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Original Article

Clinical pharmacist directed anticoagulation monitoring services: A prospective interventional study

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ABSTRACT

Background and Aims: Antithrombotic therapies are established as cornerstones of treatment for a wide variety of ischemic vascular diseases. The study aimed to develop clinical pharmacist directed anticoagulation monitoring services in the cardiology department at tertiary care referral super specialty hospital.
Method: Prospective interventional study was conducted for 12 months in the cardiology inpatient setting of a private tertiary care referral hospital in the Malabar region of Kerala. Constituted to be in three phases, they are: assessment of the present anticoagulation related practices, the development and sharing of anticoagulation protocol and finally the intervention and implementation of the system.
Results and Discussion: Monitoring of the treatment could enhance the drug selection approaches, improved adherence to clinical guidelines and health outcomes. Heparin was the commonly prescribed drug in the cardiology department which had the risk of thrombocytopenia and major bleed, whereas this risk was lesser with fondaparinux. Early detection of bleeding could prevent complications from happening to the patients. The collaboration of the clinical pharmacist into anticoagulation therapy influenced the physician to comply with the ACCP guideline.
Conclusion: The clinical pharmacist directed anticoagulation monitoring services improved the overall medical status of the patient.

Keywords: ACCP, Anticoagulation, Clinical Pharmacist, Guideline Compliance, Management service, Medication Error

INTRODUCTION

Cardiovascular diseases are the leading cause of death worldwide. Both anticoagulants and antiplatelet agents are the landmark accomplishments and the established cornerstone of therapy for a wide range of ischemic vascular abnormalities, including acute coronary syndrome (ACS), stroke, peripheral vascular disease, atrial fibrillation, deep vein thrombosis, and pulmonary embolism (Kollias et al., 2020).

Anticoagulants are one of the most sensitive drug classes that are liable to errors and adverse events. Several studies suggested the influence of anticoagulation management clinics and services to revamp the patients' therapy. Pharmacists and nurses have a pivotal role in the establishment and maintenance of such clinics.

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Monitoring is a prospective supervision, observation, and testing of an on-going process (Pranckeviciene, Kadusevicius, & Putniene, 2013). Hence, therapeutic drug monitoring should focus on the efficacy, and safety of drugs. The cooperation of patients in bequeathing the transmute in disease or treatment to the physician is also vital. However, very little consideration has been given to develop effective schemes for monitoring the contingency of adverse drug reactions concerning biochemical or haematological disturbances. Forecasting the probable adverse reactions that impart reversible or irreversible damage to the patient is another important aspect. Worldwide heparin utilization trended from 10% to 15% yearly growth in the past decade. Even though the medicine is primarily prescribed in the inpatient setting, heparin is consumed up to 10% of the total medication costs among hospitals (Kolhatkar, Cheng, Chan, Harrison, & Law, 2016). Pharmacist-directed anticoagulation management services (AMSs) have been shown to improve patient outcomes and reduce their length of hospital stay. Anticoagulation stewardship programs are mostly limited to inpatient populations and can also be expanded to outpatients. To achieve such an intrinsic multisystem process, a multidisciplinary collaborative effort is essential (Schumock et al., 2003).

American College of Clinical Pharmacy (ACCP) noted a decrease in health care cost due to clinical pharmacy services (Roberts, Patel, & Arya, 2009; Talon et al., 2020). Thus, to cut down the financial and heath crisis, we established clinical pharmacist directed anticoagulation monitoring services in the cardiology department at tertiary care referral super specialty hospital.

METHODOLOGY

The prospective interventional study was carried out for 12 months in the cardiology inpatient department of 350 bedded private tertiary care referral hospital in the Malabar region of Kerala. The Institutional Ethics Committee met on 03/02/2015, approved the proposal for the dissertation as per letter No. IEC/ASH/2015/PD/9. Informed consent was also obtained from each patient.

N-Master software was used to estimate the sample size as 45 in both the pre-interventional (control) and post-interventional groups. The expected proportion was set at 0.20 based on the pilot study conducted on 15 patients. The level of significance was set at 0.05 and precision at 15%.

Selection Criteria

Patients with age >18 years, and those who had received at least one prescription order for heparin, made up the study population. Patients who had voluntarily discharged themselves, lactating mothers, those with missing data, patients of non-Indian origin and pregnant patients were excluded.

