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Original Article

Optimizing Oral Anticoagulation Therapy: Impact of Pharmacists Intervention in Patient Knowledge and International Normalized Ratio (INR) Control

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ABSTRACT

Background: Oral Anticoagulant is a therapy indicated for thromboembolic disorders, which requires close observation of the international normalized ratio and patient education for better therapeutic outcomes. Management of Oral Anticoagulation Therapy (OAT) in cardiovascular disease is one greater concern because of numerous drug-related problems and non-compliance towards medications due to poor knowledge. As a result, the pharmacist offers patient counseling to improve knowledge. Therefore, the objective of this study is to compare the knowledge score of the patients about anticoagulation therapy and its impact on international normalized ratio levels in patients undergoing oral anticoagulation therapy. **Materials and Methods:** A randomized controlled study among 102 patients in the Cardiology department. Patient information leaflet and patient counseling on oral anticoagulation therapy were given as Interventions. Knowledge level was assessed from the baseline and followed in the first and third months. **Results:** A total of 102 patients actively participated in the study. Considering the area of knowledge, no more significant difference was seen in either group (U=1018, *p*-value=0.058) during the pre-test. Following the intervention, a notable disparity was observed in the Intervention group (U=528.00, *p*=0.0001). The mean INR is significantly different between the control and intervention groups in the therapeutic range (t=-5.80, *p*=0.0001*) and the supratherapeutic range (t=-3.42, *p*=0.002*). **Conclusion:** A collaborative educational approach with a pharmacist helps to improve the patient's knowledge of anticoagulation control. Establishing a pharmacist-managed anticoagulation service for the benefit of patients so that a clinical pharmacist can manage anticoagulation effectively and provide the best treatment.

Keywords: Oral Anticoagulation therapy, International Normalized Ratio, Anticoagulation Knowledge Assessment, Clinical Pharmacist, Patient Counseling.

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INTRODUCTION

Medications called anticoagulants, often referred to as blood thinners, help prevent dangerous blood clots from forming. These medications come in pill form and fall into two main categories. Vitamin K Antagonists (VKAs) work by interfering with the body's use of vitamin K, a crucial element for clotting factors. Warfarin is a common VKA, but it requires frequent monitoring and can be affected by other medications and foods. Newer medications called Direct Oral Anticoagulants (DOACs) take a different approach. DOACs target specific enzymes involved in clotting, offering several advantages over warfarin. These advantages include less interaction with other drugs, faster-acting effects and no need for regular blood tests to check their effectiveness.[1]

Bleeding represents the most prevalent adverse effect associated with anticoagulant medications, a factor contributing to patient apprehension and resistance towards therapy. In clinical studies involving the use of Vitamin K Antagonists (VKAs) for atrial fibrillation, the mean significant bleeding rate was 2.1 per 100 patient-years. Notably, the risk of substantial bleeding varied with direct oral anticoagulants, reaching 30% with apixaban and 38% with warfarin. Patients with Venous Thromboembolism (VTE) present distinct bleeding risk factors compared to those with atrial fibrillation, including age, concurrent use of antiplatelet medication with other medical conditions, the presence of concurrent cancers and initial anticoagulant dosages. In the context of oral anticoagulants, gastrointestinal bleeding emerges as the most common site of bleeding. Historically, VKAs have

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been utilized for the treatment and prevention of venous and arterial thrombosis.[2]

Polypharmacy increases the likelihood of adverse drug events and dosage errors in patients with Cardiovascular Disease (CVD). Furthermore, these patients are more prone to using high-risk medications, particularly anticoagulant therapies. To improve patient outcomes and reduce the financial burden associated with medication-related errors and adverse events, a focus on prevention is crucial.[3] Clinical pharmacists are healthcare professionals with a special set of skills. Their extensive training, experience and often additional certifications qualify them to deliver a unique service-Clinical Pharmacy Services (CPS). This expertise allows them to contribute significantly to patient care and collaborate effectively with the entire healthcare team. CPS encompasses various aspects, including complex medication management, medication-related transitional care and the provision of medication education for either patients or clinicians, although not exclusively limited to this areas.[3]

