ENHANCE ADHERENCE TO ORAL ANTICOAGULANT THERAPY AMONG PATIENTS WITH ATRIAL FIBRILLATION AFTER AN EDUCATIONAL INTERVENTION IN NAM DINH PROVINCIAL GENERAL HOSPITAL

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ABSTRACT

Objective: *To assess the current practice and changes in adherence to Anti-vitamin K anticoagulants therapy among cardiovascular patients with atrial fibrillation after the educational intervention at Nam Dinh Provincial General Hospital.* ***Method:*** *The one group pre-test and post-test educational intervention was conducted among 102 cardiovascular outpatients with atrial fibrillation who were under Anti-vitamin K anticoagulant therapy at least one month. The Morisky Medication Adherence Scale (MMAS-8) was applied to evaluate the outcomes before and after the education.* ***Results:*** *Before the intervention, the percentage of patients achieved the overall adherence to Antivitamin K anticoagulant therapy was only 32.4% of patients. One month after completing the intervention, this rate increased significantly at 63.7%, nearly double in comparision with this before the intervention. There were 40.2% of patients who achieved the target IRN before the intervention then this number also increased markedly to 70.6% at the point of one month later the intervention (p values of 0.01). The percentage of patients who had experienced the behaviors those related to inadequate use of anticoagulants also decreased clearly after the intervention.* ***Conclusion:*** *The study results showed the poor practice in adherence to Anti-vitamin K anticoagulant, and the significantly improvements after the educational intervention. The study revealed the real need to educate patients on adherence to Anti-vitamin K anticoagulant therapy as a supplement added to routine guidelines when patients receive a prescription.*

Keywords: *adherence, atrial fibrillation, an-tivitamin K, anticoagulants*

1. INTRODUCTION

Atrial fibrillation has been affecting millions of people worldwide, increasing the risk and severity of strokes, heart failures, and deaths [1]. Viet Nam is a country with a high rate of cardiovascular diseases in general and valvular diseases in particular. According to statistics, cardiovascular diseases requiring anticoagulant therapy are increasing [2,3]. Anti-vitamin K (AVK) anticoagulants has been widely used, especially in low-income countries, for the prevention and treatment of thromboembolism in conditions such as atrial fibrillation, venous thrombosis and pulmonary embolism, valvular heart diseases [4]. AVK anticoagulant therapies are facing two main obstacles including the wide range of pharmacological effects and the therapeutic effectiveness of AVK anticoagulants that is influenced

by many factors such as the sensitivity to medication of each patient, patient's diet, drug interactions, internal medical comorbidities (liver failure, kidney failure...), and especially depended on the patient's adherence to AVK anticoagulants [5,6].

The International Normalized Ratio (INR) test is the most reliable indicator of the therapeutic efficacy of AVK anticoagulants. The goal of treatment is to ensure the INR threshold of 2-3 or 3-4 depended on each patient, if the IRN test result below the target treatment threshold (INR < 2.0) this will put the patient at high risk of thrombosis, high INR More than the treatment target (INR > 3.5), the patient is at risk for bleeding complications. Conversely, in case the INR test result above the target treatment threshold (INR > 3.5), it will put the patient at risk of bleeding complications.

Thrombosis leading to thromboembolism caused by the inadequate use of anticoagulants that fails to reach preventing thrombosis or the use of substances that reduce the anticoagulant effect of the AVK anticoagulants, and vice versa suffering from bleeding complications by the overdose use are major consequences associated with anticoagulants. Arcording to the final report from the early self-management anticoagulation trial II published by the European Heart Journal, the rate of thrombosis was ranged from 0.01 to 2.04 per 100 patients each year and bleeding complications from 0.1 to 6.2 per 100 patients each year [7]. According to the UK National Health Authority, AVK anticoagulants are one of the five drug groups related to fatal complications and should be considered about the safety of patients [8].

Literature review of recent studies regarding knowledge and practice of adherence to anticoagulants revealed practically a serious knowledge gap in patients using anticoagulants [9], and showed interventions through health education improving adherence to anticoagulation therapies, increasing treatment efficiency, and contributing to reducing mortality from cardiovascular disease [10]. In Viet Nam, descriptive studies by Nguyen Ngoc Phuoc in 2013 [11] and Le Thi Thuy in 2014 [12] also revealed poor practice in adherence to Anti-vitamin K anticoagulant and influential factors among study samples of patients. However, there was no educational intervention in order to solve this problem. Aiming to improve patients' adherence to AVK anticoagulant therapy through patient education, the objectives of this study were to assess the current practice and changes in adherence to Anti-vitamin K anticoagulants treatment among cardiovascular patients with atrial fibrillation after the educational intervention at Nam Dinh Provincial General Hospital.

