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Impact of patient tailored clinical pharmacist intervention on inr in patients with anticoagulant and antipatelet therapy

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Abstract
In this study we sought to define, describe and categorise the nature of clinical pharmacist-initiated interventions performed and have explored the effects magnitude and rate of acceptance of interventions. Pharmacists are effective at recognizing potential and actual drug-related problems, such as drug-induced conditions and clinically relevant drug interactions. The participation of clinical pharmacist in providing interventions contributes to the optimisation of pharmacotherapy, in terms of choosing the most appropriate drug and/or the suitable dosage and may improve patient care. Here the clinical pharmacists performed the interventions on patient safety. These types of intervention is defined as any intervention that directly affects the wellbeing of the patients under antiplatelet and anticoagulant therapy. Risk of bleeding (GI bleeds) on triple therapy can be reduced with dosing adjustments and gastro protective therapy. Concomitant use of antiplatelet drugs appeared to increase the risk for major bleeding. Dosing of antithrombotic should be kept as low as possible Aspirin daily dose should be between 75 TO 100mg and acitrom 2mg.The INR should be titrated to the lowest possible dose. Target INR should be titrated between 2 to 2.5.This can lead to a significant reduction in bleeding events when patients treated with triple therapy. Target INR was achieved in 71% of the patient population. The use of Warfarin with dual antiplatelet represents a medical decision making challenge because it reduces the risks of thrombotic events together with an increased risk for bleeding.

Keywords: antiplatelet therapy, INR, intervention, anticoagulant, clinical pharmacist

Introduction

Fear related behaviours have long been recognized as the most Antithrombotic therapies are aimed at reducing the risk of thromboembolic events in patient with Atrial Fibrillation, Coronary Artery Disease, Valvular Heart Disease and Pulmonary embolism [1]. These patients are often considered critically ill and frequently undergo urgent interventions requiring discontinuation of anticoagulant or antiplatelet therapy which can increase the risk of thrombosis. Antiplatelet therapy is much needed for patients who have ACS, AF, MI, Stroke helps to prevent future cardiovascular events. This benefit can be increased by dual antiplatelet therapy [2].This also reduces subsequent vascular events. The indication for therapy to prevent thromboembolic events are based on an assessment by the absolute risk of such events potential for bleeding [3]. These are addressed through ACC/AHA guidelines with a CHADS2 score of 2 or higher, OAC is recommended. For a CHADS2 score of 1 either aspirin or OAC is recommended. In this scenario we integrated the clinical practice knowledge through evidence based medicine approach; it aims to increase the use of high quality clinical research in clinical decision making [4]. Applying evidence based guidelines and current primary literature to specific patient situations will help reduce the risk of occurrences of cardiovascular disorders and underlying end organ damage associated with high blood pressure, hence reducing the risk of morbidity and mortality [5].

The choice of optimal DAPT regimen and duration for patients with CAD requires a tailored approach based on the patient clinical presentation, baseline risk profile and management strategy [6, 7]. Dual antiplatelet therapy consists of concurrent administration of aspirin and P2Y12 inhibitor. DAPT aims at lowering the risks of ischemic eventswith more intense and longer antiplatelet therapy VS lowering the risk of bleeding events with less intense and shorter antiplatelet therapy [8, 9]. In this study we sought to define, describe and categorise the nature of clinical pharmacist-initiated interventions performed and have explored the effects magnitude and rate of acceptance of interventions [10]. Pharmacists are effective at recognizing potential and actual drug-related problems, such as drug-induced conditions and clinically relevant drug interactions [11]. The participation of clinical pharmacist in providing interventions contributes to the optimisation of pharmacotherapy, in terms of choosing the most appropriate drug and/or the suitable dosage and may improve patient care. Here the clinical pharmacists performed the interventions on patient safety [12, 13]. These types of intervention is defined as any intervention that directly affects the well-being of the patients under antiplatelet and anticoagulant therapy [14]. This study aimed to determine the impact of clinical pharmacist's interventions on INR targets in patients with antiplatelet and anticoagulant therapy [15].

Aim

To identify drug related problems in medical history/chart and also to assess bleeding complications among the patients receiving anticoagulant with dual antiplatelet therapy and antiplatelet with anticoagulant therapy.

Ethics Approval

This prospective study from 2018-2019 was approved by the Institutional Review Board (IRB) of a tertiarty care hospital in Banglore. The student clinical pharmacist used ACA/AHA guidelines to help provide evidence based recommendations for patients to help support patient care. The compliance with ethical standards was monitored all throughout the study.

Methodology

A convenience sampling method utilizing protocols developed at the tertiary hospital were used for this study. All the study participants were provided with informed consent before starting the study. The student clinical pharmacist provided medication recommendations to health care professionals and monitored blood pressure changes before and one day after the recommendation to the health care professional. Regular follow-up blood pressure measurements were continued. Patient medical records were reviewed by student clinical pharmacists to identify if a patient was eligible to participate in the study. Recommendations made to health care providers were documented along with the monitoring of coagulation workup each day and documented if recommendations were accepted or not accepted by the physician. Documentation also included the type and nature of recommendation given in terms of drug therapy. A specially designed data collection form was developed to help the student document clinical information.

