

Evaluation of Clinical and Patient-Centred Outcomes after Implementation of an Anticoagulation Clinic in a Tertiary Hospital Setting

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Abstract:

Background: Anticoagulation therapy with vitamin K antagonists requires vigilant monitoring to maintain the International Normalized Ratio (INR) within the therapeutic range. Inconsistent monitoring and lack of patient education often result in suboptimal control and adverse events. Structured Anticoagulation Clinics (ACCs) are designed to enhance therapeutic safety and patient outcomes through systematic follow-up, education, and counselling. This study aimed to assess the impact of an Anticoagulation Clinic intervention on therapeutic control and patient-centred outcomes in a tertiary care hospital.

Methods: A pre-post interventional study was conducted among 139 adult patients receiving oral anticoagulation therapy for various indications including atrial fibrillation, mechanical heart valves, and venous thromboembolism. Baseline data were collected before establishment of the Anticoagulation Clinic and compared with post-intervention data after six months of structured clinic follow-up. Primary outcomes included Time in Therapeutic Range (TTR) and INR stability. Secondary outcomes comprised adverse events, medication adherence (MMAS-8), patient satisfaction (Duke Anticoagulation Satisfaction Scale — DASS), and knowledge regarding anticoagulation. Paired t-tests and McNemar tests were applied as appropriate.

Results: The mean age of participants was 52.4 ± 13.6 years, with 59% males. Following clinic intervention, the mean TTR significantly improved from $41.6 \pm 18.1\%$ to $65.0 \pm 17.1\%$ ($p < 0.001$), and the proportion achieving TTR $\geq 65\%$ increased from 10.1% to 48.2% ($p < 0.001$). Major bleeding events decreased from 8.6% to 2.2% ($p = 0.022$), while overall adverse events reduced from 23.0% to 10.1% ($p < 0.01$). Medication adherence (MMAS-8) improved from 4.92 ± 1.51 to 6.25 ± 1.14 ($p < 0.001$), and patient satisfaction scores (DASS) improved from 59.2 ± 13.8 to 42.3 ± 11.2 ($p < 0.001$). Knowledge scores rose markedly from 3.79 ± 1.87 to 6.81 ± 1.78 ($p < 0.001$), with adequate knowledge increasing from 6.5% to 69.1%. No significant correlations were found between post-intervention TTR and adherence, satisfaction, or knowledge scores.

Conclusion: Implementation of a structured Anticoagulation Clinic significantly improved therapeutic control, reduced adverse events, and enhanced adherence, satisfaction, and patient knowledge. The findings support the integration of dedicated anticoagulation services within tertiary hospitals to optimize patient-centred outcomes and ensure safer long-term anticoagulation therapy.

Keywords:

Anticoagulation Clinic; Time in Therapeutic Range; Warfarin; Patient Satisfaction; Medication Adherence

Introduction

Anticoagulation therapy is a cornerstone in the prevention and management of thromboembolic disorders such as atrial fibrillation, deep vein thrombosis, pulmonary embolism, and mechanical heart valve replacement [1]. Worldwide, millions of patients receive long-term oral anticoagulation, predominantly with vitamin K antagonists (VKAs) such as warfarin. However, the safe and effective use of VKAs poses significant clinical challenges due to their narrow therapeutic index, interindividual variability in dose response, and multiple food and drug interactions [2]. It is have shown that nearly 30–50% of patients on warfarin therapy remain outside the therapeutic INR range at any given time, predisposing them to either bleeding or thrombotic complications [3,4].

To address these challenges, Anticoagulation Clinics (ACCs) have been developed as structured, multidisciplinary services designed to optimize anticoagulant management [5]. These clinics provide comprehensive care that includes regular INR monitoring, individualized dose adjustment, patient counseling, dietary guidance, and education about adherence and potential interactions [6]. Evidence from developed countries suggests that patients managed through dedicated ACCs achieve significantly higher Time in Therapeutic Range (TTR)—often exceeding 65–70%, compared to 40–50% among those receiving routine physician-based care [7,8]. Improved TTR has been directly associated with lower rates of major bleeding and thromboembolic events [8].