Pharmacists can clinically expertise the use of Oral Anticoagulation Therapy (OAT) for various thromboembolic disorders by analyzing the knowledge in patients and regular monitoring of the International Normalized Ratio (INR) for better therapeutic outcomes. Educating patients with relevant information about therapy is called "Patient Counselling." A study conducted among the Indian population in North India reported that only 56.4% were well educated about their OAT and exact INR range due to a lack of patient education during hospital visits.[4] Older age groups greater than 60 years had less knowledge in Indian studies conducted. A study was carried out in Punjab for two months; the interpretation supported the above statement stating that patients above 60 years had lower knowledge scores when compared with patients less than 60 years of age group. The educational status also plays a vital role in assessing the knowledge about OAT. Thus, poor health literacy leads to poor knowledge and therefore results in poor medication adherence.[5] Most of the studies about OAT knowledge associated with INR control were carried out by Clinical pharmacists in Western countries. A study conducted in Hong Kong concluded that knowledge was a determining factor of anticoagulation control.[6]

Management of OAT in the cardiology department is one greater concern because of numerous drug-related problems and non-compliance towards medications due to poor knowledge. As a result, the pharmacist offers patient counseling to improve knowledge.[7] Therefore, this study aims to compare the knowledge score of the patients about anticoagulation therapy and its impact on international normalized ratio levels in patients undergoing oral anticoagulation therapy.

MATERIALS AND METHODS

Study Design and Population

A randomized controlled trial was carried out in the Cardiology Department over six months (October 2019- March 2020). Ethical approval was obtained from the ethics committee (Reference No: KLECOP/522/2019-2020). Patients above 18 years undergoing oral anticoagulant therapy were involved in the study. Patients on antineoplastic therapy, pregnant and lactating women, a patient suffering from psychiatry disorder and patients on ventilators and coma were excluded from the study. The randomization process involved the creation of two parallel arms, divided in a 1:1 ratio using a standard envelope technique. These arms were designated as the usual care group (Control) and the pharmaceutical care intervention group (Test). In the presence of a pharmacist, the envelopes were opened and participants were assigned to their respective groups. Participants in the test group received pharmaceutical care intervention delivered by a clinical pharmacist, while those in the control group received usual care from other healthcare professionals.

Study Procedure

The patients were screened and enrolled for the study as per eligibility criteria. The patient complaints, medication history, current medication, personal habits, comorbidities, diagnosis, INR and current health condition were noted using data collection forms during baseline evaluation (Day 0).

The Anticoagulation Knowledge Assessment tool (AKA tool) developed by Briggs *et al.*[6] was used to analyze patients' knowledge of anticoagulation therapy. The AKA tool was checked for face validity in its original language (English) by specialists (two clinical pharmacists and one physician). It consists of 27 questions, out of which the first 20 questions are based on available OAC therapy. The remaining seven are specific to Warfarin, with the 25th question containing two sub-divisions. One mark was allocated for each correct answer and zero for each wrong answer, except for questions 6, 18 and 19, where three marks were assigned for correct answers and 25 (b) question 4 marks were allocated for correct answers. The total score for a correctly answered questionnaire was 35 marks (25 Marks from section A and 10 marks from section B).

Intervention

Patient Information Leaflets (PILs) designed for education and counseling were developed in English, Kannada and Marathi languages. A collaborative team consisting of general medicine physicians, pharmacists and laypersons carefully reviewed these leaflets. The intervention group received pharmaceutical guidance from the clinical pharmacist, including counseling on oral anticoagulant therapy, discussions about its adverse effects and explanations regarding its influence on International Normalized Ratio (INR). Assessments were conducted at monthly intervals,

specifically on Day -30, Day -60 and Day -90 and the results were compared to the baseline data.

Statistical Analysis

The information was inputted into Microsoft Excel and then transferred to the Statistical Package for the Social Sciences (IBM version 22.0). Patient demographic variables were summarized through the application of descriptive statistics. To evaluate knowledge before and after the intervention, the Mann-Whitney U test and the Wilcoxon Matched pair test were employed.