Assessment of current prophylactic practices and compliance to the regimen

The clinical pharmacist followed the patients from their hospital admission to discharge. Laboratory parameters and INR value of patients were documented. The collected data were compiled into graphs and tables. Calculation of the mean and standard deviation was done by using statistical calculators.

A data collection form was developed to tabulate the information relevant to the study. The form consists of the following details:

1. Patient demographics such as name, age, sex, body weight,
2. Medication Record Department number,
3. Date of admission,
4. Date of discharge,
5. Diagnosis and all other relevant information.

Phases of the study

The current anticoagulant practices in the study site were compared to the standard treatment recommended by the ACCP in its 9th antithrombotic guidelines, which was meant to assess the extent of compliance.

The 3 phases were as follows:

Phase 1- Assessment of earlier practice (Pre-interventional /Control Phase)

In the first 5 months, data associated with the earlier treatment practice (no interventions) were retrieved from the study population. A total of 45 subjects were enrolled. The recommendations of ACCP 9th antithrombotic guideline were the standard to determine the appropriateness of therapy. The cases that do not comply with ACCP regimen either in dose or INR value would be marked as non-compliant.

Phase 2- Development of anticoagulant protocol and dissemination of information (Passive Intervention phase)

The phase covered over 2 months, and it involved passive interventional strategies. Initially, we presented the data to the cardiology specialists and also conveyed the standard practices recommended by ACCP 9th guidelines. And further, the information obtained from the initial audit was disseminated within the hospital. The phase also involved the preparation of the hospital specific anticoagulant protocol based on data obtained from the control phase.

Phase 3- Active Intervention and Reassessment (Intervention phase)

This phase was carried out for the next 5 months. The patient interviews were performed, and case files were decoded for interpreting the INR values, medication errors and adverse drug reactions. bleeding risk factors of the patient were also monitored and periodically reported to the physician. The data from the intervention phase and control phase were compared to finalize the success of the program.

Clinical Pharmacist led anticoagulation service

All patients and their caregivers were counseled on anticoagulation therapy and its importance, common ADRs (Adverse Drug Reactions) and management, the importance of patient compliance, dose titration,and dietary modifications. Patients or their caregivers in the intervention group were given the contact numbers (on-call phone number) of the clinical pharmacist to report INR test results and get their anticoagulant dose titrations.

Statistical Tool

SPSS 18.0 Windows version was used to perform the statistical analysis. The tests used were one-sample and two-sample chi-square test, one sample binomial test and unpaired t-test. The power of the study was estimated using OpenEpi version 3.03 for Windows OS.

RESULTS AND DISCUSSION

A total of 90 patients were enrolled, consisting of equal samples in pre-intervention and post-intervention phases.

Demographics of evaluated population

The gender distribution portrayed 71 males and 19 females. Among them, males were more prone to cardiovascular diseases. The study found 37 (82%) and 34 (75.6%) male patients in the pre- and post- intervention phases, respectively. The prescription rate of anticoagulants is also higher among male (Sharma, Krishnamurthy, Snyder, & Mauro, 2017; Thompson et al., 2017). Numerous evidences state the prevalence of anticoagulant administration among geriatric population (Reddy, Prasad TS, Swetha, Nirmala, & Ram, 2018). We also attained similar results with mean age between 60 to 65 years. The demographic details of the patients are represented in Table 1.

Cardiovascular disease conditions of the patients

The myocardial infarction was observed to predominate in our study, with Non ST-segment elevation Myocardial Infarction (NSTEMI) being more prevalent with ≥20 percent in both pre- and post interventional phases and ST-segment elevation Myocardial Infarction (STEMI) along with 20% in post-interventional phase and 11% in pre-interventional phase (Table 2).

Cardiovascular diseases are the chief fatal lifestyle disease estimated to take away the lives of 17.9 million every year. Four

Table 1. The demographic characteristics of the subjects enrolled in the study.

Demographic characters	Pre-intervention phase	Post-intervention phase
Gender	Male=82.2% (n=37)	Male=75.6% (n=34)
	Female=17.8% (n=8)	Female=24.4% (n=11)
Age	Range=33 to 85 years	Range=39 to 85 years
	Mean=60.49 years (S.D=11.69)	Mean=62.60 years (S.D=11.762).

S.D Standard Deviation

Table 2. Diagnosis distribution in pre-interventional group and post-interventional groups.

