

A Prospective Evaluation Of Recurrence Predictors And Point-Of-Care Monitoring Innovations For Deep Vein Thrombosis In A Tertiary Care Hospital

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Abstract

Background: Recurrent deep vein thrombosis (DVT) remains a major contributor to morbidity despite advances in anticoagulation therapy. Conventional risk stratification tools and laboratory biomarkers show limited ability to predict recurrence, while real-time surveillance strategies are rarely implemented in routine clinical care, particularly in resource-limited settings.

Objectives: To evaluate predictors of recurrent DVT, assess the impact of recurrence on disease-specific quality of life, examine adherence and bleeding outcomes, and determine the diagnostic performance of wearable-based point-of-care monitoring for early detection of recurrence.

Methods: This prospective observational cohort study enrolled 169 adults with objectively confirmed proximal lower-limb DVT at a Rvs tertiary care teaching hospital in Chittoor, South India. Participants were followed longitudinally with structured clinical assessments, biomarker evaluation, anticoagulant adherence monitoring, duplex ultrasonography, and wearable-based impedance alerts. Recurrence-free survival was analyzed using Kaplan–Meier methods. Multivariable Cox proportional hazards regression was used to identify independent predictors of recurrence. Diagnostic accuracy of wearable alerts was assessed using receiver operating characteristic (ROC) analysis.

Results: During follow-up, recurrent DVT occurred in 23.1% of patients. No baseline clinical or biochemical variable independently predicted recurrence on multivariable analysis, although Wells score and C-reactive protein showed borderline associations. Recurrence-free survival did not differ significantly across anticoagulant adherence categories (log-rank $p = 0.785$). Patients with recurrent DVT demonstrated markedly lower VEINES-QOL scores compared with those without recurrence (43.7 ± 6.5 vs. 72.0 ± 7.0). Wearable-based alerts showed excellent diagnostic performance for detecting recurrence (AUC 0.862; sensitivity 84.6%; specificity 87.7%).

Conclusions: In this real-world tertiary care cohort, traditional clinical variables and single baseline biomarkers had limited prognostic value for predicting DVT recurrence. Recurrent events were associated with substantial impairment in quality of life. Wearable-based monitoring demonstrated high diagnostic accuracy and may represent a practical adjunct for early detection and surveillance in high-risk patients.

Keywords: Deep vein thrombosis, recurrence, anticoagulant adherence, biomarkers, quality of life, wearable monitoring.

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1. Introduction

Deep vein thrombosis (DVT) is a major component of venous thromboembolism and represents a substantial cause of preventable morbidity worldwide. The annual incidence of DVT is estimated to exceed 1 per 1,000 individuals, with higher rates observed in hospitalized and elderly populations. Recurrent thrombotic events create major complications that include pulmonary

embolism and post-thrombotic syndrome, which produce extended functional disability and decreased life quality [1,2]. Indian tertiary care settings frequently encounter proximal and unprovoked DVT because these conditions have high recurrence rates that lead to dangerous outcomes [3].

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The development of new anticoagulant treatments has not decreased the incidence of DVT because studies show that patients experience DVT recurrence at a rate of 20 to 30 percent within five years after their first episode [4]. The established recurrence predictors include anterior DVT and proximal clot location together with ongoing medical risk factors, yet current clinical prediction systems and single baseline biomarker tests show limited ability to differentiate results in everyday medical settings [4,5]. The standard follow-up methods use clinical appointments and imaging tests to track patient progress, but these methods do not effectively detect recurring medical events that happen after patients leave the hospital.

The latest progress which digital health technologies achieved has created wearable point-of-care monitoring systems that maintain continuous physiological data collection which produces automatic alert systems. The systems which use machine learning algorithms have shown success in identifying early pathophysiological changes which occur in cardiovascular and thrombotic disorders according to research findings [6]. The available evidence which investigates how well wearable-based monitoring can diagnose recurrent DVT shows limited research particularly among developing countries which have restricted healthcare resources and low patient follow-up rates and limited access to imaging facilities [7].

