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# EVALUATING THE ROLE OF PHARMACIST COUNSELING ON PATIENT KNOWLEDGE AND SAFETY IN WARFARIN USE

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**ABSTRACT**

Warfarin is a widely used oral anticoagulant with a narrow therapeutic index, requiring careful monitoring and patient adherence to prevent adverse events such as bleeding or thrombosis. Patient knowledge regarding dosage, dietary restrictions, drug interactions, and monitoring is critical for safe and effective therapy. This study evaluates the impact of pharmacist-led counseling on patients' understanding and management of warfarin therapy. Patients receiving counseling were assessed using structured questionnaires before and after educational interventions, focusing on key aspects of therapy, safety precautions, and adherence practices. Results indicate a significant improvement in patient knowledge and awareness post-counseling, with a marked reduction in misconceptions regarding drug interactions, INR monitoring, and lifestyle modifications. The findings highlight the vital role of pharmacists as educators in anticoagulation therapy, emphasizing the importance of structured counseling to enhance patient safety, adherence, and clinical outcomes.

## I. INTRODUCTION

Warfarin is the most widely recommended oral anticoagulant, used in the prevention of clotting among patients at risk for stroke or thromboembolic events.1 The use of warfarin is challenged by its complex pharmacology and intrinsic risk of adverse outcomes, which requires routine INR (International Normalized ratio) monitoring to ensure safe and effective therapy.2,3 Clinicians have previously cited an unwillingness to prescribe warfarin due to its interactions with diet, drugs and need for monitoring, all of which relies on patient compliance and treatment instructions and therefore is dependent on effective patient education.

Warfarin is a major contributor to potentially preventable drug-related adverse events, partly due to inadequate patient knowledge.5 A validated set of questionnaire provides a simple method of determining patients' knowledge of anticoagulation.6 Studies have concluded that patients' warfarin knowledge, a major contributor to anticoagulation control is poor and more attention should be given in educating the patients' on warfarin use.7 Hence, it is of paramount importance for patients to have proper knowledge about the factors that may lead to warfarin related complications. Various studies have found that pharmacist provided verbal counseling improves warfarin knowledge.4,8,9 This can be accomplished by counseling so as to help prevent adverse health outcomes.4 However, studies assessing impact of educational intervention among Nepalese population is limited. Therefore, the study aims to assess the impact of pharmacist's counseling in MATERIALS AND METHODS Study site and setting The study was conducted in the outpatient department of Shahid Gangalal National Heart Center, Kathmandu. This is a 200 bedded tertiary care hospital with an outpatient flow of 350 patients per day Study Duration The study was conducted for duration of 7 months from March to September 2015.

Selection of Participants Simple random sampling technique was used to assign the patients either to the intervention (pharmacist counseling) or the control group (usual care) where they had an equal chance of being allocated to either of the two groups. The patients selected in both the groups were similar in terms of socio-demographic variables. This ensured avoidance of patient

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selection bias in the study. The two homogenous groups were interviewed separately in different rooms and were kept unaware of their subjection to either intervention or control category to warrant achievement of blinding in the study. A patient who did not receive the pharmacist counseling but were similar to the intervention group in respect to other variables was the control group. All the patients who met the inclusion criteria and visited the outpatient pharmacy during the study duration were enrolled in the study. A total of 99 patients (n=53, intervention group versus n=46, control group) were interviewed and 29 patients were lost to follow up.

**Inclusion Criteria**

• Patients visiting the outpatient pharmacy of Shahid Gangalal National Heart Center aged over 15 years.

• Patients who had been taking warfarin for at least 1 month.

• Patients willing to participate in the study.

Exclusion Criteria

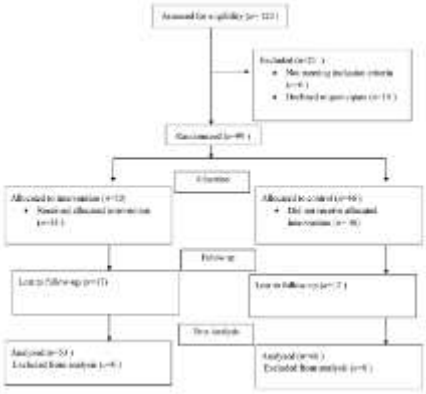
• Patients who were recent users of warfarin (Less than 1 month).

