow diagram

Additionally, 27.0% of the control group and 23.0% of the intervention group had a chronic disease and 22.0% and 12.0% of the control, and the intervention group had a recent myocardial infarction, respectively. Half of the patients in both study groups undergone aortic valve replacement surgery. In most cases, the surgery was scheduled (84.7 for the controls and 90.7% for the intervention group). Normal INR and APTT levels had most patients at ICU discharge while 42.0% and 48.0% of patients in control and intervention group respectively, had low INR and APTT levels at hospital discharge. The two patient groups were similar regarding their baseline socio-demographic and clinical characteristics, without statistically significant differences. Table 4 summarizes the 3-month incidence of hemorrhagic and thromboembolic episodes in each patient group. At three months after hospital discharge, only 1.0% of the intervention group had a hemorrhagic episode, while the correspondent percentage for the control group was significantly greater and equal to 14.0% ($p<0.001$). On the other hand, the three-month incidence of thromboembolic episodes was 4.0% and 3.0% among the patients with the control and the intervention group, respectively, a difference statistically insignificant ($p=1.000$).

Discussion

According to the main findings of our study, patients who received a nurse-led education program on oral anticoagulant therapy with acenocoumarol had significantly lower incidence of hemorrhagic episodes at 3-month follow-up, compared with controls. On the other hand, we had no significant differences in the prevalence of thromboembolic events between the two patients group.

Patients on oral anticoagulants after heart valve replacement surgery, who attend educational courses on the effective anticoagulant therapy management, have significantly lower risk of hemorrhagic episodes during the postoperative period. [6] It seems that an educational program could assist patients to improve their knowledge level on oral anticoagulants and to achieve adequate self-care management, including effective therapy adherence, better control of INR, symptom monitoring, recognition and evaluation.

Table 1 Socio-demographics for the two study groups.

	Control group (n=100)	Intervention group (n=100)	p-value
	N (%)	N (%)	
Age (years), mean (±SD)	65.0 (11.5)	65.4 (11.3)	0.804+
Gender, n (%)			
Male	61 (61.0)	57 (57.0)	0.565*
Female	39 (39.0)	43 (43.0)	
Educational level, n (%)			
Primary	65 (65.0)	72 (72.0)	0.532*
Secondary	24 (24.0)	18 (18.0)	
University	11 (11.0)	10 (10.0)	
Monthly income, n (%)			
<500 euro	25 (25.5)	34 (34.0)	0.390*
500-1000 euro	53 (54.1)	50 (50.0)	
>1000 euro	20 (20.4)	16 (16.0)	
Residence, n (%)			
Athens	64 (64.0)	55 (55.0)	0.195*
Rural	36 (36.0)	45 (45.0)	
Eating habits, n (%)			
No	79 (79.0)	72 (72.7)	0.301*
Yes	21 (21.0)	27 (27.3)	
Smoking, n (%)			
No	54 (54.0)	60 (60.0)	0.391*
Yes	46 (46.0)	40 (40.0)	
Alcohol consumption, n (%)			
No	57 (57.0)	60 (60.0)	0.667*
Yes	43 (43.0)	40 (40.0)	
Physical activity, n (%)			
No	77 (77.0)	75 (75.0)	0.741*
Yes	23 (23.0)	25(25.0)	
***Pearson's x^2 test; +Student's t-test**			

Table 2 Clinical characteristics of the two study groups.

	Control group (n=100)	Intervention group (n=100)	p-value
BMI (kg/m^2), mean ((±SD)	27.2(4.4)	28.1 (4.5)	0.154+
BMI, n(%)			
Normal	31 (31.0)	27 (27.3)	0.486*
Overweight	48 (48.0)	44 (44.4)	
Obese	21 (21.0)	28 (28.3)	0.532*
Chronic disease, n (%)			
No	73 (73.0)	77 (77.0)	0.514*
Yes	27 (27.0)	23 (23.0)	
Atrial fibrillation, n (%)			
No	59 (59.0)	70 (70.0)	0.104*
Yes	41 (41.0)	30 (30.0)	
Diabetes, n (%)			
No	75 (75.0)	78 (78.0)	0.617*
Yes	25 (25.0)	22 (22.0)	
COPD, n (%)			
No	81 (81.0)	86 (86.0)	0.341*
Yes	19 (19.0)	14 (14.0)	
Recent MI (last 90 days), n (%)			
No	78 (78.0)	88 (88.0)	0.060*
Yes	22 (22.0)	12 (12.0)	
EuroSCORE (sum), mean(±SD)	5.67 (2.69)	5.20 (2.51)	0.203+
EuroSCORE (logistic), mean(±SD)	6.42 (5.68)	6.00 (5.99)	0.614+
Type of surgery, n (%)			
MVR	14 (14.0)	24 (24.0)	0.340**
AVR	50 (50.0)	50 (50.0)	
TVR	2 (2.0)	1 (1.0)	
AVR/MVR/TVR Combination	11 (11.0)	7 (7.0)	
CABG +AVR/MVR/TVR	23 (23.0)	18 (18.0)	
Emergency, n (%)			
No	83 (84.7)	88 (90.7)	0.200*
Yes	15 (15.3)	9 (9.3)	
INR, APTT levels (at ICU discharge), n(%)			
Normal	70 (70.0)	76 (76.0)	0.136*
Low	22 (22.0)	12 (12.0)	
High	8 (8.0)	12 (12.0)	

Table 3 Clinical characteristics of the two study groups.