Study Population Inclusion/Exclusion Criteria

Patients were included in the study if they met the following criteria: >18 years of age requiring inpatient services, hypertensive patients, patients with INR above 3. Patient's visiting the outpatient department of the tertiary care facility were excluded from the study. Paediatric patients and pregnant women were excluded.

Endpoints

The study evaluated several different endpoints. The first endpoint was change in PT, APTT and INR before student recommendation and after student recommendation (Day 1 vs. Day 7). A co-primary endpoint was the difference in coagulation workup among recommendations that were accepted vs. recommendations that were not accepted. In addition, the researchers also evaluated how many recommendations made were accepted by health care professionals and what the major topic areas were for recommendations by student pharmacists.

Statistical Analysis

A sample of 104 patients was followed at the tertiary hospital. A sample size of 59 recommendations was needed to achieve a power of 80% using an alpha of 0.05 assuming a mean INR of 3 mmHg. A t-test was used to compare continuous data for two independent groups. P-values less than 0.05 were considered statistically significant. Descriptive statistics were also used in the analysis. Microsoft Excel v16 and SPSS v25 were used to conduct the analysis of the data

Results

Table 1: Type of therapy

Dual antiplatelet +anticoagulant therapy	Antiplatelt + anticoagulant Therapy
61patients	43patients

Out of 104 patients, 61patients were under dual antiplatelet (DAP) with anticoagulant therapy and 43 were under single antiplatelet with anticoagulant therapy.

Table 2: Bleeding events based on type of therapy

Bleeding events in patients with dual antiplatelet anticoagulant therapy	Bleeding events in patients with dual antiplatelet therapy
21	14

35 out of 104 experienced bleeding episodes among that patients under DAP with an anticoagulant had more bleeding episodes than patients under single antiplatelet anticoagulant therapy

Table 3: Major areas of student intervention

Challenges identified	Recommendations
Clopidogrel induced bleeding and blood in stools in patient diagnosed with DVT.The INR levels increased to 3.5	The suggestion was accepted and the dose was reduced to 75 mg. hence target INR was achieved
Acitrom (2mg) induced PT (17) AND INR elevation (3.5) in MI patient.	The suggestion was accepted and VITAMIN K was added.
ACITROM induced intracranial bleed	The suggestion was accepted and Tranexemic acid was included in the therapy
ASPIRIN induced acute episode of epistaxis	Dose reduction of aspirin was advised considering the risk benefit ratio.
INF tirofiban was on flow, concomitant administration of Ecospirin lead to elevation in PT Levels(19.2)	The suggestion made by the clinical pharmacist to stop INF TIROFIBAN was accepted by clinician

Table 4: Interventions on clinically observed and confirmed DDI's among patients

Interacting Drugs	Observed interaction effect	Pre intervention	Recommendation	Post interventional outcome
Aspirin+amlodipine	Increased blood pressure	Bp was 160/90	Suggested to have time spacing between 2 drugs and monitor the blood pressure when concurrently administered	Bp was 120/80 at the time of discharge
Clopidogrel+diclofenac	Thrombocytopenia	Platelet count was less than 75000	Suggested to d/c diclofenac and to monitor the platelet levels	Significant imrovement in platelet count was observed after 1 week (1.25lks)

Aspirin+ticagrelor	Elevated pt levels	Pt level=19.2	Suggested for timespacing and after the initial dose the maintenance doses of aspirin should be between 75-100mg.	PT levels was founf to be normal after 4 th day.
Aspirin+atenolol	Hypertension	Bp was 170/90mmhg	Suggested to d/c atenolol and to include amlodipine	On day 3 the bp was 140/80
Aspirin+tirofiban	Elevated pt levels	the pt was 17.8	Suggested to d/c tirofiban and the recommendation was acceptd	At the time of discharge pt levels became normal
Nitroglycerine+heparin	Decrease in partial thromboplastin time	The ptt was 19	Suggested to monitor the partial prothrombin levels and time spacing was advised	Thromboplastin time bounced back to normal post intevention
Alteplase+aspirin	Elevated inr	Inr was 3.5	Advised for time spacing and suggested to monitor the levels	On day inr was 2.5

