A Study on Impact of a Clinical Pharmacist in Improving Knowledge of Cardiology Out-patients about Oral Anticoagulants

Anila K N*, Emmanuel J

Department of Pharmacy Practice, Amrita School of Pharmacy, Amrita VishwaVidyapeetham, AIMS Health Care Campus, AIMS, Ponekkara P.O, Kochi, Kerala

A B S T R A C T   Submitted: 31/12/2013   Accepted: 11/03/2013

The study was conducted to find the magnitude of impact of a clinical pharmacist in improving knowledge of cardiology patients about oral anticoagulants. The interventional group received an additional care by the clinical pharmacist and was compared with a control group which received only the usual care of the physician. Patients in the intervention group were assessed for their baseline knowledge using validated questionnaire about the use of anticoagulants and counseled regarding the use of oral anticoagulants, side effects, dietary recommendations, importance of INR (International normalised ratio) tests and dose titrations, compliance and provided information booklets and contact numbers for reporting INR results and reassessed during their follow up. There was statistically significant improvement in knowledge score of patients in the intervention group as compared to control group and statistically significant increase in the number of INR's within target range for the patients in intervention group as compared to control group. The intervention group showed much better improvement in knowledge score ($p<0.05$) which was evident by the mean difference which had an increase of 5.864 points compared to control group's 0.907 points. The fraction of INRs within therapeutic range indicated better anticoagulation control in the intervention group compared to control group (0.632 vs 0.432). This study showed that knowledge of patients regarding oral anticoagulation therapy was insufficient before the clinical pharmacist's involvement. Counseling by a clinical pharmacist will improve the outcome of the patients taking oral anticoagulants as evidenced by the increase in the values of INRs and showed better anticoagulation control.

Keywords: Clinical pharmacist, patient knowledge, oral anticoagulants, knowledge

INTRODUCTION

Pharmacist can bring expertise in managing oral and parenteral anticoagulation therapy of both inpatient and out patients by providing important information regarding therapy through effective counseling and about potential interactions, in addition to daily dosing recommendations to attending physicians and other staff.[1] Most of the studies relating anticoagulation clinics and pharmacist role are based on the perspective of western countries. In the developing country like India such studies would be worthwhile to demonstrate the improvement in quality of care and can justify the need for such services with respect to the growing service needs of patients and lead to development of such patient friendly services in hospitals. It is important to manage anticoagulation therapy of patients in a department like cardiology as many drug related problems and patient non-compliance are common and hence there is a need for better pharmaceutical care and effective counseling that can be provided by a clinical pharmacist. Out-patients of one of the units of cardiology in the hospital was selected and provided with an additional care of clinical pharmacist and compared the effect with the usual care given by physician alone in another unit of cardiology.

Address for Correspondence:

Anila K N, Anila Mahal, Palace road, Chelakara P.O, Thrissur -680586

E-mail : pravina.anp@gmail.com

MATERIAL AND METHODS

Design of study: Prospective, Interventional study.

Duration of study: The study was designed for a period of one year in which data collection was done for a period of 8 months from 1st September 2011 to 30th April 2012.

Settings: Study was carried out in the cardiology outpatient department of a 1250 bedded tertiary care, teaching and super-speciality referral hospital.

Sample size: A sample size of minimum 43 patients was required in each of intervention and control groups for testing the hypothesis. From cardiology outpatient department about 44 patients were selected from a total of 62 patients based on inclusion and exclusion criteria obtained in one unit and randomly selected 43 patients from other unit were included in the control group.

Inclusion criteria: All age group patients who were on oral anticoagulants for at least 3 months and who had a follow up period of not more than 3 months were included.

Exclusion criteria: Pregnant patients, patients with severe renal insufficiency or active liver disease and who cannot provide necessary information in data collection form used.