RESULTS

In this study, 379 patients were screened, out of which 102 patients were enrolled and further divided by using the envelop method equally among each Control (51) and Intervention group (51) for assessment of patient knowledge on oral anticoagulants.

The study consisted of 60 (58.82%) males and 42 (41.18%) females. The mean age for our patients was 48.30±13.18 years. The mean weight was 68.98±8.897 kgs. The occupation profile of enrolled patients was further grouped into: farmers 19.61%, homemakers 37.25%, shop owners 10.78%, drivers 8.82% and other professionals 23.53%, respectively. The educational status of patients in the study is categorized into five groups: No schooling (27.45%), primary (42.16%), secondary (23.53%), higher secondary (5.88%) and degree (0.98%). Most of the patients in our study were neither taking alcohol nor smoking (72.55%). The remaining 17.65% were taking tobacco and 9.80% of patients were taking alcohol, as shown in Table 1.

The common diagnosis in the study was Rheumatic Heart Disease 19.61%, ischemic heart disease/Acute Myocardial Infraction 23.53%, Peripheral vascular disease 23.53%, Coronary Artery Bypass Graft Surgery/ Coronary Artery Disease 16.67% and Aortic and Mitral Valve Replacement 16.67% respectively. Among them, the most prescribed oral anticoagulants were Acenocoumarol in 67 (65.69%) patients, followed by Warfarin among 35 (34.31%) patients as shown in Table 2.

The Mann-Whitney U-test was employed to evaluate the pre-intervention knowledge scores of patients in both the control and intervention groups. The analysis indicated no substantial difference between the control and intervention groups (U=1018.00, *p*-value=0.0587). After the intervention, a significant distinction in knowledge scores was observed between the control and intervention groups (U=528.00, *p*-value=0.0001*). It is noteworthy that the predetermined significance level for the knowledge score was 5%, as outlined in Table 3.

Knowledge scoring of each question in the Control and Intervention group was compared by using the Wilcoxon

Table 1: Comparison of Control and Intervention with the Demographic Profile.

	Control	Intervention	Total	Statistic	*p*-value
Gender					
Male	35 (68.63%)	25 (49.02%)	60 (58.82%)	χ^2=4.0480	0.0440*
Female	16 (31.37%)	26 (50.98%)	42 (41.18%)		
Occupations					
Farmer	10 (19.61%)	10 (19.61%)	20 (19.61%)	χ^2=5.5000	0.2400
Housewife	14 (27.45%)	24 (47.06%)	38 (37.25%)		
Shop owner	6 (11.76%)	5 (9.80%)	11 (10.78%)		
Driver	5 (9.80%)	4 (7.84%)	9 (8.82%)		
Others	16 (31.37%)	8 (15.69%)	24 (23.53%)		
Educational status					
No schooling	15 (29.41%)	13 (25.49%)	28 (27.45%)	χ^2=1.9990	0.7360
Primary	21 (41.18%)	22 (43.1 %)	43 (42.16%)		
Secondary	13 (25.49%)	11 (21.57%)	24 (23.53%)		
High secondary	2 (3.92%)	4 (7.84 %)	6 (5.88%)		
Degree	0 (0.00)	1 (1.96%)	1 (0.98%)		
Habits					
Tobacco	13 (25.49%)	5 (9.80%)	18 (17.65%)	χ^2=4.4200	0.1100
Alcohol	5 (9.80%)	5 (9.80%)	10 (9.80%)		
None	33 (64.71%)	41 (80.39%)	74 (72.55%)		
Total	51 (100.00%)	51 (100.00%)	102 (100.00%)		

*$p<0.05$.

Table 2: Comparison of Control and Intervention with diagnosis and types of oral anticoagulants.