DVT produces considerable patient-centered outcome harm which medical practitioners link to clinical recurrence. The occurrence of recurrent DVT leads to a major decline in disease-specific quality of life which results in higher healthcare needs and economic costs, yet these effects remain less documented in prospective Indian cohorts [8]. The existing research fails to establish a clear connection between anticoagulant adherence and bleeding problems and recurrence because it observes real-world tertiary care patients, which creates difficulties in applying current research findings to standard clinical environments [9].

The researchers conducted a prospective cohort study to assess how well wearable-based alerts detect recurring deep vein thrombosis in their role as diagnostic tools. The secondary objectives included assessing how often patients experienced recurrence and how long it took before they experienced their first recurrence and studying which clinical and biochemical variables at baseline predicted recurrence

and analyzing how well anticoagulant adherence predicted DVT recurrence and bleeding complications and studying how recurrence affected disease-specific quality of life. By integrating conventional clinical assessment with wearable-based monitoring, this study seeks to address key gaps in evidence regarding recurrence surveillance and patient-centered outcomes in a real-world tertiary care setting.

2. Methods

2.1 Study Design and Setting

This is a prospective, observational cohort study conducted at a Rvs tertiary care teaching hospital in Chittoor, South India. Consecutive eligible patients with index proximal lower-limb DVT will be enrolled and followed for 24 months from the date of diagnosis.

2.2 Study Population

The sample size was estimated assuming a 24-month DVT recurrence rate of 25%. With an alpha error of 0.05, power of 80%, and an anticipated hazard ratio of 2.0 for key predictors, a minimum of 169 patients was required to allow reliable multivariable Cox regression analysis.

2.3 Inclusion Criteria

Age \geq 18 years
Objectively confirmed lower-limb proximal DVT by duplex ultrasonography
Willingness to provide informed consent and comply with follow-up

2.4 Exclusion Criteria

Active malignancy at diagnosis
Life expectancy $<$ 6 months
Prior catheter-directed thrombolysis or surgical thrombectomy
Pregnancy
Known inherited bleeding disorders

2.5 Data Collection

Baseline assessments included demographic data, comorbidities, Wells score, anticoagulant regimen, laboratory parameters (D-dimer, C-reactive protein, fibrinogen), and ultrasound findings. Follow-up evaluations incorporated clinical review, anticoagulant adherence assessment, bleeding surveillance using ISTH criteria, VEINES-QOL questionnaire, duplex ultrasonography, and wearable-derived alerts.

2.6 Outcomes

The primary outcome was objectively confirmed recurrent DVT. Secondary outcomes included recurrence-free survival, bleeding events, quality-of-life scores, and diagnostic accuracy of wearable alerts.

2.7 Statistical Analysis

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Continuous variables are presented as mean \pm standard deviation, and categorical variables as frequencies and percentages. Kaplan–Meier survival analysis with log-rank testing was used to compare recurrence-free survival across adherence groups. Cox proportional hazards regression was employed to identify predictors of recurrence. Diagnostic performance of wearable alerts was assessed using ROC analysis. A two-sided p value < 0.05 was considered statistically significant.

3. RESULTS

This prospective cohort included 169 patients with objectively confirmed proximal lower-limb DVT, with a predominance of males (62.7%) and a relatively young mean age of 46 years, reflecting the demographic profile commonly observed in Indian tertiary care settings (Table 1A). The study found that 59.2% of patients developed DVT without any obvious cause which created a situation where doctors needed to handle medically underserved patients who had a higher chance of experiencing DVT again. The study found that 33.7% of participants had hypertension and 27.2% had diabetes mellitus while 39.1% of participants actively smoked which showing that the group had a high number of cardiovascular and metabolic risk factors.

The study showed that direct oral anticoagulants established themselves as the primary medication choice which doctors currently follow. The study found that almost 50% of patients maintained good compliance with their anticoagulation treatment. The study showed that 32.5% of patients showed moderate compliance while 19.5% showed poor compliance which created persistent difficulties for doctors who needed to treat patients for extended periods. The study found that 23.1% of patients developed DVT again during the follow-up period which matches the DVT recurrence rates found in high-risk clinical populations. The study found that patients experienced bleeding events at a rate of 8.9% which met ISTH criteria. This finding indicates that anticoagulant treatment provided safe results for this patient group.