2. RESEARCH METHOD

Study participants were out-patients, diagnosed with one of cardiovascular diseases with atrial fibrillation and prescribed the AVK anticoagulant (Sintrom 4) and been managing by Nam Dinh provincial general hospital. Inclusion criteria included patients aged full 18 years or older, had been taken AVK anticoagulant for at least one month or longer up to the point of beginning of the study, had ability to follow the educational programs and consented to participate in the study. Exclusion criteria were cases who did come for re-examination but his/her condition had to be hospitalized; or patient who had participated in an educational program with similar contents. Patients who did not participate fully in all activities of the study and assessing times did not included in the analysis of the results.

A before and after study was conducted

from December 2019 to August 2020 at Nam Dinh Provincial General Hospital. The research proposal was approved by the Scientific Committee and the Boad for Research Ethics of Nam Dinh Nursing University as well as had the consent of Nam Dinh Provincial General Hospital. Followed the accepted research proposal, the data collection and educational interventions began from February 1 to April 30, 2020. According to the sample size formula for an one group pre-test and post-test study [13], the minimum sample size was 83 participants. Convenient sampling method was applied and there were 102 patients who met the inclusion criteria of the study during the period of data collection. With the desire to help as many patients who comply with AVK anticoagulant therapy as possible, all 102 of these patients were selected for the study. Therefore, the actual sample size of this study was 102 participants.

The educational intervention content was developed based on documents regarding guidelines for the use of AVK anticoagulants including *'Oral anticoagulants'* of the Viet Nam National Heart Institute 2020 [14], *'Drug interactions and attention when indicated'* by the Department of Health of Viet Nam 2015 [15] and *'What to know about the warfarin diet'* by the American Heart Association 2019 [16]. Materials for education included handouts, illustrations, flyers regarding adherence to AVK anticoagulant therapy were provided for patients in advance. The direct consulting of a three or four patient-group focused on the importance and patient's benefits from adherence AVK anticoagulant therapy, specific behaviors, possible barriers and how to response and each session lasted average of 30 minutes.

MMAS-8 [17] and Toolkit from Viet Nam National Heart Institute [11] were used to evaluate adherence practice. Any patient who got ≥ 6 points by MMAS-8 scale was counted as achieving the medication adherence. The use of substances and foods that reduce the therapeutic effects of AVK anticoagulants were assessed with levels of use included 0; 1; 2; 3 points equal to frequent; sometimes; rarely; never. Within a total of 12 points, any patient got ≥ 8 points were reported met the adherence. Achieving the alcohol / beer restriction if the amount of alcohol consumed less than 3 standardized drinks per day and 14 standardized drinks per week for men; less than 2 standardized drinks per day and less than 9 standard drinks per week for women. The patient's IRN result tests were used to evaluate objectively the adherence and patients who had the target IRN and no appear bleeding complications were counted as adherence to therapy. The study data set was analyzed by using SPSS 20.0 software.

3. RESULTS

The mean age of 102 participated patients was 63.93±11.26 years, the youngest was 33 years old and the oldest is 89 years old. The number of female/ male patients, resided in rural/urban areas and living with relatives/alone were 59/43, 75/27 and 85/17, respectively. There were only 4 of 102 patients trained at vocational secondary and college levels after leaving schools and no one of them earn a university degree.