Beyond clinical safety and efficacy, modern anticoagulation management increasingly emphasizes patient-centred outcomes, including treatment satisfaction, health-related quality of life, and medication adherence. Interventions that focus on education, shared decision-making, and self-monitoring have been shown to enhance patient empowerment and treatment success [9]. For instance, a meta-analysis reported that structured

patient education interventions in anticoagulation clinics improved adherence by up to 20–25% and reduced INR variability [10].

In India, where anticoagulation therapy use is expanding due to the rising burden of cardiovascular and thromboembolic diseases, anticoagulant monitoring remains suboptimal. Fragmented care, inadequate INR testing facilities, and limited patient education are common challenges [11]. Studies from Asian tertiary care settings have reported that only 35–45% of patients achieve target INR levels consistently, underscoring the need for organized and continuous monitoring systems [12,13]. The establishment of dedicated Anticoagulation Clinics in tertiary care hospitals could thus bridge this gap by offering standardized follow-up, systematic dose management, and patient engagement strategies aimed at improving both clinical and patient-reported outcomes [14].

Hence, the present study aimed to evaluate the impact of Anticoagulation Clinic intervention on patient-centred outcomes—including therapeutic control, adverse events, medication adherence, and treatment satisfaction—among patients receiving oral anticoagulation therapy in a tertiary care hospital. Findings from this study may provide crucial evidence to support the integration of structured anticoagulation services within the hospital framework, ultimately promoting safer and more effective patient care.

Material and methods

Study Design and Setting

This prospective interventional study was conducted at the Anticoagulation Clinic (ACC) functioning under the Department of General Medicine at a tertiary care teaching hospital in northern India. The study was carried out over a period of 2 years, from June 2022 to May 2024. The ACC was established to provide structured, multidisciplinary management for patients receiving long-term oral anticoagulation therapy. The clinic operated once weekly and was

Journal of Dermatological Case Reports

staffed by a clinical pharmacologist, a consultant physician, and a trained nurse. Each patient visit included INR testing, dosage adjustment, and individualized counseling sessions.

Study Population

The study included adult patients of either gender aged 18 years and above who were receiving oral anticoagulant therapy with vitamin K antagonists, primarily warfarin, for established clinical indications such as atrial fibrillation, deep vein thrombosis, pulmonary embolism, or mechanical prosthetic heart valves. Patients who had been on stable anticoagulation for at least three months prior to enrolment and were willing to participate in regular follow-up visits were considered eligible. Exclusion criteria included patients receiving direct oral anticoagulants (DOACs), those with known hepatic or renal dysfunction, malignancy, pregnancy, or patients who were unlikely to comply with the scheduled follow-up.

A total of 156 patients fulfilling the eligibility criteria were initially enrolled after obtaining written informed consent. Of these, 139 participants completed the six-month follow-up period and were included in the final analysis; 17 patients were excluded due to loss to follow-up or incomplete data. The sample size was calculated using the formula for paired mean comparison, assuming a 20% expected improvement in mean Time in Therapeutic Range (TTR) after clinic intervention, with a standard deviation of 40%, a 95% confidence level, and 80% power. The calculated sample size of 98 was rounded off to 120 to account for attrition.

Study Procedure

At the time of enrolment (pre-intervention phase), baseline demographic details, indication for anticoagulation, duration of therapy, comorbidities, concomitant medications, and history of bleeding or thromboembolic events were recorded in a predesigned data collection form. Baseline INR values over the preceding three months were

retrieved from laboratory records to calculate the initial TTR using the Rosendaal linear interpolation method.

Following enrolment, patients were registered in the Anticoagulation Clinic for structured management. During each clinic visit, INR testing was performed using a standardized laboratory-based coagulometer, and results were reviewed by the clinical pharmacologist in consultation with the treating physician. Warfarin dosage was adjusted according to the hospital's standardized dosing nomogram, aiming to maintain INR within the therapeutic range of 2.0–3.0 for most indications and 2.5–3.5 for patients with mechanical heart valves.

