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Original Article

Effect of Knowledge on Medication Adherence and International Normalized Ratio (INR) Control Among Patients on Oral Anticoagulants: A Randomized Controlled Trial

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ABSTRACT

Background: Anticoagulants must be provided with careful monitoring and adjusted individual dose due to their narrow therapeutic index due to significant risk of medication-drug interactions, drug-food interactions, and adverse drug reactions. Regular monitoring of INR, adequate knowledge and adherence to oral anticoagulant therapy plays a vital role in achieving better therapeutic outcomes. Thus, our study aims to assess level of adherence and knowledge of the patients. **Materials and Methods:** A prospective interventional study, enrolled 66 patients (control 33) and intervention (33) of both IPD (Inpatient Department) or OPD (Outpatient Department) patients with thromboembolic disorders between the age of 18-65 years and who were on oral anti-coagulant therapy. Utilization of Morisky medication adherence scale (MMAS-8) and Oral Anticoagulant Knowledge (OAK) questionnaire to assess adherence and knowledge on oral anti coagulation therapy. **Results:** Out of 66 patients, 56.1% male patients predominate over the 43.9% female patients, most of them were of age between 41-50 years. Majority of the patients of the intervention group were highly adhered (27.3%), moderately adhered (51.5%) and have adequate knowledge (90.9%) at follow ups after providing pharmaceutical care. Therapeutic INR has been improved among 36.4% patients. Most common cause for non-adherence is forgetfulness. **Conclusion:** Collaboration with clinical pharmacists can increase anticoagulant adherence and provide necessary information. Anticoagulant clinics run by pharmacists have shown to be helpful in managing anticoagulation treatment for both hospitalized and outpatient patients.

Keywords: Adherence, International Normalized Ratio, Knowledge, Oral anticoagulants.

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INTRODUCTION

Anticoagulants are the pharmaceutical agents that prevent or minimizes the risk of coagulation via prolonging the clotting of blood.[1] Oral anticoagulants are broadly classified into Vitamin K antagonists (VKAs) and the direct oral anticoagulants (DOACs).[2] The VKAs competitively inhibit Vitamin K epoxide reductase enzyme which is responsible for activating Vitamin K associated in coagulant factors (factor II, VII, IX, X) and antithrombotic factors.[3] Similarly, DOACs bind at the active site of coagulation enzymes and inhibit a single protease.[4] Warfarin is widely used VKAs which requires continuous monitoring and often causes drug interactions.[5] The DOACs drugs include dabigatran, apixaban, rivaroxaban and are expected to overcome the limitations of warfarin therapy.[5] DOACs drugs have more advantages than VKAs such as few drug interactions, rapid onset of action, does not require routine coagulation monitoring, predictable pharmacokinetic profiles.[2]

Thrombosis is a clotting of blood in the circulatory system (veins or arteries).[6] In 2010, 1 in every 4 deaths are known to be caused by thromboembolic disorders globally.[7] Thromboembolic disorders include deep vein thrombosis (DVT), pulmonary embolism (PE), several cardio and cerebro vascular diseases.[6] As anticoagulants are narrow therapeutic index drug, they have to be administered with monitoring and modified individual dosage regimen risk of drug-drug interactions, drug-food interactions,

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adverse drug reactions.[8] The number of patients on anticoagulant medication has risen significantly in recent years, which requires decentralized monitoring.[8] Monitoring needs include blood coagulation levels with prothrombin time (PT) to derive international normalized ratio (INR).[8] Although the DOACs does not require regular monitoring which makes it convenient to use, this could leads to potential hazard due to lack of opportunity for assessment of anticoagulation in an individual, adherence and knowledge reinforcement.[9] Patients with optimum knowledge and adherence to oral anticoagulant therapy are more likely to achieve optimal treatment outcomes, compared to those who do not.[10] Thus our study aims to assess medication adherence and knowledge about oral anticoagulants among patients of prescribed therapy.