The percentages of patients who adherenced to AVK anticoagulant use, diet, alcohol restriction and overall therapy (combined by adherence to all three criteria) before and after the educational intervention were demonstrates in Figure 1.
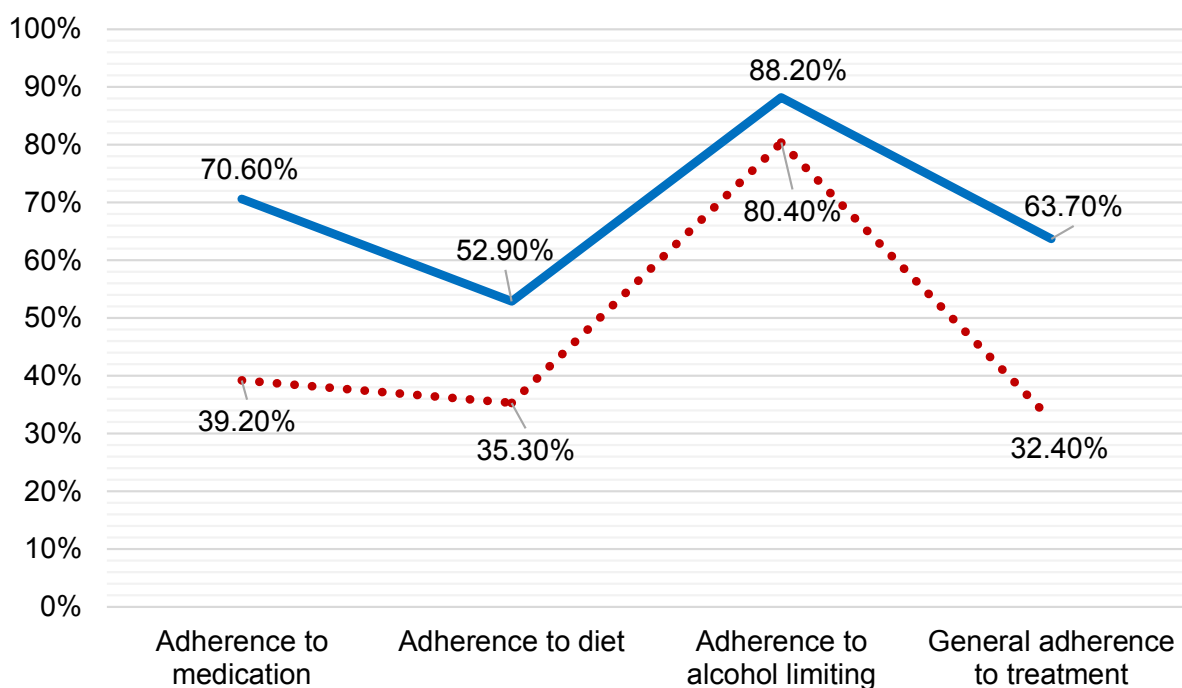
Figure 1. Adherence to AVK anticoagulant therapy (n=102)

Before the study, except the adherence to alcohol restriction that appeared already at high rate of patients (80.4%), the percentages of patients who adherence to AVK anticoagulant use, diet and overall therapy were all low at 39.2%, 35.3% and 32.4%, respectively. After the educational intervention, these percentages all increased at 70.6%, 52.9% and 63.7%.

Table 1. IRN result tests of participated patients (n=102)

Time points for testing	Achieved the target IRN		p value (Chi square)
	Number of patients	%	
One month before the education (T0)	48	47.1	
Right before the education (T1)	41	40.2	p (1-0) = 0.72
One month after the education (T2)	72	70.6	p (2-1) = 0.00

Table 1 showed the percentages of patients with IRN result tests met the target IRN values from one month before and right before the educational intervention were 47.1% and 40.5%, respectively. One month after completing the educational intervention, the percentage of patients with IRN values within the target IRN range considerably increased up to 70.6% in comparision with that before the intervention (p<0.01).

Table 2. Hemorrhage signs of participated patients (n=102)

Manifestations of hemorrhage	Right before the education		One month after the education	
	Number of patients	%	Number of patients	%
Total	9	8.82	4	3.92
Natural petechiae under the skin	1	0.98	1	0.98
Prolonged bleeding after traumas such as shaving; cut hands; brushing teeth or any minor wound	8	7.84	3	2.94

At the time before participating the educational program, 9 of 102 patients had already manifestations of hemorrhage, among these patients, one was appeared natural hemorrhage under the skin. One month after completing the intervention, there were only four of these patients remained signs of hemorrhage including the patient who had had natural hemorrhage under the skin since the previous time.
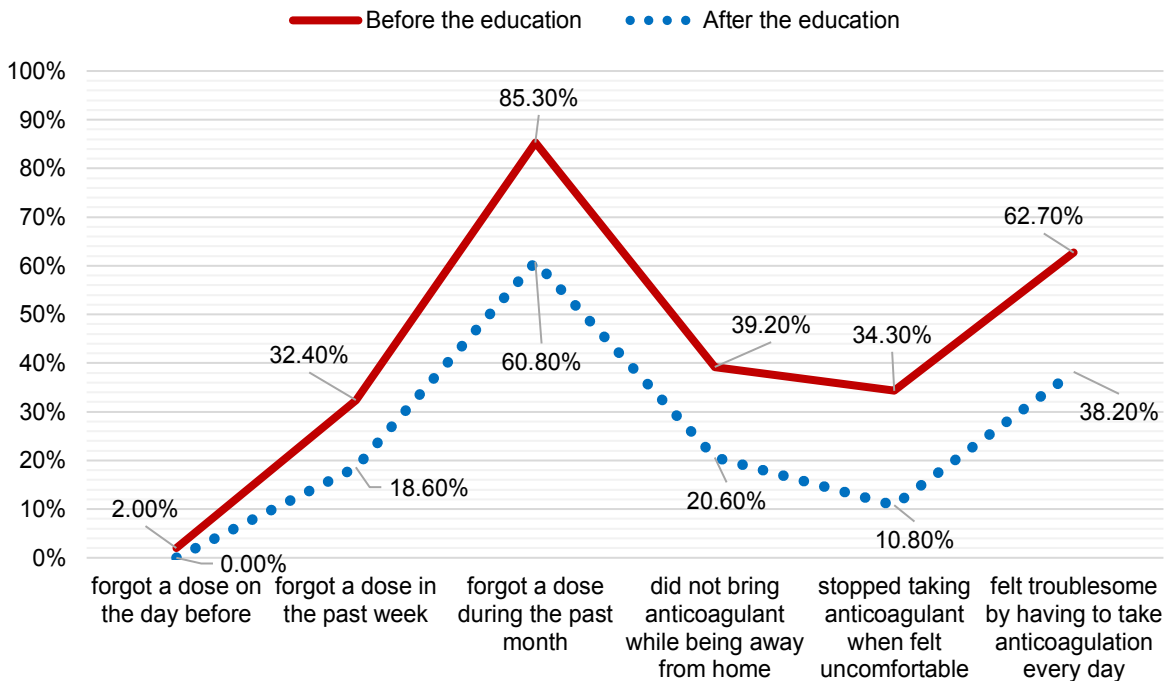