	Control	Intervention	Total
Diagnosis			
Rheumatic Heart Disease	11 (21.57%)	9 (17.65%)	20 (19.61%)
Ischemic Heart disease/ Acute Myocardial Infraction	12 (23.53%)	12 (23.53%)	24 (23.53%)
Peripheral vascular disease	15 (29.41%)	9 (17.65%)	24 (23.53%)
Coronary Artery Bypass Graft Surgery/ Coronary Artery Disease	7 (13.73%)	10 (19.61%)	17 (16.67%)
Aortic and Mitral Valve Replacement	6 (11.76%)	11 (21.57%)	17 (16.67%)
Name of OAC			
Acenocoumarol	32 (62.75%)	35 (68.63%)	67 (65.69%)
Warfarin	19 (43.25%)	16 (31.37%)	35 (34.31%)
Total	51 (100.00%)	51 (100.00%)	102 (100.00%)

Table 3: Comparison of Control and Intervention with total pre-test and total post-test AKA by Mann-Whitney U test.

Time	Control			Intervention			U-value	Z-value	*p*-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Pre-test	6.82	3.17	57.04	5.74	3.95	45.96	1018.00	-1.8907	0.0587
Post-test	6.94	3.23	36.35	14.13	7.05	66.65	528.00	-5.1701	0.0001*

*$p<0.05$.

Table 4: Comparison of total pre-test and post-test AKA scores percentage changes in Control and Intervention by Wilcoxon matched-pairs test.

Changes from	Control			Intervention		
	% of change	Z-value	p-value	% of change	Z-value	*p*-value
Pretest-Posttest	1.72	1.4737	0.1406	146.32	6.2146	0.0001*

*$p<0.05$.

Table 5: Comparison of mean INR range between both control and intervention group.

INR	Control			Intervention			T-statistics	*p*-Value
	n	Mean	SD	*n*	Mean	SD		
Sub-therapeutic (<2) (*n*=44)	25	1.35	0.24	19	1.43	0.33	-1.74	0.092
Therapeutic (2.0-3.0) (*n*=35)	16	2.52	0.21	19	2.28	0.25	-5.80	0.0001*
Supra therapeutic (>3) (*n*=23)	7	3.69	0.46	16	4.61	1.95	-3.42	0.002*

matched-pairs test. It is observed that the change in knowledge among the Intervention group was 146.32% compared to the Control group at 1.72%. Hence, there was a significant change in knowledge score between the groups (Z=6.2146, p=0.0001*), as shown in Table 4.

The mean INR is significantly different between the control and intervention groups in the therapeutic range (t=-5.80, p=0.0001*) and the supratherapeutic range (t=-3.42, p=0.002*) as shown in Table 5.

There is a change in the post-intervention knowledge score, which is much better in the intervention group, as represented in Table 6. There is a significant difference in the knowledge score between the control and intervention groups in the sub-therapeutic (t=-4.67, p=0.001*) and therapeutic category (t=-5.29, p=0.001*) of INR as shown in Table 6.

DISCUSSION

The research revealed an enhancement in patients' understanding of oral anticoagulation therapy following counseling sessions with pharmacists. The study conducted in China emphasized the

Table 6: Comparison of Post-test knowledge score between the INR category in both control and intervention group

INR	Control			Intervention			% Change	t-statistic	*p*-value
	n	Mean	SD	n	Mean	SD			
Sub-therapeutic (*n*=44)	25	6.94	3.20	19	13.76	6.77	98.27	-4.67	0.001*
Therapeutic (*n*=35)	19	7.28	3.16	16	14.13	6.98	94.09	-5.29	0.001*
Supra therapeutic (*n*=23)	7	7.00	3.24	16	12.87	6.81	83.86	-1.63	0.118

significance of effective treatment, highlighting the crucial role of educational counseling and the monitoring of INR levels. Notably, the study in China found that 90.8% of participants lacked sufficient knowledge.[8] The establishment of an Anticoagulation Management Service (AMS) leads to superior clinical outcomes for patients compared to standard care.[9] Throughout the study, the assessment of knowledge was conducted using AKA questionnaires developed by Briggs *et al.*[10] In general, the findings indicate that patients undergoing therapy had a restricted comprehension of the importance of oral anticoagulation and INR. Evaluating knowledge scores among patients is primarily influenced by their educational qualifications. In the study conducted, 28 (27.45%) patients were under the No Schooling category and 43 (42.16%) under the Primary Schooling level. The total percentage of change in knowledge about each question was 1.72% in the control group, which subsequently increased to 146.32% in the intervention group. While comparing the total pre-test and total post-test of the Control and Intervention group, it was found that the control group had a mean score of 6.82+3.17 in the pre-test and 6.94+3.23 in the post-test.