Each participant received personalized counseling and education on the importance of adherence, recognition of bleeding or thrombotic symptoms, dietary restrictions, and avoidance of drug interactions. Educational sessions were conducted using visual aids and printed pamphlets in the local language. Reinforcement counseling was provided at every visit to address individual queries and barriers to adherence.

Patients were followed up for six months after enrolment. During this period, follow-up visits were scheduled every two to four weeks depending on INR stability. At the end of the study, post-intervention data on INR control, adverse events, medication adherence, and patient satisfaction were collected and compared with baseline values.

Outcome Measures

The primary outcome of the study was the change in therapeutic control of anticoagulation as measured by the Time in Therapeutic Range (TTR). Secondary outcomes included the incidence of bleeding and thromboembolic events, patient adherence to therapy, treatment satisfaction, and patient knowledge regarding anticoagulation. Adherence was assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8), which categorizes patients into high, medium, and low adherence groups. Treatment

Journal of Dermatological Case Reports

satisfaction was evaluated using the Duke Anticoagulation Satisfaction Scale (DASS), which includes domains assessing burden, positive psychological impact, and dissatisfaction related to anticoagulation therapy. Patient knowledge was assessed through a structured questionnaire developed for this study, comprising 10 items on medication purpose, INR monitoring, dietary precautions, and adverse effect recognition.

All questionnaires were administered in the local language by a trained investigator to ensure consistency. Clinical outcomes such as minor or major bleeding and thromboembolic complications were recorded at each visit. Bleeding events were classified according to the International Society on Thrombosis and Haemostasis (ISTH) criteria.

Data Collection and Management

All clinical and questionnaire data were entered into a predesigned case record form and later digitized into a secured database. INR values and dosing adjustments were verified from laboratory and clinic records. Data accuracy was ensured by double entry and cross-verification by two independent researchers. Each participant was assigned a unique identification number to maintain confidentiality.

Results

The study enrolled 139 patients with a mean age of 52.4 ± 13.6 years; males constituted the majority (82, 59.0%). The predominant indication for anticoagulation was atrial fibrillation (46.0%), followed by venous thromboembolism (23.0%) and mechanical heart valve replacement (20.1%). The mean duration of anticoagulant therapy was 14.2 ± 9.8 months. Hypertension (56.1%) and diabetes

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables such as TTR, MMAS-8, and DASS scores were expressed as mean \pm standard deviation (SD), while categorical variables were presented as frequencies and percentages. The normality of data distribution was checked using the Shapiro-Wilk test. Pre- and post-intervention comparisons were made using the paired t-test for normally distributed data and the Wilcoxon signed-rank test for non-parametric data. The chi-square test or Fisher's exact test was applied for categorical variables. A p-value less than 0.05 was considered statistically significant.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment. All procedures were conducted in accordance with the ethical standards of the Declaration of Helsinki. Confidentiality of patient data was strictly maintained, and participation was voluntary with the right to withdraw at any point without affecting their medical care.

mellitus (28.1%) were the most common comorbidities, while 18.7% of patients were concurrently receiving antiplatelet agents. At baseline, the mean INR was 2.7 ± 0.9 , and the mean TTR was relatively low at $41.6 \pm 18.1\%$, indicating suboptimal therapeutic control before clinic intervention (Table 1).

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants (n = 139).

Variable	Frequency (%) / Mean \pm SD
Age (years)	52.4 ± 13.6
Gender	
Male	82 (59.0%)

Journal of Dermatological Case Reports

Female	39 (41.0%)
Indication for anticoagulation	
Atrial fibrillation	64 (46.0%)
Mechanical valve	28 (20.1%)
Venous thromboembolism (DVT/PE)	32 (23.0%)
Other (eg. cardiomyopathy, others)	15 (10.9%)
Duration of anticoagulation (months)	14.2 ± 9.8
Comorbidities	
Hypertension	78 (56.1%)
Diabetes mellitus	39 (28.1%)
Coronary artery disease	21 (15.1%)
Concomitant antiplatelet use	26 (18.7%)
Baseline INR	2.7 ± 0.9
Baseline TTR (%)	41.6 ± 18.1

After six months of structured anticoagulation clinic follow-up, the mean TTR improved significantly from $41.63 \pm 18.09\%$ to $64.98 \pm 17.14\%$, reflecting a mean gain of $+23.35\%$ ($p < 0.001$). The proportion of patients achieving adequate therapeutic control ($TTR \geq 65\%$) increased from only 10.1% pre-intervention to 48.2% post-intervention ($p < 0.001$).

