# DEVELOPMENT AND VALIDATION OF SAT-ANT: A SAFETY ASSESSMENT TOOL FOR ANTICOAGULANT THERAPY

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***ABSTRACT***

**Background**

Atrial fibrillation, deep vein thrombosis, pulmonary embolism, and acute coronary syndromes are among the thromboembolic illnesses that are commonly prevented and treated with anticoagulant therapy. Anticoagulant therapy has advantages, but it also has a high risk of adverse events, medication mistakes, and drug-related problems (DRPs), which emphasizes the need for a standardized safety evaluation technique.

**Objective**

To develop and validate Safety Assessment Tool (SAT-ANT) for patients receiving anticoagulant therapy.

**Methodology**

Over the course of eight months, a prospective observational study was carried out at a tertiary care hospital in the department of general medicine and cardiology. The study included 83 adult patients on anticoagulant therapy. Fifteen experts designed and validated the Anticoagulation Therapy Adherence Questionnaire (ATAQ) and the SAT-ANT. Cronbach's alpha was used to evaluate reliability. Using clinical information examined, including DRPs, serum creatinine, and INR.

**Results**

SAT-ANT demonstrated good reliability (Cronbach's alpha = 0.841), while ATAQ showed excellent reliability (Cronbach's alpha = 0.901). Most participants were males aged 20–60 years (62.7%). Enoxaparin sodium was the most frequently prescribed anticoagulant (43.4%). A total of 83 DRPs were identified, with dose-related problems being the most common (47.0%). Increased bleeding risk was the predominant adverse event. Warfarin overdose and warfarin–aspirin interaction were the most frequent DRPs. Most patients had elevated INR values & knowledge regarding anticoagulant therapy.

**Conclusion**

Pharmacist-led anticoagulation stewardship is supported by SAT-ANT, a dependable and clinically beneficial technique for detecting safety concerns in anticoagulant medication.

**Keywords:** Anticoagulant therapy, drug-related problems, safety assessment tool, SAT-ANT, pharmacovigilance, bleeding risk, medication adherence, clinical pharmacy.

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## INTRODUCTION

Thromboembolic disorders include venous thromboembolism (VTE), atrial fibrillation (AF), acute coronary syndromes (ACS), ischemic stroke, and pulmonary embolism (PE). These conditions together make up one of the most common and dangerous types of cardiovascular disease in the world. With a projected 59.7 million people affected globally in 2019—a 111% increase from 1990—the prevalence of AF alone is expected to rise by more than 60% by 2050. In those under 55, the prevalence of AF can be as low as 0.1%, while in people over 80, it can reach 9.0%.

In actuality, venous thromboembolism, which encompasses PE and deep vein thrombosis (DVT), is the third most common cardiovascular disease overall and results in considerable morbidity,[3] death, and recurrence risk. Due to the significant clinical and cost burden of these disorders, clinicians need safe and effective anticoagulant drug treatment as a crucial part of management.

The epidemiology of thromboembolic disease is complicated by the fact that the age of onset of cardiovascular illnesses is younger in India than in the West. This seems to be related to metabolic risk factor profiles, rapid urbanization and dietary habits, as well as genetic predisposition.[14] In tertiary care cardiac centers throughout the Indian subcontinent, patients are mostly prescribed anticoagulants due to ischemic heart disease and AF, and the proportion of patients requiring long-term anticoagulant therapy is rising. With an ageing population, the trend is likely to grow in India. The need for organized safety evaluation is a critical clinical need because of the risks of anticoagulant therapy in a highly variable and resource-poor population with limited access to monitoring infrastructure.

Anticoagulant drugs have changed significantly during the last 70 years. Vitamin K antagonists (VKAs), mainly acenocoumarol and warfarin, have been the mainstay of oral anticoagulation since the 1950s. Hepatic vitamin K epoxide reductase is normally competitively inhibited by VKAs, which hinders the carboxylation and consequent functional activation of coagulation factors II, VII, IX, and X as well as the anticoagulant proteins C and S.[2] Despite their excellent track record for treating AF and mechanical heart valves, they have a narrow therapeutic index and considerable pharmacokinetic heterogeneity between and within patients. To maintain the target anticoagulation range (INR 2.0–3.0 for most uses), patients need to have their international normalized ratios regularly monitored. Additionally, there are a number of drug-drug and drug-food interactions, especially those involving dietary vitamin K.[2,9]