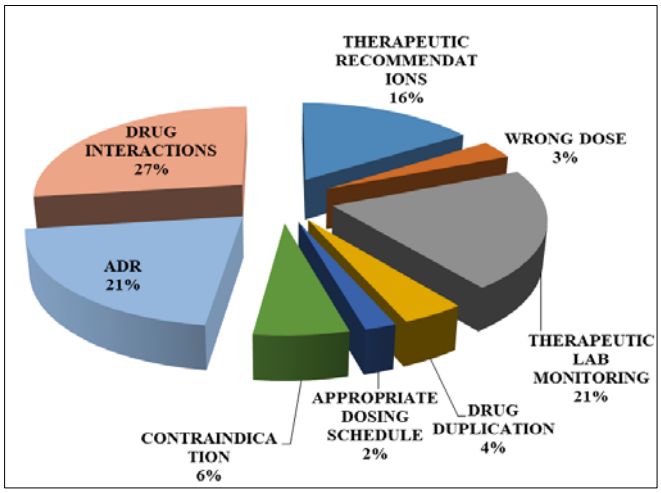

Fig 1

Table 5: Severity of the intervened medication errors

Nature	Count
Major	22
Moderate	17
Minor	11

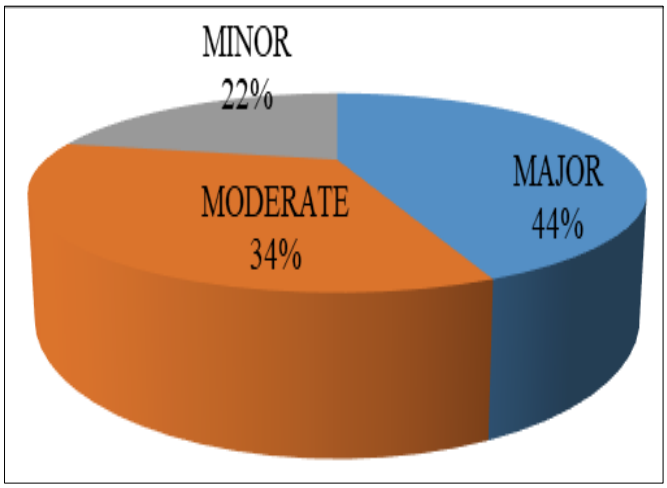

Fig 2

As depicted in the figure 44% of the interventions were carried out mainly to address the major significant errors. Moderately significant interventions were observed in 43% and 22% of them were having impact on minor medication errors.

Table 6: Post interventional target INR achieved/not achieved

Target INR achieved	Target INR not achieved
74	30

The target INR was achieved in 74 patients and in 30 patients target was not achieved

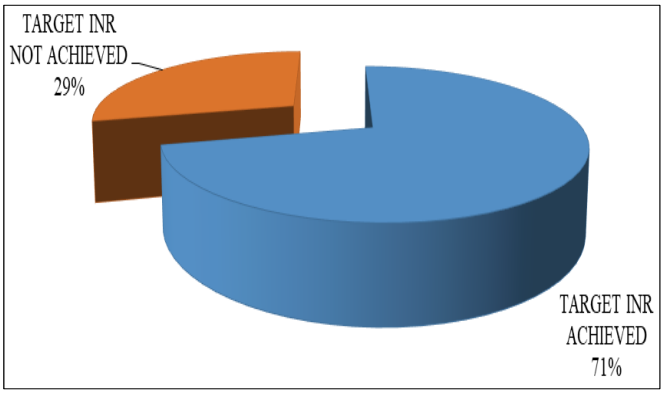

Fig 3

Limitations

In our study the major limitation was there were barriers to the practice of evidence based medicine. The gap between the demand for health care and resources available to meet that demand is growing and results in clinicians having to care for more patients in less time. There were shortages of scientific evidence in some cases and even when evidence did exist; there were challenges in applying evidence to the care of specific individual patients.

Conclusion

The study suggests that clinical pharmacist driven interventions can aid patients to achieve significant therapeutic outcome and also assists the physicians to provide better patient care with added safety. The study concludes that involving clinical pharmacists services in patient care can significantly help to identify, resolve and prevent DRP's in the hospital thereby enhancing the patient outcomes. Risk of bleeding (GI bleeds) on triple therapy can be reduced with dosing adjustments and gastro protective therapy. Concomitant use of antiplatelet drugs appeared to increase the risk for major bleeding. To avoid bleeding events Dosing of antithrombotic should be kept as low as possible, Aspirin daily dose should be between 75 to 100mg and acitrom 2mg.The INR should be titrated to the lowest

possible dose.Target INR should be titrated between 2 to 2.5.This can lead to a significant reduction in bleeding events when patients treated with triple therapy, the target INR was achieved in 71% of the patient population. The use of Warfarin with dual antiplatelet represents a medical decision making challenge because it reduces the risks of thrombotic events together with an increased risk for bleeding. A collaborative approach of physician and a pharmacist can provide better patient care.

Acknowledgment
We would like to express our gratitude to the department of cardiology and medicine, for providing opportunity to execute our research work.

Conflict of Interest
The authors declare no conflict of interest.

Abbreviations
ADR: Adverse Drug Reactions
DI: Drug Interactions
QOL: Quality of life
INR: Internationl Normalised Ratio
PT: Prothromin Time
PTT: Partial prothrombin Time
DRP: Drug Realted Problems.

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