• Patients admitted in the hospital.

## II. RESEARCH TOOL

The study was conducted using a questionnaire comprising of 15 questions on knowledge assessment, adapted from the pre-validated AKA (Anticoagulant Knowledge Assessment) Questionnaire and OAK (Oral Anticoagulant Knowledge) Questionnaire. The questionnaire was validated by pretesting. A pilot study was performed on 10 percent of the total expected sample size to strengthen the reliability and validity of the research. Each correct answer scored 1 point whereas an incorrect answer scored zero point. As a counseling aid, an information leaflet on warfarin therapy was provided to the patients in the intervention group. The information leaflet was compiled from "Oral Anticoagulant Therapy - Important information for patients" published by The National Patient Safety Agency, London and "The patient information, Warfarin Guide for patient and families" published by the John Hopkins Hospital. The information included in the leaflet was translated into Nepali language which was checked and approved by an expert

Study Procedure A prospective randomized controlled study was conducted over a period of 7 months to assess the effect of pharmacist provided counseling in the knowledge of patients on warfarin. The study was approved by the ethical review board in Shahid Gangalal National Heart Center. The questionnaire was administered to the participants by the researcher himself. In the control group, the pharmacist did not intervene and only documented the baseline knowledge on warfarin therapy, on the first visit as well as on the subsequent visit after 2 months. In the intervention group the pharmacist obtained the baseline data and provided counseling to the patients for 20 min on warfarin therapy and its significance, dietary discipline, commonly observed adverse drug reactions and related preventive measures, significance of INR monitoring and warfarin drug interactions. A pharmacist prepared, leaflet containing necessary information on warfarin was also provided to the patients in the intervention group. After 2 months, the same questionnaire was used to assess the effect of counseling in the knowledge level of the patients who had received the educational intervention. In addition, INR (International Normalized Ratio) value in both the groups was collected at two time points, on the day of first interview and after 2 months. Twenty-nine patients were lost to follow up. Follow up data of only 36 patients in the intervention group and 34 patients in the control group could be obtained. Demographic details such as patients' age, gender, duration of warfarin therapy, INR value on the day of first interview and other clinically relevant information such as indication of warfarin therapy was also collected in the patient performa.



A comparison of the number of patients with adequate knowledge in the intervention and the control group was done. Furthermore, a comparison of the number of patients with INR within the target goal was done, pre and post-intervention in the counseled group. Similarly, the difference in the number of patients with their INR value within the target range was also noted in the control group after 2 months. Disparity between percentages of patients answering each question correctly in the intervention and the control group was also observed. The data collected were entered in a separate spreadsheet of EXCEL and was analyzed using Statistical package for social sciences (spss) software version 20. (Figure 1) Statistical Analysis Application of the binomial distribution The questionnaire comprised of 15 questions with four options given as choice p=¼ where, p is the probability of choosing the correct answer from the four options provided to the interviewee. If X is the random variable denoting number of correct answers provided by the interviewee, then X is distributed as a binomial with parameter n = 15 and p = ¼ Then E(X) = np = 15(1/4) = 3.75 This implies that on average a person answers 4 questions correctly even if he/she has no knowledge of the subject. So, if P (X≤ a) =0 .95, the value of a =7 was obtained from the binomial table provided n=15 and p = 1/4 so the P (X≥a) = 0.05. This implies that if a person answers out of 15, 8 or more questions correctly we can conclude with 95% confidence that the person has adequate knowledge. Impact of pharmacist provided counseling in knowledge level of patients on warfarin was statistically analyzed using the Z test at 95% confidence interval. Similarly, separate evaluation of difference in number of patients with therapeutic INR after duration of 2 months in the intervention group as well as in the control group was done using the paired t-test. P value RESULTS Table 1 shows the demographic details of the study participants. A larger proportion of the patients were of the age group 31 to 50 years in both the intervention (40%, n=21) and the control group (39%, n=18). Counseled and the non-counseled group comprised of 64% (n=34) and 52% (n=24) of the female patients respectively. Most of the patients in our study had been taking warfarin for duration of more than 5 years. Table 2 illustrates the distribution of the study population as per the indication of warfarin. Majority of the male patients (32%, n=13) in our study had been taking warfarin for DVR (Double Valve Replacement) whereas the majority of the female patients had been taking warfarin for MVR (Mitral Valve Replacement) (36%, n=21). The most common indication for the use of anticoagulation was found to be MVR (30%, n=30).