Table 1A. Categorical Variables – Frequencies (n = 169)

Table A1. Sex Distribution (n = 169)

Category	n (%)
Male	106 (62.7)
Female	63 (37.3)

Table A2. Provoked Deep Vein Thrombosis

Category	n (%)
Yes	69 (40.8)
No	100 (59.2)

Table A3. History of Prior DVT

Category	n (%)
Yes	58 (34.3)
No	111 (65.7)

Table A4. Diabetes Mellitus

Category	n (%)
Yes	46 (27.2)
No	123 (72.8)

Table A5. Hypertension

Category	n (%)
Yes	57 (33.7)
No	112 (66.3)

Table A6. Smoking Status

Category	n (%)
Yes	66 (39.1)
No	103 (60.9)

Table A7. Type of Anticoagulant Used

Category	n (%)
DOAC	122 (72.2)
VKA	47 (27.8)

Table A8. Duration of Anticoagulation Therapy

Category	n (%)
3 months	41 (24.3)
6 months	83 (49.1)
12 months	45 (26.6)

Table A9. Anticoagulant Adherence

Category	n (%)
Good	83 (49.1)
Moderate	45 (26.6)
Poor	41 (24.3)

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Good	81 (47.9)
Moderate	55 (32.5)
Poor	33 (19.5)

Table A10. Recurrent Deep Vein Thrombosis

Category	n (%)
Yes	89 (32.1)
No	130 (46.9)

Table A11. Bleeding Events (ISTH Criteria)

Category	n (%)
Yes	16 (8.9)
No	154 (91.1)

D-dimer (ng/mL)	2346.37 ± 912.17	807–3979
CRP (mg/L)	16.94 ± 7.59	4.3–29.9
Fibrinogen (mg/dL)	511.11 ± 93.24	350–699
VEINES-QOL score	65.50 ± 13.80	30–84
Total cost (INR)	30,427 ± 17,219	15,033–79,536

Table 2. Predictors of Recurrent DVT

Table 2 shows the Multivariable Cox proportional hazards regression analysis demonstrated that none of the evaluated baseline clinical or biochemical variables

independently predicted recurrent DVT. Age, body mass index, duration of anticoagulation therapy, adherence score, and baseline coagulation biomarkers did not show statistically significant associations with recurrence risk.

The Wells score showed a borderline relationship with recurrence which carried an adjusted hazard ratio of 1.52 and achieved a p value of 0.065. The elevated base clinical risk resulted in higher recurrence rates while this relationship did not reach the standard threshold for statistical significance. The study found that C-reactive protein showed a borderline relationship with inverse association which achieved a p value of 0.050. The research shows that inflammation interacts with treatment response and the timing of recurrence which brings about this effect instead of showing a true protective benefit.

Table 2. Multivariable Cox Regression – Final Model

Variable	Adjusted HR (95% CI)	p-value
Age	1.01 (0.98–1.04)	0.53
BMI	0.92 (0.81–1.05)	0.21
Wells score	1.52 (0.97–2.37)	0.065

The study population had a mean age of 46.03 ± 17.01 years (range 18–74), indicating that DVT affected a relatively young cohort. The average body mass index of the study population showed a value of 26.99 which had a standard deviation of 3.30 kg/m² and this measurement placed most patients into the overweight category while they showed a substantial metabolic risk burden. The first laboratory tests revealed D-dimer levels (2346.37 ± 912.17 ng/mL) and C-reactive protein levels (16.94 ± 7.59 mg/L) and fibrinogen levels (511.11 ± 93.24 mg/dL) which showed active thrombosis together with an underlying state of inflammation and hypercoagulability. The basic VEINESQOL score at first assessment showed a value of 65.50 with a standard deviation of 13.80 which demonstrated that patients with this condition had moderate disease-specific quality of life impairment while their individual scores showed wide-ranging differences. The economic burden of care was considerable, with a mean total treatment cost of INR 30,427 ± 17,219, highlighting the financial impact of DVT management in a tertiary care setting as shown Table 1B.