MATERIALS AND METHODS

A prospective interventional study was conducted at cardiology department in tertiary care Charitable hospital. The study was conducted for the duration of six months. We enrolled 66 patients (control 33) and intervention (33) of both IPD (Inpatient Department) or OPD (Outpatient Department) patients with thromboembolic disorders between the age of 18-65 years and who were on oral anti-coagulant therapy. Patients who were unwilling to participate, loss of follow up or critically ill condition were excluded from the study. This study was initiated after the approval from the institutional ethics committee on the human subject (Ref. No. KLECOP/665/2018-19) and written informed consent was obtained from each participant before the enrolment. The enrolled patients were randomized to control and intervention group. The control group received usual standard care whereas the intervention group were counselled about the disease, its complication, plan of treatment, dosage regimen, need for the adherence to the treatment, side effects and need for follow up along with the usual standard care. The relevant data on adherence and knowledge of patient on oral anticoagulant therapy were collected using self-designed data collection form. Morisky medication adherence scale (MMAS-8) and Oral Anticoagulant Knowledge (OAK) questionnaire to assess adherence and knowledge on oral anti coagulation therapy. The patients were followed up for the duration of 2 months.

The data was analyzed for descriptive statistics using SPSS (Statistical Package for Social Sciences) version 22.0 (IBM statistics). The detailed work flow of the study has been depicted in the Figure 1.

RESULTS

Demographic data

A total of 66 patients were randomly enrolled in the study out of which 50% (33) were assigned to control group and 50% (33) were into intervention group. Out of 66 patients, in control 57.6% (19) were males and 42.4% (14) were females. Whereas, in intervention 54.5% (18) were males and 45.5% (15). The mean age of control group and intervention group patients is 44.4 and 43.9 years i.e.; most of them were of age between 41-50 years 27.3% (9) and 27.3% (3) respectively. The majority of patients from control group were diagnosed with rheumatic heart disease 21.2% (7), followed by MI 15.2% (5), unstable angina 12.1% (4), Vascular surgery/ prosthetic heart valve 12.1% (4), Defibrillation syndrome 9.1% (3), PE 9.1% (3), stroke 6.1% (2), DVT 3% (1), CHF 3% (1), IHD 3% (1). Likewise, MI 21.2% (7), unstable angina 15.2% (5), cerebrovascular disease 12.1% (4), Vascular surgery/ prosthetic heart valve 9.1% (3), DVT 9.1% (3), rheumatic heart disease 9.1% (3), PE 6.1% (2), stroke 6.1% (2), IHD 6.1% (2), Defibrillation syndrome 3% (1), CHF 3% (1) were the medical condition associated with intervention group. Alcohol consumption, tobacco chewing and smoking were the most frequently associated social habits among the both control and intervention group. The demographics and clinical characteristics is summarized in Table 1.

Morisky medication adherence scale (MMSA-8)

On assessment of medication adherence in the control group, 6.1% (2) were highly adherent followed by 54.5% (18) moderately adherent and 39.4% (13) low adherent at baseline. At follow up after 2 months, 6.1% (2) highly adherent, 42.45 (14) moderately adherent and 51.5% (17) low adherent in the control group. Likewise, in the intervention group, only 3% (1) patients were highly adherent, 51.5% (17) moderately adherent and 45.45 (15) low adherent at baseline. But at follow up after 2 months, 27.3% (9) patients were highly adherent followed by 51.5% (17) moderately adherent and 21.2% (7) low adherent (Table 2). Also, the major cause for non-adherence was found to be forgetfulness (at baseline -control: 42.4%, intervention 39.4%), (at follow up-control: 45.5%, intervention: 45.5%), stopping the medication once felt better (at baseline -control: 39.4%, intervention 36.4%), (at follow up- control: 33.3%, intervention: 30.3%) and lack of proper knowledge about regimen (at baseline -control: 18.2%, intervention 24.2%), (at follow up- control: 21.2%, intervention: 24.2%) as shown in Table 2.

Oral Anticoagulant Knowledge (OAK) questionnaire

OAK questionnaire was evaluated at baseline as well as at follow up for both control and intervention group. The patient knowledge mean score for the control at baseline is 10.48±2.8 of which 87.9% (29) patients were having poor knowledge and only 12.1% (4) were having adequate knowledge. At the follow up patient knowledge mean score for the control is 11.94±3.0, 66.7% (22) with poor knowledge and 33.3% (11) with adequate knowledge. Patients baseline mean score of knowledge for the intervention is 11.8±2.7, 60.7% (22) with poor knowledge and 30.3% (10) adequate knowledge. The mean score of knowledge among intervention group patients at follow up is 16.8±2.5, adequate knowledge 90.9% (30) and poor knowledge 9.1% (3). At