Diagnosis	Pre-intervention phase No.(%)	Post-intervention phase No.(%)
Non ST Segment Elevation Myocardial infarction (NSTEMI)	10 (22.2)	9(20.0)
Inferior Wall Myocardial Infarction (IWMI)	6 (13.3)	4(8.9)
Cerebrovascular Accident	2(4.4)	0(0)
Steroid Abuse	1(2.2)	(0)0
Pulmonary Arterial Hypertension	1(2.2)	0(0)
ST Segment Elevation Myocardial Infarction	5(11.1)	9(20.0)
Anterior Wall Myocardial Infarction (AWMI)	4(8.9)	5(11.1)
Transient Ischemic Attack	1(2.2)	0(0)
Coronary Artery Disease	5(11.1)	2(4.4)
Unstable Angina	1(2.2)	0(0)
Ischemic Heart Disease	2(4.4)	0(0)
Acute Coronary Syndrome	1(2.2)	5(11.1)
Not Specified	1(2.2)	0(0)
IWMI/STEMI	1(2.2)	5(11.1)
IWMI/NSTEMI	2(4.4)	1(2.2)
AWMI/STEMI	1(2.2)	2(4.4)
AWMI/NSTEMI	1(2.2)	2(4.4)

STEMI: ST Segment Elevation Myocardial Infarction, NSTEMI: Non ST Segment Elevation Myocardial Infarction, IWMI: Inferior Wall Myocardial Infarction, AWMI: Anterior Wall Myocardial Infarction

out of five deaths related to cardiovascular disease are due to heart attacks and strokes, and one-third of these deaths occur among people under 70 years of age. The mean age of both the control and intervention groups was greater than 60 years, which indicated the age to be one of the major risk factors for cardiovascular diseases. Changes in the diet pattern and sedentary lifestyle are the major confounders for precipitating and worsening the disease (Akesson, Larsson, Discacciati, & Wolk, 2014; Mosca, Barrett-Connor, & Wenger, 2011). Large proportions of people in the Perinthalmanna locality are financially overwhelmed, which tempt them towards junk foods and improper exercise. This had a colossal negative impact on the health status of the people.

Anticoagulants

Heparin, enoxaparin and fondaparinux are commonly prescribed agents. The mechanism of action of heparin showed to inhibits multiple clotting factors (i.e. Xa, IXa,Xia,XIIa) and antithrombin III, whereas enoxaparin act on factor Xa with little effect against thrombin. This change in the pharmacodynamics of unfractionated heparin was stated to trigger excess hemorrhage among patients (Heparin induced Thrombocytopenia) comparing to its derivative (Bauer, 2001). Fondaparinux is a factor Xa inhibitor similar to low molecular weight heparin that does not inhibit thrombin (Yau et al., 2011). The PENTALYSE study demonstrated fondaparinux to be safer compared to unfractionated heparin (Coussement et al., 2001). Table 3 portrays the prescription pattern of anticoagulant therapy among patients.

Table 3. The categorization of patients based on the anticoagulant therapy at pre and post-intervention phases.

Anticoagulant used	Pre-intervention phase	Post-intervention phase
Heparin	27	31
Enoxaparin	9	9
Fondaparinux	1	1
Heparin +Fondaparinux	1	0
Nil	7	4

Adverse reactions associated with anticoagulant use

The incidence rate of ADRs or medication errors is evident in patients treated with anticoagulants. In the pre-intervention phase, 48.9% (n=22) of patients came across adverse drug reactions (ADR). When we tested the observation with one sample Binomial test, it was statistically significant with p-value=0.037. In the post-intervention phase, 26.7% (n=12) patients had ADRs. Similarly, one sample Binomial test yielded highly significant findings (p-value=0.007). Hence, we erected a slight reduction in the frequency of ADR due to the intervention.

Hematuria and major bleeding was prominently observed in the study, apart from them, gastrointestinal bleeding and postmenopausal bleeding do exist in a slight lower proportion (Ahmed, Majeed, & Powell, 2007). Other side effects identified were ecchymosis, epistaxis, oral bleeding, conjunctival hemorrhage, middle ear bleeding, and hematospermia. The Naranjo scale defined all the adverse events to be definite. The mortality rate and healthcare expense were higher in the patients who had been reported with adverse events (Piazza et al., 2011). Assessment of risk factors for bleeding should become an integral part of the drug monitoring system, and it is represented in figure 4 A and 4 B for pre- and post-interventional phases, respectively.