Methodology: Ethical clearance was obtained from the hospital ethical committee. Patient data relevant to the study was obtained by personnel interview with patients or caregivers, their response to questionnaires that was given for answering, examination of patient's medical record etc. Patient information sheet was given to the patients to let them know about the study behaviour and an informed consent was

obtained from the patient and/or patient's care givers before interviewing them. A standardized data collection form was prepared and necessary data like demographics, indication for anticoagulation, INR lab results, and dose of anticoagulants was obtained from patients and/or patient's caregivers. Patient's baseline knowledge was assessed using a validated questionnaire i,e. Oral Anticoagulation Knowledge questionnaire (OAK questionnaire of *Zeolla MM, Brodeur MR, Dominelli A, Haines ST, Allie N)* both in intervention group and control group. Scores 1 and 0 were given for each right and wrong answer. Patients or their caregivers in the intervention group were given the contact number (oncall phone number) of clinical pharmacist to report INR test results and get their anticoagulant dose titrated. Patients were asked to notify the investigator the occurrence of any ADRs. The knowledge of the patients was reassessed using same validated questionnaire when they came for review. All the data were tabulated, analyzed and compared with data from other studies. The collected data were compiled using Microsoft excel and were presented in graphical format using pie charts, histograms etc. Calculation of the mean and standard deviation were done by using statistical calculators. The significance of the study results were assessed using Independent sample t test and Paired sample t test. The percentage of INR within the target range of intervention group was compared with control group and also the knowledge improvement was checked and compared with the control group.

RESULTS

The tables 1-5 below describe the distribution of gender and age, educational status, comorbidities, various indications for oral anticoagulants and recommended target INRs respectively.

Here the paired sample t-test was used to compare the patient knowledge score before and after the intervention. Table 7 shows that all the p-values are less than the significance value 0.05. Hence, we conclude that knowledge score is significant at 5% level in both control and intervention groups. Moreover, from the mean difference column it is clear that the intervention group shows much better improvement in knowledge score as there was an increase of 5.864 points compared to control group's 0.907 points.

Table 1: Gender distribution of cardiology patients in the control group and intervention groups

Gender	Control group		Intervention group	
	No. of patients	% of patients	No. of patients	% of patients
Male	24	55.8	26	59.1
Female	19	44.2	18	40.9
Total	43	100	44	100

Table 2: Age distribution of cardiology patients in the control group and intervention groups

Age Group	Control group (n=43)		Intervention group (n=44)	
	No. of patients	% of patients	No. of patients	% of patients
< 40 Years	5	11.6	5	11.4
40 - 49 Years	8	18.6	6	13.6
50 - 59 Years	11	25.6	14	31.8
60 - 69 Years	15	34.9	10	22.7
⩾ 70 Years	4	9.3	9	20.5
Total	43	100	44	100

Table 3: Educational status of cardiology patients in the control group and intervention groups

Educational Level	Control group (n=43)		Intervention group (n=44)	
	No. of patients	% of patients	No. of patients	% of patients
Mid School	6	14.0	3	6.8
High School	8	18.6	4	9.1
Higher Secondary	8	18.6	10	22.7
Graduate	11	25.6	15	34.1
Pos Graduate	1	2.3	1	2.3
Diploma	4	9.3	6	13.6
Professional	5	11.6	5	11.4
Total	43	100	44	100

Table 4: Comorbidities of cardiology patients in the control group and the intervention group

Comorbidities	Control group (n=43) [No. (%)of Patients]	Intervention group (n=44) [No. (%)of Patients]
Diabetes mellitus	14 (32.5%)	17 (38.6%)
Hypertension	29 (67.4%)	27 (61.3%)
Asthma	3 (6.9%)	0
Hyperthyroidism	1 (2.3%)	0
Hypothyroidism	3 (6.9%)	6 (13.6%)
Stroke	8(18.6%)	8 (18.1%)
Dyslipidemia	22 (51.1%)	25 (56.8%)
Acute bronchitis	0	3 (6.8%)
GI ulcer	3 (6.9%)	4 (9.0%)
Seizures	2 (4.6%)	2 (4.5%)
COPD	6 (13.9%)	2 (4.5%)
Anaemia	2 (4.6%)	2 (4.5%)
Rheumatic heart disease/ coronary artery disease	14 (32.5%)	14 (31.8%)
Osteoarthritis	1 (2.3%)	1 (2.2%)
CHF- Congestive heart failure	3 (6.9%)	4 (9.0%)
BPH2	(4.6%)	0
Glaucoma	2 (4.6%)	0

Table 5: Indications and target INRs recommended for cardiology patients in the control group and the intervention group

Indication		Control group (n=43)		Intervention group (n=44)	
	INR Range	No. of patients	% of patients	No. of patients	% of patients
Aortic valve replacement, Double valve replacement	2.0-2.5	2	4.7	3	6.8
Atrial fibrillation, Pulmonary embolism, Myocardial infarction	2.0-3.0	28	65.1	25	56.8
Double valve replacement, Mitral valve replacement	2.5-3.0	2	4.7	5	11.4
Mitral valve replacement	2.5-3.5	11	25.6	10	22.7
Total		43	100	44	100