The main way that enoxaparin sodium and other low molecular weight heparins (LMWHs) work is by using antithrombin to block Factor Xa. Because of their consistent pharmacokinetics, they are the accepted treatment for acute inpatient anticoagulation in ACS and VTE and can be used subcutaneously without requiring regular coagulation monitoring.[3] Direct oral anticoagulants (DOACs), such as the Factor Xa inhibitors apixaban, rivaroxaban, and edoxaban and the direct thrombin inhibitor dabigatran etexilate, have dramatically changed outpatient anticoagulation since their release in 2008. With significantly lower rates of cerebral hemorrhage and fewer major bleeding episodes, DOACs were either superior to or non-inferior to warfarin for preventing stroke in atrial fibrillation, according to landmark randomized controlled trials like ARISTOTLE (apixaban), ROCKET-AF (rivaroxaban), and RE-LY (dabigatran).[11,12,13]

There are still serious safety issues with DOACs despite their clinical advantages. Since the kidneys eliminate about 27% of apixaban, 35% of rivaroxaban, and 80% of dabigatran, renal clearance is a crucial pharmacokinetic factor. When renal function deteriorates, dose modification is required because increasing plasma levels can increase the risk of bleeding.[3,6] Due to changed volume of distribution and body mass-dependent medication clearance, obesity makes administration even more difficult. According to published studies, 12.8–34.0% of hospitalized patients experience dose errors in DOAC therapy, which is a serious but underappreciated patient safety issue.[5]

One of the most prevalent drug classes linked to preventable dose errors, adverse drug reactions (ADRs), and drug-related hospital admissions globally is anticoagulants. They are categorized as high-alert medications by the Institute for Safe Medication Practices (ISMP) and the World Health Organization (WHO) because of their potential to have disastrous effects.8 The severity of anticoagulant-associated bleeding can vary from modest symptoms like epistaxis, gingival bleeding, and ecchymosis to potentially deadly bleeding, brain bleeding, and gastrointestinal bleeding.

Drug-related problems (DRPs) associated with anticoagulant therapy are common in all therapeutic settings. One therapeutically important DRP category is drug-drug interactions (DDIs). When antiplatelet drugs like aspirin, clopidogrel, and ticagrelor are taken alongside anticoagulants, the risk of bleeding increases significantly. The risk of gastrointestinal bleeding is also increased by non-steroidal anti-inflammatory drugs (NSAIDs). Fluoroquinolones, macrolides, and azole antifungals are examples of antibiotics that can increase plasma levels of DOACs and VKAs by blocking CYP3A4 and P-glycoprotein efflux.[4,9] One prevalent and often disregarded factor in anticoagulant safety and treatment failure is medication non-adherence. Patients on long-term oral anticoagulation often report clinically significant non-adherence rates of 20–40%, especially when validated self-report techniques are used.[1]

Within the multidisciplinary healthcare team, clinical pharmacists have a special role in maximizing the efficacy and safety of anticoagulant therapy. Across a variety of healthcare settings, pharmacist-managed anticoagulation services have shown statistically significant improvements in time in therapeutic range (TTR), decreases in severe bleeding and thromboembolic events, and improved drug adherence.[13] However, such interventions could not be dependable, quantifiable, or generalizable in the absence of a methodical and verified safety evaluation framework. This study opens the way for integrated, patient-focused care methods in the management of chronic diseases by supporting the pharmacist's role in enhancing pharmaceutical safety and patient-centered outcomes.[6]

The study aims to develop, validate, and implement a Safety Assessment Tool for patients on Anticoagulant Therapy (SAT-ANT), and to assess

the prevalence of adverse events associated with anticoagulation therapy before and after its implementation.

**Methodology**

The study was carried out at tertiary care hospital in the department of general medicine and cardiology. After eight months of data gathering, one month was dedicated to data analysis and publication submission. The study used a prospective observational strategy.

Ethical clearance was obtained with reference number KLECOPBGMEC/D002-2025.

Study materials included an informed consent form, a patient data collection form, the Safety Assessment Tool for Anticoagulant Therapy (SAT-ANT), and a medication adherence tool.