Figure 2. Behaviors related to inadequate dosage of AVK anticoagulant (n=102)

This figure showed that after the educational intervention, there was a clearly decreased trend in the proportion of patients who previously had behaviors related to inadequate use of AVK anticoagulants.

4.DISCUSSION

Published studies, even mentioned the same problem, still had different features. Literature review showed two descriptive studies regarding adherence to AVK anticoagulant therapy by Nguyen Ngoc Phuoc in 2013 [11], and by Shehab A et al in 2019 [18], those applied the same tool and criteria for measurement and assessment as which were applied in this study, therefore they were used for discussion on assessing the situation of patients' adherence to AVK anticoagulant therapy. There was currently no educational interventions available regarding enhance patients' adherence to AVK anticoagulant, so discussion on the effectiveness of educational intervention based on a recent study regarding educational intervention to improve adherence to hypertension treatment by Nguyen Thi Thu Thuy in 2018 that also used the same design and Morisky scale (MMAS-8) for measurement of compliance [19].

The results of our study (Figure 1) together with the results from the studies mentioned above [11,18] reflected poor adherence to AVK anticoagulant therapy. In fact, all patients coming to hospital for medical treatment were instructed for medication use when received a prescription. However, routine instructions were likely not enough to make patients be aware of the importance of adherence, to believe in the benefits and how to compliance as well as key factors that help patients to be confident and follow instructions [20]. This indicated a real need for more appropriate interventional programs.

After completing the educational intervention, there were significantly increased percentages of patients who did adhered to all three categories at approximately double in compared with that before the education as seen in the Figure 1. In our study, the patients' IRN values of one month before and right before the educational intervention were used as an objectively to evaluate the effect of the intervention and Table 1 demonstrated a clearly improvement in patients' adherence to AVK anticoagulant therapy after the education by 70.6% of patients who had IRN values within the target IRN range in comparision with 40.5% right before the intervention. This result confirmed that the patients who participating in the education of this study had actually compliance to practical instructions provided from the education. In other words, this was a convincing evidence of the effectiveness of the implemented educational intervention. In addition, a reducing trend in the number of patients with manifestations of hemorrhage seen in Table 2 as well as in the number of patients with behaviors related to inadequate medication use presented in Figure 2 also contributed to the effectiveness of the education of this study. Along with the positive changes in the improvements of adherence to hypertension treatment after the educational intervention in the study by Nguyen Thi Thu Thuy [20]. This study showed again the need of proper educational interventions for outpatients regarding the enhance to treatment of cardiovascular diseases in general.

Although, the study showed positive changes in the patients' adherence to AVK anticoagulant therapy it was also inevitable limitations that were no control group to be compared with and the time interval for evaluation was not long enough to confirm the sustainability of adherence [21,22]. However, to some extent, this study

contributed to increased effectiveness of using AVK anticoagulants. Naturally, adherence to specific therapies is likely to be reduced over time, it is suggested that appropriate educational programs on adherence for target patients should be developed and regularly implemented in order to reinforce, strengthen and maintain patients' adherence practice, online educating methods should be also considered.

5. CONCLUSION AND RECOMMENDATION

Poor practice of adherence to AVK anticoagulants was seen in the participated patients within this study and there were significantly improvements after the educational intervention. This study showed the need to provide patients with atrial fibrillation an adequate education to enhance their adherence to anticoagulant therapy in addition to the routine counseling that they receive during their re-examination.

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