Medication errors associated with anticoagulant use

In the pre-intervention phase, the medication errors of the patients were identified 65% related to heparin, 14% of fondaparinux, and about 25% because of enoxaparin administration. Out of 22 (48.9%) medication errors; 15 were prescribing errors, 2 dispensing errors, 4 drug administration errors and a patient error (Figure 1). However, the post-intervention phase showed 63%, 23% and 8% medication errors among patients on heparin, enoxaparin and fondaparinux therapy, respectively. Of the total 12 (26.66%) medication errors, 7 had prescribing errors, 2 dispensing errors, 2 drug administration errors and a patient error. Table 4 and 5 represent the prescribing errors reported in our study population. A study reported 8.3% anticoagulant medication error; most were encountered associated with low molecular weight heparin. They emphasized the necessity to peer on the prescribing phase of error. The difference between our pre- and post- intervention groups regarding medication error was statistically significant (with chi-square value=4.727 and p-value=0.0297). Within a short period of time, the adherence to the treatment protocol slightly decreased the fallacy. Every quarter of the year, compliance to the treatment guideline should be measured, and this periodical reviewing would enhance patient safety. The pharmacist should support the physician for patient follow-up by collecting and interpreting their previous laboratory investigations or encouraging discontinuation of drugs, when indicated. There is evidence that justified and proved the ex-

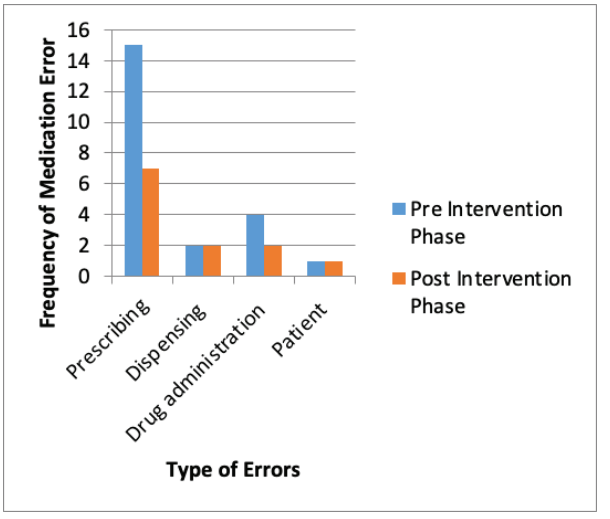

Figure 1. The frequency and type of medication error in Pre and Post intervention groups.

Table 4. The prescription errors concerning Heparin and Enoxaparin.

	Pre-intervention phase (rate of infusion)		Post-intervention phase (rate of infusion)	
Anticoagulants used	**Specified in prescription**	**Not Specified in prescription**	**Specified in prescription**	**Not Specified in prescription**
Heparin	7	19	21	10
	Pre-intervention phase(dose)		**Post-intervention phase(dose)**	
Anticoagulant used	**Specified in prescription**	**Not Specified in prescription**	**Specified in prescription**	**Not Specified in prescription**
Enoxaparin	3	7	9	0

Table 5. Categorization of medication errors with respect to the drug at pre and post-intervention phases.

Anticoagulants	Percentage of errors in pre-intervention phase	Percentage of errors in post-intervention phase
Heparin	63%	67%
Enoxaparin	23%	25%
Fondaparinux	14%	8%

traordinary contribution of clinical pharmacists in attenuating medication errors in hospital settings (Tariq, Vashisht, Sinha, & Scherbak, 2021).

Researchers observed profound incidences of fatal and severe medication issues and claimed preponderance of them to be preventable. Anticoagulants, being a class with aloft utilization, warrant close monitoring of blood parameters (Lakshminarayan, Solid, Collins, Anderson, & Herzog, 2006). Excess or insufficient dosing would impart significant detrimental consequences to the patients (Henriksen, Nielsen, Hellebek, & Poulsen, 2017). In our study, within a 6-month period, there was a drastic improvement (48.9% to 26.66%) in medication error, and compliance to treatment guidelines was ameliorated from 46.7% to 62.22%. This positive shift reflected the physician's acceptance for our interventions. Meanwhile, most of the errors we noticed resulted from lack of written guidelines/policies (i.e. standardized heparin dosing nomogram) and from the limitation in implementing the weight-based heparin dose adjustment in the Cardiology Department. Figure 2 A and 2 B depict the prime complications of anticoagulant therapy identified in pre-intervention and post-intervention phases, respectively.