The inclusion criteria are Patients receiving anticoagulation therapy aged 18 years and above were eligible for inclusion. These encompassed patients prescribed any anticoagulant (warfarin, unfractionated heparin, LMWH, or any DOAC) in either inpatient or outpatient settings, provided they were able to provide written informed consent or had a legally authorized representative to do so.

Exclusion criteria are Patients under 18 years of age were excluded, along with pregnant and lactating women, and those who refused or were unable to provide informed consent.

**Results**:

**Table 1: Demographic Details of Expert Validators of SAT-ANT and AATQ Questionnaire**

| Sl. No. | Variables | Category | Frequency (n) |
|---|---|---|---|
| 1 | Gender | Male | 13 |
| | | Female | 02 |
| 2 | Qualification | MBBS, MD | 01 |
| | | Pharm D | 02 |
| | | M Pharm | 09 |
| | | B Pharm | 03 |
| 3 | Specialization | Cardiology | 01 |
| | | Pharmacy Practice | 04 |
| | | Clinical Research | 10 |

Table 1 presents the process of validating the questionnaire involved fifteen validators with a range of professional experiences. There were two females and thirteen males. The bulk of validators (nine participants) had an M.Pharm degree, followed by B.Pharm (three participants), Pharm.D. (two participants), and MBBS/MD (one participant). Clinical research specialists made up the largest group (ten validators) in terms of specialization, followed by cardiology (one validator) and pharmacy practice (four validators). The SAT-ANT tool's scientific validity, applicability, and dependability were enhanced by the involvement of specialists from these various backgrounds.

**Table 2: Reliability Test – SAT-ANT Tool & Anticoagulation Therapy Adherence Questionnaire (ATAQ).**

| Reliability Measure | Value (SANTANT) | Value (ATAQ) |
|---|---|---|
| Number of items | 14 | 13 |
| Cronbach's Alpha | 0.167 | 0.886 |
| Cronbach's Alpha Based on Standardized Items | 0.841 | 0.901 |

Table 2 demonstrates there were fourteen items on the SAT-ANT questionnaire. Although the standardized Cronbach's alpha was 0.841, suggesting strong reliability after item standardization, the raw Cronbach's alpha score was 0.167, indicating poor internal consistency. Variability in item variances and scaling is reflected in this disparity & the 13-item Anticoagulation Therapy Adherence Questionnaire (ATAQ) showed good reliability and strong internal consistency, with a standardized Cronbach's alpha of 0.901 and a Cronbach's alpha of 0.886. These results validate the high degree of consistency with which the questionnaire items measured the desired construct.

**Table 3: Distribution of Demographic Characteristics & Comorbidities of Study Participants (n=83)**

| Variable | Category | Frequency (n) | Percentage (%) |
|---|---|---|---|
| Age (Years) | 20–50 | 33 | 39.7 |
| | 51–60 | 33 | 39.7 |
| | 61–65 | 9 | 10.84 |
| | 66–75 | 5 | 6.0 |
| | 76–85 | 3 | 3.6 |
| Gender | Male | 51 | 62.7 |
| | Female | 32 | 37.3 |
| Comorbidities | CAD | 23 | 27.7 |
| | CAD-TVD | 9 | 10.8 |

| Variable | Category | Frequency (n) | Percentage (%) |
|---|---|---|---|
| | CAD, HTN | 18 | 21.7 |
| | CKD | 2 | 2.4 |
| | Dyspnoea | 4 | 4.8 |
| | HTN | 24 | 28.9 |
| | T2DM | 2 | 2.4 |
| | Total | 83 | 100.0 |

CAD: Coronary Artery Disease; TVD: Triple Vessel Disease; CKD: Chronic Kidney Disease; HTN: Hypertension; T2DM: Type 2 Diabetes Mellitus

Table 3 represents the age ranges of 20–50 years and 51–60 years comprised the bulk of patients, with 33 individuals (39.7%) in each group. Nine patients (10.84%) were in the 61–65 age range, whereas the percentages in the 66–75 (6.0%) and 76–85 (3.6%) age categories were lower. These results imply that anticoagulant therapy was more common among middle-aged and early-elderly groups in this cohort. There were 32 patients (37.3%) who were female and 51 patients (62.7%) who were male. Hypertension (28.9%, n=24) was the most prevalent concomitant condition, followed by coronary artery disease (CAD) in 23 individuals (27.7%). Eighteen patients (21.7%) had a combined burden of HTN and CAD, whereas nine individuals (10.8%) had CAD with triple vascular disease (CAD-TVD). Two patients (2.4%) each had T2DM and CKD, while four patients (4.8%) experienced dyspnea. One patient (1.2%) had both type 2 diabetes and hypothyroidism.