Similarly, the percentage of INR readings within the target range per patient rose from $45.2 \pm 20.4\%$ to $71.5 \pm 18.7\%$ ($p < 0.001$). These results demonstrate a substantial and statistically significant improvement in INR stability and overall therapeutic control due to the clinic-based intervention (Table 2).

Table 2. Therapeutic Control (TTR and INR Stability) Before and After Anticoagulation Clinic (Paired Comparison, $n = 139$).

Parameter	Pre-intervention	Post-intervention	p-value
	Frequency (%)/Mean ± SD	Frequency (%)/Mean ± SD	
TTR (%)	41.63 ± 18.09	64.98 ± 17.14	<0.001
Proportion achieving TTR $\geq 65\%$	14 (10.1%)	67 (48.2%)	<0.001
% of INR readings within target range (mean per patient)	45.2 ± 20.4	71.5 ± 18.7	<0.001

The incidence of adverse events showed a clear decline following the establishment of the Anticoagulation Clinic. Major bleeding events decreased from 12 (8.6%) to 3 (2.2%), which was statistically significant ($p = 0.022$). Minor bleeding episodes reduced from 17 (12.2%) to 10 (7.2%), although this reduction was not statistically significant ($p = 0.189$). Thromboembolic

complications, including stroke, DVT, or PE, decreased from 5 (3.6%) to 1 (0.7%) ($p = 0.125$). Overall, any adverse event (major, minor, or thromboembolic) fell from 23.0% to 10.1% ($p < 0.01$), reflecting improved clinical safety outcomes with structured monitoring and dose adjustment (Table 3).

Table 3. Incidence of Adverse Events Before and After Anticoagulation Clinic ($n = 139$, Paired).

Event	Pre-intervention	Post-intervention	p-value
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Journal of Dermatological Case Reports

	Frequency (%)		
Major bleeding (ISTH criteria)	12 (8.6%)	3 (2.2%)	0.022
Minor bleeding	17 (12.2%)	10 (7.2%)	0.189
Thromboembolic events (stroke/PE/DVT)	5 (3.6%)	1 (0.7%)	0.125
Any adverse event (major or minor or thromboembolic)	32 (23.0%)	14 (10.1%)	<0.01

There was a statistically significant improvement in patient adherence to anticoagulation therapy following the intervention. The mean MMAS-8 score increased from 4.92 ± 1.51 at baseline to 6.25 ± 1.14 after clinic participation ($p < 0.001$). The proportion of patients with high adherence (score = 8) rose from 1.4% to 9.4%, and those with medium adherence (scores 6–7) increased from 27.3% to 48.2%. Correspondingly, the percentage of low-adherence patients (<6) decreased markedly from 71.2% to 42.4%. A significant improvement in patient satisfaction was observed after participation in the Anticoagulation Clinic. The mean total DASS score decreased from 59.22 ± 13.84 to 42.26 ± 11.17 ($p < 0.001$), indicating greater satisfaction and reduced treatment burden. Subdomain analysis

showed significant reductions in the “burden” domain (22.4 ± 6.3 to 15.7 ± 5.1 ; $p < 0.001$) and “positive psychological impact” domain (18.6 ± 5.1 to 14.0 ± 4.2 ; $p < 0.001$). Knowledge about anticoagulation improved markedly following the clinic-based educational program. The mean knowledge score increased from 3.79 ± 1.87 to 6.81 ± 1.78 ($p < 0.001$). The proportion of participants demonstrating adequate knowledge (score ≥ 7) rose from 6.5% before intervention to 69.1% afterward. Patients showed the greatest improvement in understanding the purpose of INR testing, dietary precautions, and recognition of bleeding or thrombotic warning signs (Table 4).