Compliance to treatment guideline

The anticoagulant compliance rate with the ACCP guideline was nominal (Hajj et al., 2021; Yu, Dylan, Lin, & Dubois, 2007). Our adherence assessment of the pre-intervention therapy to American College of Chest Physicians Antithrombotic guidelines 9th edition (Table 6) revealed that 46.7% (n=21) of the anticoagu-

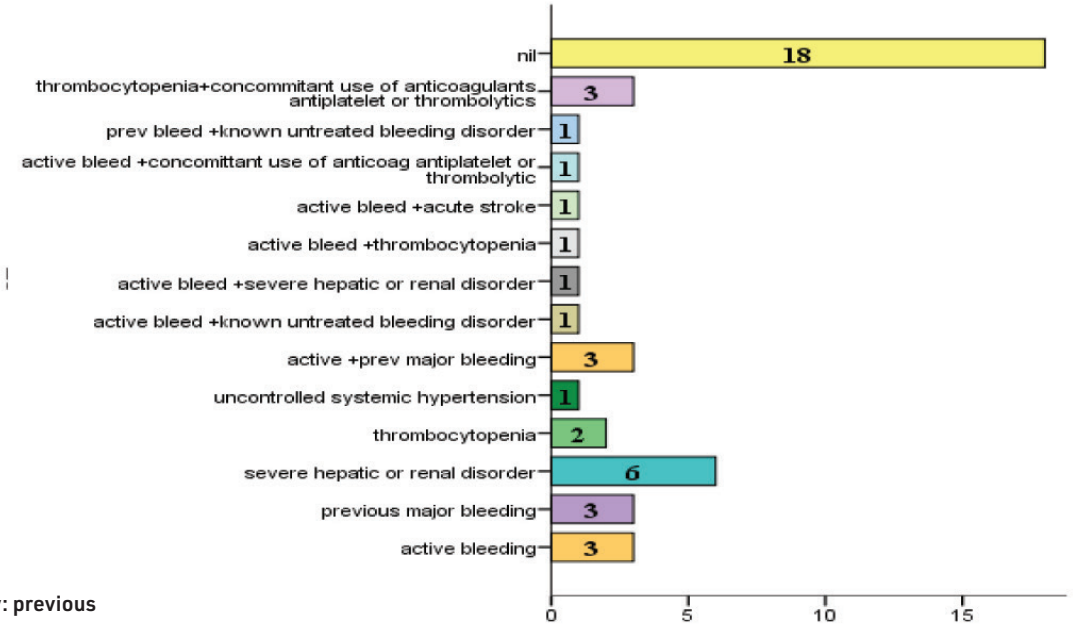

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Figure 2A. Bar graph representing bleeding risk factors among pre-intervention subjects.