**Table 4: Distribution of Anticoagulant Drugs Prescribed Among Study Participants (n=83).**

| Anticoagulant Drug | Frequency (n) | Percentage (%) |
|---|---|---|
| Acenocoumarol | 22 | 26.5 |
| Apixaban | 17 | 20.5 |
| Enoxaparin Sodium | 36 | 43.4 |
| Warfarin Sodium | 8 | 9.6 |
| Total | 83 | 100.0 |

Table 4 demonstrates with 36 patients (43.4%), enoxaparin sodium was the most often prescribed anticoagulant. This is in line with its quick onset of action and extensive usage in the prevention and treatment of thromboembolic disease in hospitalized patients. The increasing use of DOACs is demonstrated by the prescription of acenocoumarol to 22 patients (26.5%) and apixaban to 17 patients (20.5%). Due to its limited therapeutic index, extensive INR monitoring, and drug-food interactions, warfarin sodium was prescribed to 8 patients (9.6%).

**Table 5: Distribution of Drug-Related problems (DRP), Among Study Participants (n=83).**

| Sl.no | Categories of DRP | Frequency(n=83) | Percentage % |
|---|---|---|---|
| 1 | Dose-Related | 39 | 46.9 |
| 2 | Interaction-Related | 12 | 14.4 |
| 3 | Indication-Related | 11 | 13.2 |
| 4 | Adherence-Related | 10 | 12.0 |
| 5 | Monitoring-Related | 10 | 12.0 |
| 6 | Dose and Interaction-Related | 1 | 1.20 |
| | Total | 83 | 100.0 |

Among the 83 identified drug-related problems (DRPs), dose-related problems were the most common, accounting for 46.9% (n=39). Interaction-related DRPs constituted 14.4% (n=12), followed by indication-related DRPs at 13.2% (n=11). Adherence-related and monitoring-related DRPs each contributed 12.0% (n=10). A small proportion of DRPs (1.2%, n=1) were both dose- and interaction-related. Overall, dose-related issues represented the major category of DRPs identified during the study in Table 5.

**Table 6: Distribution of INR & Serum Creatinine Levels Among Study Participants (n=83).**

| Sl. No. | Parameter | Category | Frequency (n=83) | Percentage (%) |
|---|---|---|---|---|
| 1 | INR | Within normal range (0.8–1.2) | 2 | 2.4 |
| | | Above normal range (>1.2) | 81 | 97.5 |
| 2 | Serum creatinine | Within normal range (0.6–1.3 mg/dL) | 76 | 91.5 |

| Sl. No. | Parameter | Category | Frequency (n=83) | Percentage (%) |
|---|---|---|---|---|
| | | Above normal range (>1.3 mg/dL) | 7 | 8.4 |

Table-6 represents two individuals (2.4%) fell within the normal range of 0.8–1.2, while the vast majority of participants (97.5%, n=81) had INR values beyond the usual reference range (>1.2). This primarily raised pattern is consistent with the therapeutic goal of VKA therapy and indicates active anticoagulation in the research population. However, a more thorough evaluation of anticoagulation quality is limited by the lack of a comprehensive INR sub-categorization (sub-therapeutic, therapeutic, and supratherapeutic). Seven patients (8.4%) had increased creatinine levels (>1.3 mg/dL), a sign of renal insufficiency, whereas the majority of participants (91.5%, n=76) had serum creatinine values below the normal reference range (0.6–1.3 mg/dL). In patients on anticoagulants, renal impairment is clinically significant since it can worsen drug elimination, raise plasma drug levels, and increase the risk of bleeding. Therefore, routine monitoring of renal function is crucial, especially for individuals using renally cleared medications like apixaban and enoxaparin sodium.