Here the paired sample t-test was used to compare the patient knowledge score before and after the intervention. The Table No. 7 shows that all the p – values are less than the significance value 0.05. Hence we conclude that knowledge score is significant at 5% level in both control and intervention groups. Moreover, from the mean difference column it is clear that the intervention group shows much better improvement in knowledge score as there was an increase of 5.864 points compared to control group's 0.907 points.

From the table 8, it is seen that there is an increase in the total number of INR checks after the intervention. In the intervention group 63.2% of total INRs checked were within target range after the intervention. Whereas at baseline only 38% of the INRs checked were within normal range. 43.5% of the INRs checked were within normal range in the control group. At baseline 13.5% of the INRs checked were < 1 in the intervention group whereas after the intervention it was reduced to 4.5%. Similarly 16.1% of the total INRs checked was above normal range in the intervention group at baseline. But after intervention only 9.0% of the INRs checked were above normal range.

The fraction of INRs within therapeutic range was 0.632 for the intervention group and 0.432 for the control group indicating better anticoagulation control in the intervention group.

The independent samples t-test procedure compares means for two groups of cases. A low significance value (p-value) for the t-test (typically less than 0.05) indicates that there is a significant difference between the two group means. Here the independent sample t-test was used to compare means for control and intervention groups. The Table No. 10 shows that the p – values corresponding to INRs in target range, > target range and > 5 are less than the significance value 0.05. Hence we conclude that INRs in target range, > target range and > 5 are significant at 5% level. I.e. INRs in target range, > target range and > 5 are different in control and intervention groups.

Table 6: Knowledge assessment of cardiology patients in the control group and intervention group.

	Knowledge score	
Study groups	Baseline	Follow up visit
Control	11.4 ± 3.39	12.3 ± 3.48
Intervention	11.1 ± 2.39	17.0 ± 2.47

Table 7: Paired sample t – test for comparing the scores of patient knowledge assessment.

groups	Differences of the mean	t - value	Df	p – value
Control group	-0.907	-4.027	42	0.000
Intervention group	-5.864	-16.631	43	0.000

t-value: student's t test value, p-value: probability of obtaining a test statistic
Df: degrees of freedom

Table 8: Evaluation of INR results of cardiology patients in the control and intervention groups

INR results	Intervention group(n=44)		
	Control group (n=43)	Baseline	After the end of follow up
INRs within target range [No. (%)]	95(43.2)	73(38.0)	141(63.2)
INRs above target range [No. (%)]	45(20.5)	31(16.1)	20(9.0)
INRs below target range [No. (%)]	80(36.4)	84(43.8)	64(28.7)
INRs > 5 [No. (%)]	12(5.5)	2(1.0)	3(1.3)
INRs > 8 [No. (%)]	4(1.8)	0(0.0)	1(0.4)
INRs < 1 [No. (%)]	19(8.6)	26(13.5)	10(4.5)
Total INRs checked	220	192	223

Table 9: Fraction of INRs in therapeutic range for the cardiology patients in the control and intervention groups

INR results	Intervention group(n=44)		
	Control group (n=43)	Initial	After the end of follow up
Total INRs checked	220	192	223
INRs within Target Range	95	73	141
Fraction of INRs within target range	0.432	0.380	0.632

Table 10: Independent sample t – test for comparing the INR results in the control group and intervention group.				
Initial Details	Differences of the mean	t - value	Df	p – value
Total INRs	0.048	0.154	85	0.878
INRs in target range	-0.995	-3.808	85	0.000
INRs > target range	0.592	3.194	85	0.002
INRs < target range	0.406	1.456	85	0.150
INRs > 5	0.211	2.456	85	0.017
INRs > 8	0.070	1.166	85	0.248
INRs < 1	0.215	1.615	85	0.111

Paired samples t-test procedure compares the means of two variables that represent the same group at different times (e.g. before and after an event). A low significance value (p – value) for the t-test (typically less than 0.05) indicates that there is a significant difference between the two group means. Here the paired sample t-test was used to compare the evaluation of INR before and after the intervention. The Table No. 11 shows that the p – values corresponding to total no. of INRs, INRs in target range, < target range and INRs < 1 are less than the significance value 0.05. Hence we conclude that total INR, INRs in target range, < target range and INRs < 1 are significant at 5%.