**Table 1: Characteristics of study population**

| Variables | Intervention Group (no. (%) of patients n=53 | Control Group (no.(%) of patients n=46 |
|---|---|---|
| **Age (Years)** | | |
| 15-30 | 10 (19) | 16 (35) |
| 31-50 | 21 (40) | 18 (39) |
| 51-65 | 17 (32) | 10 (21) |
| 65+ | 5 (9) | 2 (4) |
| **Gender** | | |
| Male | 19 (36) | 22 (48) |
| Female | 34 (64) | 24 (52) |
| **Warfarin duration** | | |
| >6 months | 11 (21) | 8 (17) |
| 6 months-1 year | 4 (8) | 3 (7) |
| 1-5 years | 18 (34) | 13 (28) |
| >5 years | 20 (38) | 22 (48) |

**Table 2: Distribution of patients as per indication of warfarin**

| Indications | Male (no.(%) of patients) n=41 | Female (no. (%) of patients) n=58 |
|---|---|---|
| Aortic Valve Replacement | 10 (22) | 8 (14) |
| Double Valve Replacement | 13 (32) | 10 (17) |
| Deep Vein Thrombosis | 3 (7) | 6 (10) |
| Mitral Valve Replacement | 9 (22) | 21 (36) |
| Tricuspid Valve Replacement | 6 (15) | 13 (23) |

**Table 3: Evaluation of results of patients with adequate knowledge on warfarin in the intervention and control group**

| No. (%)of patients scoring more than 7 in follow up in control group( n=34)] | No. (%)of patients scoring more than 7 after counseling in Interventional group (n=36)] |
|---|---|
| 13 (38) | 32 (89) |

## III. RESULTS

Table 1 shows the demographic details of the study participants. A larger proportion of the patients were of the age group 31 to 50 years in both the intervention (40%,n=21) and the control group (39%, n=18). Counseled and the non-counseled group comprised of 64% (n=34) and 52% (n=24) of the female patients respectively. Most of the patients in our study had been taking warfarin for duration of more than 5 years. Table 2 illustrates the distribution of the study population as per the indication of warfarin. Majority of the male patients (32%, n=13) in our study had been taking warfarin for DVR (Double Valve Replacement) whereas the majority of the female patients had been taking warfarin for MVR (Mitral Valve Replacement) (36%, n=21). The most common indication for the use of anticoagulation was found to be MVR (30%, n=30).control group Table 3 shows a comparison of the number of patients with adequate knowledge on warfarin therapy in the intervention (38%, n=13) and the control group (89%, n=32). A significant improvement in warfarin knowledge was seen in the intervention group than in the control group ($p<0.05$) Evaluation of results of patients with adequate knowledge on warfarin in intervention Group Table 4 shows the number of patients with adequate knowledge on warfarin therapy before counseling (22%, n=8), which rose to a figure of (89%, n=32) after counseling. A significant increment in the number was observed 2 months after counseling ($p<0.05$). Table 5 illustrates the comparison of percentage of patients giving correct answers between the intervention and the control groups. It is representative of the data collected 2 months after the counseling. Majority of the questions were answered correctly in the counseled group when compared to the non-counseled group. Exception was the question related to interaction with alcohol (Question 5) and question related to interaction with vitamin (Question 9) where the non- counseled group achieved a slightly higher score than the counseled group. All of the patients both in the counseled and the non-counseled group knew the best time of the day to take warfarin.