**Table 7: One-Sample t-Test of Study Questionnaire Items (N=80)**

| Variables | Mean ± SD | t | p value | 95% CI of Difference |
|---|---|---|---|---|
| Indication appropriateness | 0.01 ± 0.11 | 1.00 | 0.320 | 0.01 to 0.04 |
| Agent selection | 0.14 ± 0.34 | 3.55 | 0.001* | 0.06 to 0.21 |
| Dose appropriateness | 0.53 ± 0.50 | 9.52 | <0.001* | 0.42 to 0.64 |
| Monitoring in place | 0.31 ± 0.46 | 5.98 | <0.001* | 0.21 to 0.41 |
| DDI | 0.80 ± 0.40 | 18.03 | <0.001* | 0.71 to 0.89 |
| DFI | 0.83 ± 0.38 | 19.57 | <0.001* | 0.74 to 0.91 |
| Peri procedural plan | 0.11 ± 0.32 | 3.16 | 0.002* | 0.04 to 0.18 |
| BI factors | 0.49 ± 0.50 | 8.84 | <0.001* | 0.38 to 0.61 |
| TR optimization | 0.20 ± 0.40 | 4.44 | <0.001* | 0.11 to 0.29 |
| Adherence and dosing instructions | 0.21 ± 0.41 | 4.61 | <0.001* | 0.12 to 0.30 |
| Patient counselling documented | 0.11 ± 0.32 | 3.16 | 0.002* | 0.04 to 0.18 |
| Renal/hepatic contraindication | 0.37 ± 0.49 | 6.86 | <0.001* | 0.26 to 0.48 |
| Lab/therapy follow-up arranged | 0.40 ± 0.49 | 7.23 | <0.001* | 0.31 to 0.50 |
| High-risk concomitant therapy | 0.44 ± 0.50 | 8.00 | <0.001* | 0.33 to 0.56 |

***Statistically significant ($p < 0.05$).**

Table-7 presents the patient's knowledge of anticoagulant therapy was assessed using a one-sample t-test. When compared to the test value of zero ($p < 0.05$), the majority of items displayed statistically significant responses. Drug-food interactions (DFI: 0.83 ± 0.38) and drug-drug interactions (DDI: 0.80 ± 0.40) had higher mean scores, indicating somewhat better awareness in these domains. Nevertheless, despite statistical significance, a number of items—such as agent selection, peri-procedural planning, TR optimization, adherence instructions, and patient counseling—showed poor mean scores, indicating a lack of comprehension. There was no statistically significant difference in indication appropriateness (Q1) ($p = 0.320$). The results show that patients' awareness of anticoagulant medication is inadequate, highlighting the need for better patient education and organized counseling programs.

**Table 8: One-Sample t-Test Analysis for Medication Adherence.**

| Knowledge Domain | Mean ± SD | Mean Difference | t value | p value | 95% CI |
|---|---|---|---|---|---|
| Medication Taking Behaviour | 1.65 ± 1.14 | 1.65 | 13.17 | <0.001 | 1.40 – 1.90 |
| Therapy Related Concerns | 0.75 ± 0.73 | 0.75 | 9.32 | <0.001 | 0.59 – 0.91 |
| Monitoring Instructions | 0.77 ± 0.70 | 0.77 | 9.98 | <0.001 | 0.62 – 0.92 |
| Knowledge Understanding | 1.54 ± 0.85 | 1.54 | 16.62 | <0.001 | 1.36 – 1.73 |

***Statistically significant (p < 0.001).**

Table-8 represents the mean scores for every medication adherence domain were statistically significant when compared to the test value of zero ($p < 0.001$). Knowledge Understanding ($1.54 \pm 0.85$) and Medication Taking Behaviour ($1.65 \pm 1.14$) had the highest mean scores, indicating relatively adequate engagement with adherence-related behaviours. Inadequate comprehension of monitoring requirements and therapeutic precautions was indicated by lower ratings for Monitoring Instructions ($0.77 \pm 0.70$) and therapeutic Related Concerns ($0.75 \pm 0.73$). The statistical robustness of these results was confirmed by the fact that all 95% confidence intervals excluded zero.