Table 11: Paired Sample t – test for comparison of INR results in the intervention group at the baseline and after the intervention				
Initial Details	Differences of the mean	t - value	Df	p – value
Total INRs	0.048	0.154	85	0.878
INRs in target range	-0.995	-3.808	85	0.000
INRs > target range	0.592	3.194	85	0.002
INRs < target range	0.406	1.456	85	0.150
INRs > 5	0.211	2.456	85	0.017
INRs > 8	0.070	1.166	85	0.248
INRs < 1	0.215	1.615	85	0.111

DISCUSSION

Anticoagulation management is a challenging task for healthcare professionals especially for clinical pharmacists. It is because of the individual variability in response to the anticoagulants, alterations in a patient's consumption of vitamin K-rich foods and alcohol, change in medications, or change in health status all of which can alter the INR values[2]. Proper educational guidance and monitoring of the INR status regularly is the only step for the successful anticoagulation. Several other studies[3, 4,5,6,7] have showed the effectiveness of clinical pharmacists in outpatient and inpatient anticoagulation management. Improper anticoagulation can result in bleeding complications or further aggravation of the thromboembolic conditions. Anticoagulation management

service is to monitor and adjust one's anticoagulation medications for the period of time they need to be on anticoagulation therapy[8]. They are run mostly by pharmacists and also nurses which help in assisting physicians. A growing body of reports[9,10,11,12] has suggested that implementing an anticoagulation management service (AMS) helps patients to achieve better clinical outcomes than care provided by their personal physicians (i.e. usual care).From the results it was found that the fraction of INRs within therapeutic range was 0.632 for intervention group and 0.432 for control group. Intervention group had fewer INRs above the target range than control group (16% reduced to 9% after intervention vs.20.5%) and INRs below 1 were reduced in the intervention group compared to control (13.5 % to 4.5% vs. 8.6%).

The patient's knowledge on warfarin was shown to be a determinant of anticoagulation control[13] and patient education and counseling is an integral component of a successful warfarin therapy. In this study, the patient's knowledge of warfarin therapy was evaluated during the interview sessions. They were interviewed and multiple choice oral anticoagulation knowledge tests were given to answer at first encounter. Scoring was given for each correct answer. Same questionnaire was given to answer during the follow up. Even though the p<0.05 in both control and intervention groups, the significant differences in the means of 2 groups show better knowledge improvement in intervention group than in the control group. Control group showed only a gradual change while the intervention group after proper education and follow up showed a marked improvement in knowledge level about anticoagulation. On interviewing the patients it was found that they were receiving only a basic knowledge on anticoagulation therapy and the busy clinic cannot be blamed for the same. The limited time of the clinicians to interact with the patients is a barrier and the services like anticoagulation management by clinical pharmacists can solve the problem to an extent. There might be flaws in the nature and extent of information provided by healthcare personnel on anticoagulation, as well as the method of delivery. The other possible factor involved, might be the patient's inability to understand and retain the advice given. Insufficient education is more devastating than the total lack of education. Poor doctor-patient communication can be overcome by the involvement of a clinical pharmacist. Moreover they can act as good communicators between physicians and patients. More effective communication arises from understanding the patient's expectations, involving the patients in negotiating their treatment plan and the continuity and accessibility of the staff[14]. Better levels of the knowledge of the patients may also be achieved if the information is reinforced by simple measures such use of written materials. The study had an aim to establish such services for the benefit of the patients and clinicians in the hospital departments where there are patients on anticoagulation. Oncall phone was provided for the clinical pharmacist to follow up patients and help in dose

titration of oral anticoagulants based on INR results. The patients had good cooperation and contact with the service. Telephonic management of the INR and resolving other issues regarding anticoagulation therapy was found to be better through the anticoagulation service. Similar studies[15, 16] also support the fact of better anticoagulation management by the clinical pharmacist through telephonic means. They found that most patients received helpful information from an anticoagulation service and the convenience, accessibility, and services provided by anticoagulation service personnel were "better than expected".