	Control group (n=100)	Intervention group (n=100)	p-value
INR, APTT levels (at hospital discharge), n(%)			
Normal	45 (45.0)	38 (38.0)	0.598*
Low	42 (42.0)	48 (48.0)	
High	13 (13.0)	14 (14.0)	
Hospitalization in ICU (days), mean (±SD)	2.33 (1.46)	2.40 (0.98)	0.692+
Total,hospitalization (days), mean (±SD)	8.72(3.99)	9.07(3.02)	0.485+
***Pearson's x^2 test; **Fisher's exact test; +Student's t-test**			
APTT =Activated Partial Thromboplastin Time, AVR = Aortic Valve Replacement, BMI =Body Mass Index, CABG = Coronary Bypass Grafting, COPD = Chronic Obstructive, Pulmonary Disease, ICU = Intensive Care Unit, INR = International Normalized Ratio, MI = Myocardial Infarction, MVR = Mitral Valve Replacement, TVR = Tricuspid Valve Replacement			

Table 4 Three-month incidence of hemorrhagic & thromboembolic episodes in each patient group.

Outcome	3-month incidence		p-value
	Control group (n=100)	Intervention group (n=100)	
Hemorrhagic,episode, n (%)	14 (14.0)	1 (1.0)	<0.001*
Thromboembolic,episode, n(%)	4 (4.0)	3 (3.0)	1.000*
***Pearson's x^2test**			

In line with the results of our study, Christensen et al. [3] in their prospective multi-centre study of 615 patients with surgical heart valve replacement, concluded that those with adequate education and effective management of their anticoagulant therapy are low-risk patients for hemorrhage episodes, postoperatively. Likewise, White and his colleagues [7] in an extensive series of heart valve replacement patients stated that patients with high knowledge level on anticoagulants management, due to their participation in an educational program, had a significantly lower incidence of hemorrhagic episodes during their rehabilitation.

Additionally, Koertke et al. [4] conducted a multi-centre study of 3300 heart valve replacement surgical patients, who allocated to controls and those who received specific education on their oral anticoagulants. According to the study mentioned above and in line with our results, the authors stated that patients in the intervention group had reduced related to surgery complications, including reduced incidence of hemorrhagic events. In the currently available published research, there are many studies which highlight the positive effect of patient education on the frequency of hemorrhagic episodes among patients who underwent heart valve replacement surgery. [8-11] However, contrary to our results, Heneghan et al. [2] and Thompson et al. [12] failed to documented that patients' education on their oral anticoagulant therapy management can affect positively, the incidence of postoperative complications, including hemorrhagic episodes.

As aforementioned, another important finding of the present study was the lack of significant differences in the 3-month incidence of thromboembolic events between controls and the patients, who had received the nurse-led education program. We could explain this result considering the relatively small sample size and the short-term follow-up period of our study. The presence of a larger sample size and the longer follow-up period for complications, such as thromboembolic episodes, could lead to statistically significant differences between the two patient groups.

By our results, many studies have failed to indicate strong evidence regarding the significant reduces the incidence of thromboembolic episodes, postoperatively, due to the patient education program. [4,5,12,13] However, and in contrast with the above mentioned, it is well known that a high knowledge level, due to adequate patient education on oral anticoagulants, has been strongly associated with the significantly lower incidence of postoperative thromboembolic episodes among heart valve replacement patients. [2,3,8]

Finally, it is worth mentioned the homogeneity of the two patient groups of our study, regarding their baseline socio-

demographic and clinical characteristics. This similarity indicates the absence of significant confusing variables which could affect the validity of our study findings.

Study limitations

To the best of our knowledge, the present study was the first to examine the effect of a nurse-led patient education program for oral anticoagulants on the incidence of postoperative complications, such as hemorrhagic and thromboembolic events, among patients undergoing heart valve replacement surgery in Greece. However, our study has some limitations: the small sample size, the collection of data from one cardiac surgery center the quasi-experimental design and the lack of double-blinding could affect our study validity and impede our ability to generalize the study findings to the general population of patients undergoing heart valve replacement surgery.

Conclusion

The ineffective patient management of oral anticoagulant therapy, after heart valve replacement surgery, has been associated with poor outcomes and can be considered as an independent predictor of increased morbidity and mortality rated. [14] It seems promising that the implementation of a systematic and structured nurse-led education program on oral anticoagulants management appears to be superior to the general patient education, leading to significantly lower 3-month incidence of hemorrhagic episodes. Simultaneously, this educational nursing intervention failed to show effectiveness on the 3-month incidence of thromboembolic events, probably due to the short patient follow-up. In any case, our findings indicate the critical and valuable role that cardiac nurses can play in heart valve replacement surgical patients' rehabilitation improvement, ensuring lower morbidity rates and better self-care behavior. Our study limitations indicate the need for further research with randomized controlled and multi-centre trials with longer patient follow-up to emphatically address the beneficial effect of nurse-led education on patients outcomes, after heart valve replacement surgery.

Authors' Statements

Competing Interests

The authors declare no conflict of interest.

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