**DISCUSSION:**

In order to offer a comprehensive cross-sectional assessment of drug-related problems (DRPs) and side effects in an actual clinical setting, 83 patients on anticoagulant medication were enrolled in the current prospective observational study. The age distribution in the demographic profile was bimodal, with the largest presence in the 20–50 and 51–60 age groups (39.7%, n=33 each). This younger tilt is in contrast to trends in high-income nations, where anticoagulant usage is more concentrated in older populations because VTE and atrial fibrillation are more common in people over 65. The male preponderance (62.7%, n=51) is in line with epidemiological data from the South Asian setting, where men are more likely to suffer from cardiovascular conditions including hypertension and CAD. In their prospective observational study, Vijayakumar et al. (2023) also noted a male-dominated population study of patients receiving anticoagulants, demonstrating regional trends in gendered prescription practices.

The most often administered anticoagulant (43.4%, n=36) was enoxaparin sodium, which is in keeping with clinical recommendations that suggest LMWH for bridging therapy and acute thromboprophylaxis during hospital stays. Apixaban came up at 20.5% (n=17), followed by acenocoumarol at 26.5% (n=22). Despite its proven safety and performance profile, the comparatively reduced DOAC share could be due to budgetary limitations, formulary restrictions, or prescriber familiarity in settings with limited resources. In a similar vein, Chow et al. (2024) observed that heparins and VKAs are still widely used in low- and middle-income nations, with accessibility and price being the primary driving forces.

One of the biggest barriers to oral anticoagulation was found to be patient awareness gaps, which were linked to lower safety and efficacy. By effectively managing factors such patient education, medication adherence, lifestyle changes, drug and food interactions, and regular INR monitoring, patient outcomes can be improved. In a study on anticoagulant knowledge and INR control among 225 patients, male patients (53%) outnumbered female patients (46.6%) with a mean age of 70 years. In the current study, out of 66 patients, 56.1% (37) were male and 44% (29) were female, with the majority coming from the 41–50 age group.[19]

The majority of the comorbidity profile was cardiovascular: 28.9% (n=24) of patients had hypertension, 27.7% (n=23) had CAD, and 21.7% (n=18) had both CAD and HTN. Because patients with CAD and HTN often take concurrent antiplatelet medication, which significantly increases bleeding risk when paired with anticoagulants, this high cardiovascular load is clinically relevant. Patients on triple antithrombotic medication showed a markedly increased risk of bleeding (Sridharan and Sivaramakrishnan, 2025). Given the direct effect of renal impairment on anticoagulant pharmacokinetics and the increased risk of drug accumulation, the presence of CKD in 2.4% (n=2) of patients is also noteworthy.

Increased bleeding risk (62.7%, n=52) dominated the adverse event profile and was the main safety issue related to anticoagulant medication in this population. This high rate points to a systemic shortcoming in the clinical setting's assessment and monitoring of anticoagulant risk. In a large-scale pharmacovigilance investigation, Hong et al. (2026) found that bleeding was the main safety signal among anticoagulant users, highlighting the need for standardized bleeding control procedures. 28.9% (n=24) of patients had manic episodes, which calls for more pharmacovigilance research into possible pharmacological interactions between anticoagulants and psychoactive medicines.

Dose-related DRPs accounted for 39 of all diagnosed issues, making them the most common category. The most frequent single problem (30.8%, n=12) was warfarin overdose, highlighting the well-known difficulty of controlling this medication's limited therapeutic index. These results are in line with those of Chow et al. (2024), who found that one of the most frequent DRPs in anticoagulant therapy is inappropriate dose, and Bassam et al. (2022), who found that the main reason for pharmaceutical therapy imbalances is the failure to adapt dosage. The most prevalent anticoagulant DRPs, according to Gakome et al. (2023), who worked in a tertiary hospital in Kenya, were dose errors and inadequate INR monitoring, indicating the challenge's global universality.

The Warfarin-Aspirin combination accounted for the greatest share (33.3%, n=4) of interaction-related DRPs found in 12 cases. Warfarin is especially vulnerable to clinically significant DDIs due to its vulnerability to both pharmacokinetic and pharmacodynamic interactions. According to Quintens et al. (2022), among the most frequent DRPs in hospitalized patients were anticoagulant medication interactions, especially those involving warfarin. In order to reduce this danger, Spyropoulos and Douketis (2022) recommended the minimum length of dual antithrombotic overlap medication. In their expert NOAC guidelines from India, Singh et al. (2022) also specifically cautioned against the reckless concurrent use of NSAIDs and oral anticoagulants.