Many of the patients in the intervention group had sub therapeutic INR earlier as they were not doing regular INR tests. Interview with patients revealed that they face the problem in getting their dose titrated frequently due to the busy staff who attends the phones to report INR results. And the lack of knowledge regarding the importance of INR tests and dose titration and the inconvenience they face to get their dose titrated many of them hesitate to do the tests and report it or does self management. Long period for review with doctors is another reason for reduced INR checks. Many of the patients do their INR tests only when they come for review. Many patients who are considered to be stable in their anticoagulation go sub therapeutic or supra therapeutic as the frequency of INR checking is low. After the interventional study there was an improvement in total number of INRs checked, % of INRs which were in the target range, knowledge level about anticoagulation medications and therapy. It was found that patient's awareness of the INR values is correlated with improved accuracy of anticoagulation control. The study results reflect the impact of a clinical pharmacist on anticoagulation management and the need for anticoagulation services in the hospital settings.

CONCLUSION

Education of patients by a clinical pharmacist in the outpatient clinic of cardiology improved patient understands of use of oral anticoagulants and as a result a greater percentage of patients in intervention group had their INR within recommended therapeutic range as compared to the control group.

Since a clinical pharmacist can efficiently manage anticoagulation and provide optimal care, it is recommended that major hospitals both in government and corporate sector should consider providing clinical pharmacist managed anticoagulation service/ clinic for the benefits of patients.

ACKNOWLEDGEMENT

REFERENCES

1. Health notes published by California state board of pharmacy. Available from URL http://www.pharmacy.ca.gov/publications/health_notes_drug_therapy. pdf. Accessed on 15/8/2011

2. Baker JW, Pierce KL, Ryals CA. INR Goal Attainment and Oral Anticoagulation Knowledge of Patients Enrolled in an Anticoagulation Clinic in a Veterans Affairs Medical Center. *J Manag Care Pharm* 2011; 17:133-42.

3. Witt DM, Sadler MA, Shanahan RL, Mazzoli G, Tillman DJ. Effect of a centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. *Chest* 2005; 127:1515–22.

4. Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes and health care costs. *Arch Intern Med* 1998; 158:1641–7.

5. Dager WE, Gulseth, *Michael P.* Implementing anticoagulation management by pharmacists in the inpatient setting. *Am J Health Syst Pharm* 2007; 64: 1071-9.

6. Wilt VM, Gums JG, Ahmed OI, Moore LM. Outcome analysis of a pharmacist-managed anticoagulation service. *Pharmacother* 1995; 15:732–9.

7. Bounda GA. Impact of Clinical Pharmacist in an Anticoagulation Management Service in several countries. *The doctor's online* 2009; 19.

8. Ansell J, Jack H, Walen J, Bussey H, Anderson D, Poller L et al. Managing oral anticoagulation therapy. *Chest* 2001; 119: 225-385

9. Garabedian Ruffalo SM, Gray DR, Sax MJ et al. Retrospective evaluation of a pharmacist-managed warfarin anticoagulation clinic. *Am J Hosp Pharm* 1985; 42: 304 –8

10. Wilt VM, Gums JG, Ahmed OI. Outcome analysis of a pharmacist-managed anticoagulation service. *Pharmacother* 1995; 15: 732–9

11. Samsa G, Matchar D, Goldstein L et al. Quality of anticoagulation management among patients with atrial fibrillation: results of a review of medical records from 2 communities. *Arch Intern Med* 2000; 160: 967–73.

12. Cortelazzo S, Finazzi G, Viero P et al. Thrombotic and hemorrhagic complications in patients with mechanical heart valve prosthesis attending an anticoagulation clinic. *Thromb Haemost* 1993; 69: 316 –20.

13. Othilia E, Tang YL, Lai CSM, Lee KKC. Relationship between Patients' Warfarin Knowledge and Anticoagulation Control. *Ann Pharmacother* 2003; 37: 34-9.

14. Karen Baxter. Stockley's drug interactions.7th ed. Royal pharmaceutical society of Great Britian; 2006: p-275, 289.

15. Wittkowsky AK, Nutescu EA, Blackburn J. Outcomes of Oral Anticoagulant Therapy Managed by Telephone vs In-Office Visits in an Anticoagulation Clinic Setting. *Chest* 2006; 130: 1385-9.

16. Waterman AD, Banet G, Milligan PE. Patient and physician satisfaction with a telephone-based anticoagulation service. *Journal of General Internal Medicine* 2001; 16; 460-3.