Table 4. Medication Adherence, Patient Satisfaction and Patient Knowledge Before and After Anticoagulation Clinic ($n = 139$).

Metric	Pre-intervention	Post-intervention	p-value
	Frequency (%) / Mean \pm SD		
MMAS-8 score	4.92 ± 1.51	6.25 ± 1.14	<0.001
Adherence categories			
High adherence (score = 8)	2 (1.4%)	13 (9.4%)	0.006
Medium adherence (6–7)	38 (27.3%)	67 (48.2%)	
Low adherence (<6)	99 (71.2%)	59 (42.4%)	
DASS total score	59.22 ± 13.84	42.26 ± 11.17	<0.001
DASS domains			
Burden domain	22.4 ± 6.3	15.7 ± 5.1	<0.001
Positive psychological impact	18.6 ± 5.1	14.0 ± 4.2	<0.001
Knowledge score (out of 10)	3.79 ± 1.87	6.81 ± 1.78	<0.001
% with adequate knowledge (score ≥ 7)	9 (6.5%)	96 (69.1%)	<0.001

Exploratory correlation analysis between post-intervention TTR and patient-centred parameters revealed no statistically significant linear

relationships. Post-intervention TTR showed minimal correlation with adherence ($r = 0.011$, $p = 0.895$), satisfaction ($r = 0.103$, $p = 0.129$), or

Journal of Dermatological Case Reports

knowledge scores ($r = -0.095$, $p = 0.277$). Similarly, changes in TTR (Δ TTR) were not significantly correlated with corresponding changes in MMAS-8,

DASS, or knowledge scores ($p > 0.05$ for all) (Table 5).

Table 5. Correlation Between Therapeutic Control (TTR) and Patient-Centred Outcomes (Post-Intervention, $n = 139$).

Correlation pair	Pearson r	p-value
TTR vs MMAS-8 (post)	0.011	0.895
TTR vs DASS (post)	0.103	0.129
TTR vs Knowledge (post)	-0.095	0.277

Waist circumference emerged as the strongest independent predictor ($\beta=0.12$, $p=0.002$), followed by triglyceride levels ($\beta=0.015$, $p=0.021$) and BMI ($\beta=0.18$, $p=0.011$). HbA1c also demonstrated a modest but significant association ($\beta=0.25$, $p=0.023$).

HDL-C was inversely associated with HOMA-IR ($\beta=-0.05$, $p=0.034$). Age did not show any significant effect ($p=0.427$). The overall model explained 42% of the variance in HOMA-IR (Adjusted $R^2=0.42$, $p<0.001$) (Table 6).

Discussion

This study demonstrated that establishment of a structured Anticoagulation Clinic (AC Clinic) led to marked and statistically significant improvements in anticoagulation control, medication adherence, patient satisfaction, and knowledge, while reducing adverse events among patients receiving long-term oral anticoagulant therapy.

The mean Time in Therapeutic Range (TTR) improved substantially from $41.6 \pm 18.1\%$ at baseline to $65.0 \pm 17.1\%$ following intervention ($p < 0.001$). Nearly half (48.2%) of patients achieved a TTR $\geq 65\%$, compared to only 10.1% before clinic establishment. This 23-percentage-point rise in TTR signifies a robust enhancement in INR stability and treatment efficacy. Comparable improvements have been reported in Indian tertiary centers. Chebrolu et al., observed mean TTR improvement from 45% to 67% after structured follow-up, while Sasidharan et al., documented an increase from 42% to 70% within six months of clinic initiation [15,16]. Internationally, mean post-clinic TTRs of 65–75% are common benchmarks, as seen in Gateman et al., and McKenzie et al., [17,18]. Thus, the present

findings indicate that the local AC Clinic achieved therapeutic control comparable to global best practices.

A notable decline in major bleeding was observed—from 8.6% to 2.2% ($p = 0.022$)—and the overall incidence of any adverse event (major, minor, or thromboembolic) reduced from 23.0% to 10.1% ($p < 0.01$). These improvements mirror the reductions reported in other clinic-based programs. Alotaibi et al., found major bleeding decreased from 7% to 2%, while Urbonas et al., similarly showed 60% fewer serious events after structured monitoring [19,20]. Study by Little et al., and Wychowski et al., consistently demonstrate 40–60% lower major bleed and thromboembolic rates with managed anticoagulation services compared with usual care [21,22]. The observed decline in adverse outcomes in the current study can be attributed to more consistent INR monitoring, timely dose adjustments, and patient education—each a core component of the AC Clinic model.