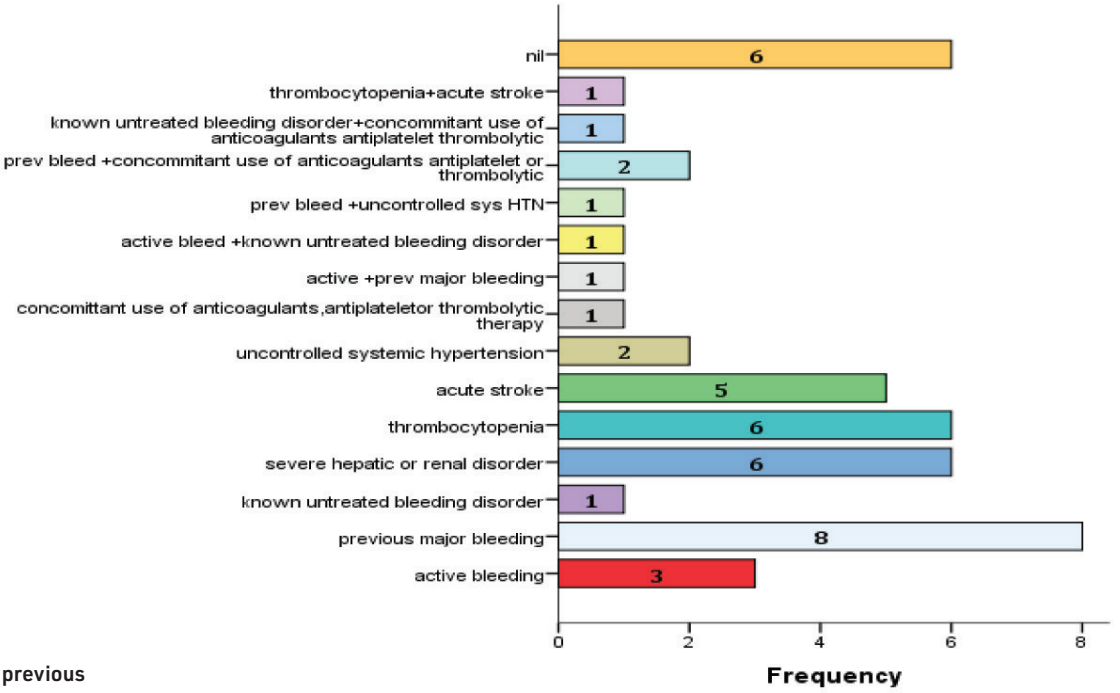

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Figure 2B. Bar graph representing bleeding risk factors among post-intervention subjects..

lation therapy was non-compliant with the regimen (Table 7). Partial compliance to the standard treatment was demonstrated by 24.4% (n=11). On the other side, our clinical pharmacist led anticoagulation monitoring service incremented (62.22%) the physician's compliance to ACCP guideline treatment, and partial compliance was also escalated (26.67%, n=12).

Table 6. The monitoring parameters requisite to the assessment of compliance to anticoagulant protocol.

Parameters for Full compliance	Parameters for Partial compliance	Parameters for Non-compliance
Baseline values APTT, PT, INR, serum creatinine, AST, ALT, ALP **Other orders;** Blood urea, serum creatinine, PCV, Total RBC Platelet count, Hb, TLC, serum ALP, SGOT, SGPT **Order of heparin;** Bolus dose according to specific diagnosis **Infusion rate;** Specified	**Baseline values** APTT, PT, INR, serum creatinine, AST, ALT, ALP ONLY other orders like blood urea, serum creatinine, total RBC, platelet count, Hb **Order of heparin;** Bolus dose according to specific diagnosis **Infusion rate;** Not specified	No baseline values obtained OR only APTT/PT, INR are obtained NO VALUES obtained OR only APTT/ PT, INR are obtained Not specified Not specified

APTT: Activated platelet thromboplastin time, INR: International normalized ratio, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, RBC: Red blood Cell, Hb: Hemoglobin, PT: Prothrombin Time, SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase

Table 7. ACCP Compliance in Pre and Post interventional phases.

ACCP Compliance	Pre-intervention	Post-intervention
Yes	13(28.9%)	28(62.22%)
No	21(46.7%)	5(11.11%)
Partial	11(24.4%)	12(26.67%)

A study of 500 patients for two years concluded that implementation of pharmacist directed anticoagulation monitoring services provides 73% transition of care metric compliance occurred in pharmacist led group; also, there was a 32% reduction in the composite safety end point in the pharmacist led group (Schillig et al., 2011). Here, we could not consider transition care metrics due to limited availability of patients on warfarin therapy. Instead, compared two groups of people (before

and after intervention) with equal demography, there was no significant difference in gender, age, admission setting, days of hospitalization, and route of administration. Pharmacist-managed group of patients were found to have no major risk of bleeding (Mamdani et al., 1999).

CONCLUSION

Inappropriate anticoagulant dosing would increase the risk of developing significant bleeding diathesis with failure to produce a therapeutic response. The pharmacist directed anticoagulation monitoring system took the edge of medication error and also was able to anticipate the ADRs. The involvement of the clinical pharmacist and his/her cooperation with physicians prompted their prescription orders in line with the ACCP guideline.

Abbreviations

a. AMS - Pharmacist-directed Anticoagulant Monitoring Services

b. INR – International Normalized Ratio

c. CVD – Cardiovascular Diseases

Peer-review: Externally peer-reviewed.

Ethics Committee Approval: This study was approved by the Institutional Ethics Committee (03/02/2015, No. IEC/ASH/2015/PD/9).

Informed Consent: Written consent was obtained from the participants.

Author Contributions: Conception/Design of Study- A.S., A.M., M.S.K., A.R.; Data Acquisition- A.S., A.M., M.S.K., A.R.; Data Analysis/Interpretation- A.S., A.M., M.S.K., A.R.; Drafting Manuscript- A.S., A.M., M.S.K., A.R.; Critical Revision of Manuscript- A.S., A.M., M.S.K., A.R.; Final Approval and Accountability- A.S., A.M., M.S.K., A.R.

Conflict of Interest: The authors have no conflict of interest to declare.

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