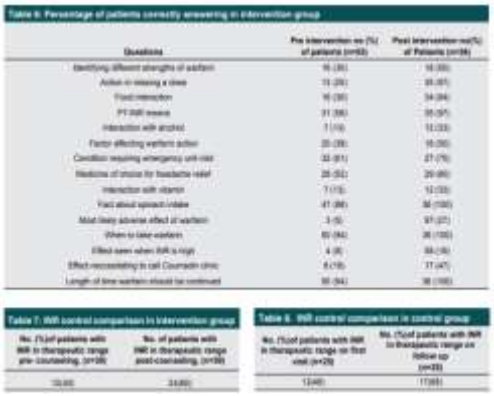
Table 6 displays the percentage of patients answering each question correctly before and after the counseling. The results showed an increase in the percentage of patients answering each question correctly post counseling. Furthermore, the results illustrated that a high percentage (70%, n=37) of the patients had less idea of identifying the different strengths of warfarin tablets (Question no.1). Knowledge concerning the administration time (Question no. 12) was also assessed. The proportion of patients who knew the correct administration time was almost (94%, n=50) even before counseling which rose to a perfect (100%, n=53) after pharmacist's counseling. Only (25%, n=13) of the patients knew about the action to be taken after missing a dose (Question no. 2) but the proportion increased to a whopping ( 97%,

n=35) after counseling. An increase in mean knowledge score from 6.58 to 10.05 was observed after the intervention. The patient's knowledge was assessed on the following criteria: importance of INR monitoring, warfarin-food interactions, warfarin drugs interactions, adverse events of warfarin and actions to be taken when they occur and

Correlation between age, gender, duration of warfarin therapy and knowledge No significant association was found between age, gender, duration of warfarin therapy and the knowledge level of the patients ($p>0.05$) Assessment of the impact of pharmacist counseling on control of INR Comparison of the number of patients with INR within therapeutic range between the first day of interview and after 2 months, in the intervention and control groups is provided in Table 7 and Table 8 respectively. A significant increase in number of patients with INR within target range was obtained using paired t-test at 95% confidence interval in the intervention group (n=30, p= 0.005) whereas no significant change was observed in the control group (n=25; p= 0.083).

## IV. DISCUSSION

The study shows that majority of the warfarin users in both the intervention and control groups were of the age group 31-50 years (40% vs 39%). Percentage of female patients using warfarin was higher than their male counterparts in both the categories (64%, intervention group and 52%, control group). A larger proportion of patients had been under warfarin therapy for more than 5 years. (Table 1) The study revealed the most common indication for warfarin among male patients was DVR whereas it was MVR among the female patients (32% and 36%) respectively. (Table 2)



Pharmacist provided counseling can serve as a strong supportive measure to enhance warfarin related knowledge among the patients8,9 which further can serve as a major contributor to anticoagulation control.7 The results of this research also adheres to the above finding. This study examined whether pharmacist provided counseling improved the knowledge of patients regarding their warfarin therapy. Only (38%, n=13) of patients in the control group was found to have adequate knowledge on warfarin against a good number of (89%, n=32) in the intervention group. Table 3. Quite interestingly, a strikingly significant increase in percentage of patients with adequate knowledge was observed in the intervention group, 2 months post counseling (22%, n=8 vs. 89%; n=32). Table 4. This is consistent with the findings by Lakshmi et al. where mean knowledge score of patients' on anticoagulation rose significantly from 5.6(SD=3.2) to 13.8(SD=0.94) (P=0.000) after receiving counseling from clinical pharmacist, whereas no significant enhancement was observed in the control group (p=0.218).9 Another study by Collins et al. is reflective of similar findings where an increment of 34.9% in terms of number of patients achieving a passing score was noted after receiving verbal counseling on warfarin.8 But it is not in line with the result acquired by Hassan et al. which showed no significant differences in the knowledge of warfarin between the counseled and the non-counseled groups. However, the result by Hassan et al. is based on only 3 knowledge categories namely mechanism of action, interactions between alcohol and

warfarin, side effects of warfarin. The reason for this difference probably is due to inclusion of 15 different knowledge assessment criteria in the present study which might have possibly produced a result contrary to Hassan et al. 10 A positive impact of pharmacist provided counseling has also been demonstrated by the fact that most of the questions had been correctly addressed by patients in the intervention group as compared to those in the control group. (Table 5)

## V. CONCLUSION

Patients' who received pharmacists' counseling had better knowledge on warfarin therapy than those who did not receive the counseling. Our findings conclude that pharmacists' counseling aided by informational leaflets can play an important role in improving patients' warfarin related knowledge and probably have a remarkably positive

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