Medication adherence, as measured by the MMAS-8 scale, improved significantly from 4.92 ± 1.51 to 6.25 ± 1.14 ($p < 0.001$), with high adherence rising

Journal of Dermatological Case Reports

from 1.4% to 9.4%. This trend parallels findings from Shambhu et al., where periodic counseling improved adherence by approximately 25% [23]. Similar gains have been noted internationally: Tadesse et al., observed adherence rates increasing from 50% to 80% following education-based clinic intervention [24]. In our study, improved adherence likely contributed indirectly to higher TTR and fewer complications, though direct correlation analyses did not reach statistical significance, suggesting multifactorial determinants.

The Duke Anticoagulation Satisfaction Scale (DASS) showed significant improvement, with total scores declining from 59.2 ± 13.8 to 42.3 ± 11.2 ($p < 0.001$), reflecting reduced treatment burden and greater confidence. Similar findings have been reported by Chebrolu et al., who noted a 30% improvement in satisfaction scores after integrating pharmacist counseling and telephonic follow-up [15]. Internationally, Alshaiban et al., demonstrated that structured clinics improve satisfaction through better continuity, communication, and perceived safety [25]. The improvement in our cohort underscores the psychosocial benefits of personalized care and consistent provider-patient interaction.

Patient knowledge regarding anticoagulation principles increased markedly, with mean scores rising from 3.79 ± 1.87 to 6.81 ± 1.78 ($p < 0.001$) and the proportion of adequately informed patients increasing from 6.5% to 69.1%. These gains are higher than those reported by Kotte et al., and Shrestha et al., where knowledge adequacy improved from 15% to 55% post-education [26,27]. Study by Samuel et al., showed similarly demonstrated that targeted education substantially enhances patient understanding, adherence, and safety awareness [28]. The larger improvement in our study likely reflects use of local-language educational materials and repeated interactive sessions—approaches known to improve retention in low- and middle-income settings.

Interestingly, post-intervention TTR did not correlate significantly with adherence ($r = 0.01$),

satisfaction ($r = 0.13$), or knowledge ($r = -0.09$). This lack of statistical association echoes observations from Tadesse et al., where improvements across multiple domains occurred independently [29]. Factors such as genetic variability, dietary vitamin K intake, comorbidities, and laboratory turnaround times may modulate INR stability beyond patient behavior alone.

Clinical and Public-Health Implications

Collectively, these results affirm that a dedicated AC Clinic model yields substantial clinical and educational benefits. The post-intervention mean TTR of ~65% places this center within internationally acceptable quality thresholds. Considering the baseline TTR (41.6%) was typical of routine Indian outpatient care, the observed 23-point improvement demonstrates the potential of structured clinics to bridge the “therapeutic gap” widely documented in South Asian settings. Implementation of such clinics, even at district-hospital level, could translate to fewer bleeding/thrombotic events, lower healthcare costs, and improved quality of life for anticoagulated patients.

Limitations

Major strengths include the paired pre-post design, comprehensive patient-centered outcomes, and use of validated instruments (Rosendaal TTR, MMAS-8, DASS). However, absence of a control group and single-center design may limit external generalizability. Follow-up duration, though adequate for stabilization, may not capture long-term sustainability. Future multicenter randomized studies incorporating pharmacogenetic and dietary profiling could yield deeper insight.

Conclusion

In summary, establishment of a structured Anticoagulation Clinic resulted in statistically and clinically significant improvement in TTR, adherence, satisfaction, and knowledge, with a

Journal of Dermatological Case Reports

concurrent reduction in bleeding and thromboembolic events. These outcomes are consistent with findings from leading Indian institutions and comparable to international standards, underscoring the critical role of dedicated anticoagulation services in optimizing therapeutic outcomes and patient safety.

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