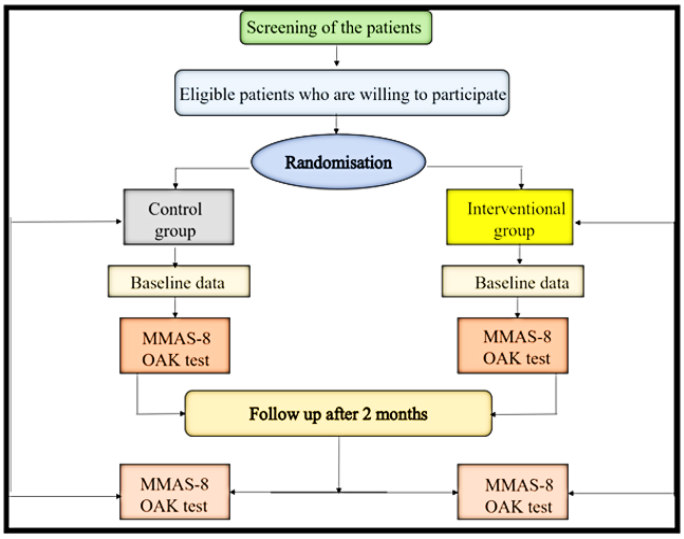

Figure 1: Flow chart of the study.

Table 1: Demographic and habits details.

Parameters		Frequency		Percentage	
Control group		33		50%	
Interventional group		33		50%	
Groups		**Control group**		**Intervention group**	
Variables		**Frequency**	**Percentage**	**Frequency**	**Percentage**
Age Control (Mean =44.4±10.57) Intervention (Mean= 43.8±12.6)	18-30 Years	3	9.1%	5	15.1%
	31-40 Years	10	30.3%	9	27.3%
	41-50 Years	9	27.3%	9	27.3%
	51-65 Years	11	33.3%	10	30.3%
Gender	Female	14	42.4%	15	45.5%
	Male	19	57.6%	18	54.5%
Habits	Smoking	5	15.2%	6	18.2%
	Alcohol	10	30.3%	8	24.2%
	Tobacco	5	15.2%	8	24.2%
	No habits	13	39.4%	11	33.3%
Diagnosis	DVT	1	3%	3	9.1%
	Unstable angina	4	12.1%	5	15.2%
	MI	5	15.2%	7	21.2%
	Cerebrovascular disease	2	6.1%	4	12.1%
	Rheumatic heart disease	7	21.2%	3	9.1%
	Vascular surgery, prosthetic heart valve	4	12.1%	3	9.1%
	Defibrillation syndrome	3	9.1%	1	3%
	PE	3	9.1%	2	6.1%
	Stroke	2	6.1%	2	6.1%
	Congestive heart failure	1	3%	1	3%
	IHD	1	3%	2	6.1%

Table 2: Causes for Non- Adherence.

Parameters	Control		Intervention	
Causes for non-adherence	At baseline	At follow up	At baseline	At follow up
Forgetfulness	42.4% (14)	45.5% (15)	39.4% (13)	45.5% (15)
Stopping medication once felt better	39.4% (13)	33.3% (11)	36.4% (12)	30.3% (10)
Lack of knowledge about regimen	18.2% (6)	21.2% (7)	24.2% (8)	24.2% (8)

Table 3: Medication Adherence and OAK.

Medication adherence					
MMAS-8		Control group		Intervention group	
	Parameters	Frequency	Percentage	Frequency	Percentage
At baseline	Highly adherent (Score=8)	2	6.1%	1	3%
	Moderately adherent (Score 6-8)	18	54.5%	17	51.5%
	Low adherent (Score <6)	13	39.4%	15	45.4%
At follow up	Highly adherent (Score=8)	2	6.1%	9	27.3%
	Moderately adherent (Score 6-8)	14	42.4%	17	51.5%
	Low adherent (Score <6)	17	51.5%	7	21.2%
Oral Anticoagulation Knowledge					
OAK		Control group		Intervention group	
	Baseline	Follow up		Baseline	Follow up
Adequate knowledge (score 14-20)	4 (12.1%)	11 (33.3%)		10 (30.3%)	30 (90.9%)
Poor knowledge (score 0-<14)	29 (87.9%)	22 (66.7%)		20 (60.7%)	3 (9.1%)
Mean ±SD	10.48±2.8	11.9±3.0		11.8±2.7	16.8±2.5
International Normalised Ratio (INR)					
	INR value	Control group		Intervention group	
		Frequency	Percentage	Frequency	Percentage
At baseline Control (Mean ±SD) (1.74±0.8) Intervention (Mean ±SD) (1.60±1.0)	Subtherapeutic range: <1- 2	25	75.7%	24	72.7%
	Therapeutic range :2- 3.5	6	18.2%	5	15.2%
	Supratherapeutic range ≥3.5	2	6.1%	4	12.1%
At follow up Control (Mean ±SD) (2.17±0.8) Intervention (Mean ±SD) (2.5±1.2)	Subtherapeutic range <1- 2	21	63.6%	12	36.3%
	Therapeutic range :2- 3.5	8	24.2%	12	36.4%
	Supratherapeutic range: ≥3.5	4	12.1%	9	27.3%