In contrast to the Intervention group, the Control group exhibited a mean score of 5.74+3.95 in the pre-test and 14.13+7.05 in the post-test. The analysis indicated that there was no noteworthy increase in knowledge among patients in the Control group. Conversely, in the Intervention group, there was a statistically significant improvement in knowledge (p=0.0001*) with a 5% confidence interval. This rise in the level of knowledge was attributed to the effective patient counseling provided by the pharmacist in the Intervention group.

In Germany, a comprehensive intervention study was conducted, comprising both Intervention and Control groups. The intervention group underwent case management and received education On Oral Anticoagulant Therapy (OAT). This intervention was compared with the Control group, which received standard care. At baseline, both groups had comparable knowledge scores. However, after 12 months, there was a noteworthy enhancement in knowledge within the Intervention group. Similarly, after 24 months, both groups demonstrated statistical significance (0.6+2.6 vs. 0.3+2.3, p=0.0001). Consequently, the study concluded that patient education should be a standard practice to enhance knowledge.[11]

In Qatar, a cross-sectional study utilized a 20-item questionnaire to assess the knowledge quality concerning Warfarin and its influence on INR. Among the 140 patients participating in the study, only 49 had their INR within the therapeutic range. Seventy-nine patients (75%) exhibited sufficient knowledge, while approximately 42% demonstrated a lack of understanding regarding medications and drug-related issues. The study's conclusion emphasized the necessity for clinical pharmacists to offer educational counseling to enhance patient comprehension and adherence.[12]

Drawing from the literature, the optimal therapeutic INR range is identified as 2.0-3.0, with values above 3 indicating a risk of bleeding and below 2 suggesting a risk of clotting.[13] In this study, INR was classified into three categories based on this literature.[13] The control group exhibited a mean therapeutic INR of 2.28+0.25, while the intervention group showed a therapeutic INR of 2.52+0.21. Patient interviews revealed variations in INR levels due to irregular INR check-ups. Many patients only conducted INR checks during follow-ups, indicating a lack of awareness about the importance of regular INR monitoring. The interpretation of the results led to the conclusion that effective patient counseling had been provided. Following proper education, patients were monitored again and the desired therapeutic range was achieved. The study ultimately determined that knowledge about oral anticoagulation therapy directly correlated with patients' INR values. Previous studies have emphasized the importance of patient counseling on the significance of INR in anticoagulation therapy.[14] In our study, with 27.45% uneducated and 42.16% primarily educated patients, knowledge scores varied based on educational status. Tang *et al.* highlighted that a lack of education could result in lower knowledge scores, emphasizing the need for increased attention to elderly and illiterate individuals. [6] Consequently, the study concluded that patients' awareness and knowledge of INR were associated with improved anticoagulation management, reflecting positively on the role of clinical pharmacists in OAT management. In a developing country like India, conducting such studies would be valuable to showcase the enhancement in the quality of care. This could justify the necessity of such services, aligning with the increasing service demands of patients. Consequently, it may pave the way for the establishment and growth of patient-friendly services within hospitals.

The collaborative educational approach involving pharmacists in anticoagulation clinics proved effective in enhancing patients' understanding of anticoagulation control.[15] Special attention is advised for the elderly and those with low health literacy, tailoring educational strategies based on their qualifications and

language preferences. Providing counseling aids such as Patient Information Leaflets in the preferred language contributes to better comprehension. The study highlighted that individual with higher education levels exhibit a better understanding of oral anticoagulation therapy and INR-level management.

CONCLUSION

The study recommends the establishment of clinical pharmacist-managed anticoagulation services or clinics in major hospitals, both public and private, to ensure effective anticoagulation management and optimal patient care. In conclusion, pharmacist interventions in oral anticoagulation therapy were found to enhance treatment adherence, improve clinical outcomes and reduce the risk of complications.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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