The ideal therapeutic INR range, as determined by the literature, is 2.0–3.0, where values above 3 indicate a danger of bleeding and below 2 indicate a risk of clotting.13. Based on this research, INR was divided into three groups for this investigation.13 The intervention group's mean therapeutic INR was 2.52+0.21, whereas the control groups were 2.28+0.25. Variations in INR values caused by sporadic INR check-ups were discovered through patient interviews. A lack of knowledge regarding the significance of routine INR monitoring was evident in the fact that many patients only performed INR checks at follow-ups. Effective patient counseling had been given, according to the analysis of the data. Patients were monitored once more after receiving the appropriate education, and the intended therapeutic range was achieved.[20]

Eleven cases had indication-related DRPs, with warfarin given without a legitimate clinical justification being the most frequent (36.4%, n=4). Patients who receive such unsuitable prescriptions run the danger of bleeding without receiving any therapeutic benefit. Although a sizable percentage of anticoagulant orders in tertiary care settings lack sufficient clinical reason, Quintens et al. (2022) showed that pharmacist-led structured reviews greatly improved the appropriateness of anticoagulant treatment.

DRPs related to monitoring and adherence were found in ten cases each. 40.0% of adherence-related DRPs were caused by forgetfulness-related missed warfarin doses, but the most common monitoring-related problem (50.0%, n=5) was the lack of routine INR monitoring. According to Burnett et al. (2022), the main cause of treatment failure and thromboembolic recurrence is patient non-adherence. According to Schulman et al. (2024), systematic monitoring programs are crucial parts of anticoagulant therapy and monitoring gaps are a modifiable risk factor.

The cohort's active anticoagulation was validated by laboratory parameter analysis, with INR values above the normal reference range in 97.5% of patients. Time in therapeutic range (TTR) is still the gold standard for evaluating overall anticoagulation quality because there is no comprehensive INR sub-categorization. According to the 2024 EHRA guidelines, patients taking VKAs with a TTR of less than 70% should switch to DOACs. 8.4% of the group had renal impairment, which emphasizes the necessity of routine renal monitoring and tailored dose adjustment for anticoagulated individuals.

The thorough identification of 83 DRPs in five categories—dose (n=39), interaction (n=12), indication (n=11), adherence (n=10), monitoring (n=10), and combined dose-interaction (n=1)—confirms the importance of proactive pharmacist involvement in anticoagulant medication. These results support the findings of Chow et al. (2024), who stated that among patients taking anticoagulants, pharmacist-led prescription record checks greatly aided in the identification and resolution of DRPs. Quintens et al. (2022) also showed that anticoagulant prescribing quality significantly improved as a result of pharmacist-led medication appropriateness reviews. All of the study's findings point to the need for organized anticoagulation stewardship programs that include patient education materials, consistent INR monitoring schedules, multidisciplinary teamwork, and drug reconciliation processes. A scalable and evidence-based approach to maximize the safety and efficacy of anticoagulant medication in both inpatient and outpatient settings is to include validated structured tools, like the SAT-ANT used in this study, into standard hospital workflows.

**CONCLUSION:**

The Safety Assessment Tool for Anticoagulant Therapy (SAT-ANT) and the Anticoagulation Therapy Adherence Questionnaire (ATAQ), both of which showed satisfactory reliability, were effectively created, validated, and applied in this prospective observational study. A broad range of medication-related issues were found in the dose, interaction, indication, adherence, and monitoring areas among 83 patients receiving anticoagulant therapy. The most common adverse event was increased bleeding risk, which was followed by drug

interaction issues and dose-related mistakes, especially warfarin overdose. Laboratory results showed a subset with renal impairment that required dose modification, as well as nearly universal rise of INR over the normal range, which is consistent with active anticoagulation. Assessments of patient knowledge and adherence revealed serious deficiencies in monitoring compliance and therapy-related comprehension. In order to minimize avoidable drug-related damage and improve patient outcomes, our results collectively highlight the vital need for pharmacist-led, structured anticoagulation management programs in tertiary care settings.

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**Ethics approval and consent to participate:**
The research was approved by the Institutional Ethics Committee of KLE College of Pharmacy Belagavi, KLECOPBGMEC/D002-2025. and certifies that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Written informed consent was obtained from the participants.

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