follow up, 66.7% and 9.1% were found to have poor knowledge and 33.3% and 90.9% were found to have adequate knowledge among control and intervention group respectively (Table 3).

International Normalized Ratio (INR)

Majority 75.7% (25) of patients in the control group were having subtherapeutic level (<1-2) of INR followed by 18.2% (6) were in therapeutic range (2- 3.5) and 6.1% (2) were supratherapeutic range (≥3.5) at baseline whereas 63.6% (21) were in subtherapeutic, 24.2% (8) in therapeutic range and 12.1% (4) in Supratherapeutic range at follow up. Likewise, for the intervention group, 72.7% (21) were in subtherapeutic, 15.2% (5) were in therapeutic range and 12.1% (4) in supratherapeutic at baseline whereas 36.4% (12) were in therapeutic, 36.3% (12) in subtherapeutic, and 27.3% (9) in supratherapeutic range at follow up (Table 2).

DISCUSSION

Gaps in patient awareness were determined to be one of the most significant obstacles to oral anticoagulation and were associated to decreased safety and efficacy. It is possible to improve patient outcomes by successfully controlling the determinants like patient education, prescription adherence, lifestyle modification, drug and food interactions, and INR monitoring frequently. In the present study out of 66 patients, 56.1% (37) males and 44% (29) were females with majority from the age group of 41-50 years which is in parallel to a study on anticoagulant knowledge and INR control among 225 patients where male (53%) patients were dominant in compared to female (46.6%) with the mean age of 70 years.[11] According to the criteria of MMAS-8 for medication adherence, the total range of scoring is 0 to 8 where the score <6 indicates low adherence, 6-8 indicates moderately adherence and 8 indicates high adherence.[12] Our study showed that at baseline both the control and intervention groups were having low adherence i.e., 39.4% (13) control and 45.4% (15) intervention. However, level of adherence gradually improved among intervention group from baseline [low adherence 45.4% (15), medium adherence 51.5% (17), high adherence 3% (1)] to follow up [low adherence 27.3% (9), medium adherence 51.5% (17), high adherence 21.2% (7)]. This improvement strongly shows importance of pharmaceutical care provided by clinical pharmacist such as patient education, awareness about medication adherence, knowledge on disease related complications, adverse effects and importance about regular check-ups. Increase level of adherence led to achieve therapeutic range of INR in majority of the patients among intervention group i.e., from 15.2% patients in therapeutic range at baseline to 36.4% in therapeutic range at follow up. Meanwhile, control group wasn't provided with any pharmaceutical care this resulted in very poor adherence pattern at baseline [low adherence 39.4% (13), medium adherence 54.5% (18), high adherence 6.1% (2)] and at follow up [low adherence 51.5% (17), medium adherence 42.4% (14), high adherence 6.1% (2)]. As patients were not provided with any awareness by pharmacist there was no much improvement in INR therapeutic range i.e., only 18.2% patients were therapeutic range at baseline which slightly improved at follow up i.e., 24.2% achieved therapeutic range. Similarly, a Brazilian study on impact of knowledge of warfarin therapy and its relation with adherence towards therapy and INR level among 60 patients revealed that 86.7% patients were low adherent to prescribed therapy of which about 61.5% patients were found to have subtherapeutic or supratherapeutic INR range.[13] Likewise, an Australian survey found that only 54.9% of total 386 atrial fibrillation participants were highly adherent to the oral anti-coagulant therapy where females were more likely to be adherent in comparison to men. Thus, significant predictors of adherence were age, gender, treatment satisfaction, lack of adequate knowledge, misuse and cost of OACs.[14] A Chinese study among 170 patients who were on anticoagulation therapy for 3 months were assessed for adherence and factors associated with adherence where they found 50 patients (29.4%) were poorly adhered and 120 (70.6%) were highly adhered. Forgetting to take the medication (21.20%) and ceasing to take the medication when they feel better (9.40%) were the two main causes of poor adherence. Factors such as number of drugs, types of comorbidities, monthly income, and self-efficacy were other factors associated with the poor adherence.[15] Likewise, In the present study the major cause for non-adherence was forgetfulness followed by stopping of the medication once felt better and lack of proper knowledge on rational use of anticoagulants (Table 3).

OAK questionnaire consists of 20 questions pertaining to several domains such as indication, missed dose, effects of food, other drugs and vitamins on oral anticoagulation, test for PT/INR, safety considerations. For each correct answer a score of 1 is given. OAK has been categorised into poor knowledge (score <14) and adequate knowledge (score 14-20).[13] At the baseline, 87.9% patients were having poor knowledge and only 12.1% (4) were having adequate knowledge among the control group whereas 66.7% were with poor knowledge and 33.3% (11) with adequate knowledge at follow up. Similarly, 60.7% patients were with poor knowledge and 30.3% with adequate knowledge whereas the knowledge was highly increased after 2 months of post counselling which resulted in 90.9% patients with adequate knowledge and only 9.1 % were having poor knowledge. This improvement in knowledge among intervention group led in attaining huge differences in therapeutic range INR in comparison to control group. Similarly, a study in Saudi Arabia carried out a face-to-face interview for all the patients who were on anticoagulant therapy. A total of 162 patients were questioned to test their knowledge regarding anticoagulation therapy. They found that

53.1% of patients with poor knowledge out of which < 50% were medium adherence and 24% were highly adherent to the therapy. However, a controlled INR was present in 53.2% of patients with good knowledge whereas it is around 27% in patients with poor knowledge.[16] Rahmani *et al.*, conducted a study to assess the knowledge of anticoagulants using OAK questionnaire and association between level of knowledge, INR control and adverse effects among 225 patients on oral anticoagulants. A mean OAK score of 12 was obtained in which 64% had very less score. Patients with younger age and better education were able to understand and were having sufficient knowledge on anticoagulants. Patients presented with 22 bleeding episodes and 5 thrombosis where INR of 57.3% patients were therapeutic level, 25.1% at subtherapeutic, and 17.4% at supratherapeutic level.[11] A prospective Malaysian study assessed the knowledge of 215 atrial fibrillation patients on anticoagulant medications using OAK questionnaire. OAK scores of 47.6±17.6 was found among the patients.[17]

One of the major obstacles in developing countries affecting adherence is cost of the medication. However, by providing generic medicines which are proven to have similar effect to that of branded drugs could be a great strategy to overcome the financial burden among patients. [18] Therefore, proper knowledge and low-cost therapy will improve level of adherence that would decrease unnecessary hospitalizations, therapeutic complications and mortality. Similar to our study, Ahmed H *et al.*, carried out a cross sectional study to evaluate the association between patients' knowledge and adherence to anticoagulants where 76.2% were found to be adherent to warfarin therapy (MMAS score 6) and only 20.45% were of high adherence (MMAS score of 8). The results of the OAK test showed a strong positive correlation with TTR (time in therapeutic range). The correlation between medication adherence and TTR as a measure of INR control was found to be statistically significant and positive.[19]

CONCLUSION

We conclude that forgetfulness, lack of knowledge, negligence and discontinuation of treatment after partial recovery were the common reasons for non-adherence. However, providing counselling to patients on importance of adherence to therapy led to compliance towards the treatment which has positive impact on surrogate marker as well as clinical outcomes. Thus, Pharmacist oriented anticoagulation clinics could be one of the milestones in future both in the inpatient and outpatient setting.

Limitation

The present study was conducted for short period of time with a limited sample size.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CHF: Congestive Heart Failure; **DOACs:** Direct Oral Anticoagulants; **DVT:** Deep Vein Thrombosis; **IHD:** Ischemic Heart Disease; **INR:** International Normalized Ratio; **IPD:** Inpatient Department; **MI:** Myocardial Infraction; **MMAS-8:** Morsiky Medication Adherence Scale-8; **OAC:** Oral Anticoagulant; **OAK:** Oral Anticoagulant Knowledge; **OPD:** Outpatient Department; **PE:** Pulmonary Embolism; **PT:** Prothrombin Time; **TTR:** Time in Therapeutic Range,; **VKAs:** Vitamin K Antagonists.

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