Table 1B. Continuous Variables (n = 169)

Variable	Mean ± SD	Min–Max
Age (years)	46.03 ± 17.01	18–74
Body Mass Index (kg/m ²)	26.99 ± 3.30	19.6–37.9

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CRP (mg/L)	0.95 (0.90–1.00)	0.050
D-dimer	1.00 (1.00–1.00)	0.99
Fibrinogen	1.00 (0.99–1.00)	0.62
Duration of therapy	0.99 (0.88–1.11)	0.83
Adherence (numeric)	1.04 (0.61–1.79)	0.88

Recurrence-Free Survival and Anticoagulant Adherence

Kaplan–Meier survival analysis demonstrated no statistically significant difference in recurrence-free survival across adherence categories (log-rank $p = 0.785$) as shown in Table 3. Although patients with poor adherence experienced a shorter mean and median time to recurrence compared with those with good or moderate adherence, the observed differences did not reach statistical significance (fig 1).

Table 3. Recurrence-Free Time by Anticoagulant Adherence

Adherence group	N	Mean population time to recurrence (months)	Median time to recurrence (months)
Good adherence	81	10.1	6.0
Moderate adherence	55	10.1	6.0
Poor adherence	33	7.5	4.0

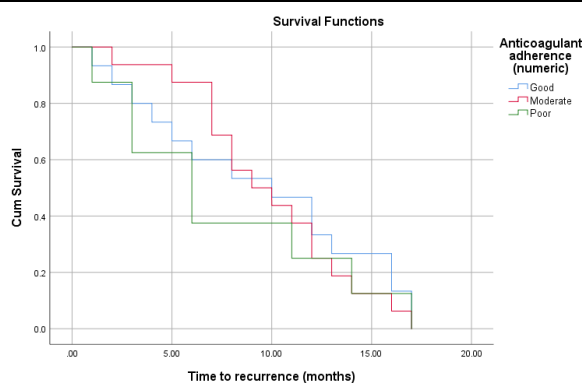


Fig 1: Kaplan–Meier curves showing time to recurrent deep vein thrombosis stratified by anticoagulant adherence.

Association Between Adherence and Recurrent DVT

The study found that patients with moderate adherence (29.1%) and poor adherence (24.2%) showed higher recurrence rates than those who maintained good adherence (18.5%) according to the categorical recurrence rate analysis. However, these differences were not statistically significant ($p = 0.351$) (Table 4).

Table 4. Adherence vs Recurrence

Adherence	Recurrence Yes n (%)	Recurrence No n (%)	p-value
Good	15 (18.5)	66 (81.5)	0.351
Moderate	16 (29.1)	39 (70.9)	
Poor	8 (24.2)	25 (75.8)	

Adherence and Bleeding Events

Bleeding complications were infrequent across all adherence categories and did not differ significantly between groups ($p = 0.779$) (Table 5). This indicates that higher adherence to anticoagulation was not associated with an increased bleeding risk in this

Adherence	Bleeding Yes n (%)	Bleeding No n (%)	p-value
Good	6 (7.4)	75 (92.6)	0.779
Moderate	6 (10.9)	49 (89.1)	
Poor	3 (9.1)	30 (90.9)	

Prognostic Value of Biomarkers

Table 6 shows the baseline coagulation and inflammatory biomarkers showed no significant prognostic value for predicting recurrent DVT in this cohort. On Cox proportional hazards regression analysis, D-dimer levels were not associated with recurrence risk (adjusted HR 1.000, $p = 0.812$), indicating that incremental increases in baseline D-dimer did not translate into higher recurrence hazard. Similarly, baseline C-reactive protein levels demonstrated no statistically significant association with recurrence (adjusted HR 0.976, 95% CI 0.937–

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1.017; $p = 0.246$), suggesting limited predictive utility of inflammatory burden measured at diagnosis. Fibrinogen levels also failed to predict recurrence (adjusted HR 1.000, 95% CI 0.997–1.004; $p = 0.851$).

Table 6. Prognostic Value of Baseline Biomarkers for Recurrent DVT

Cox proportional hazards regression (n = 169)

Biomarker (baseline)	Adjusted Hazard Ratio (HR)
D-dimer (per ng/mL increase)	1.000
C-reactive protein (per mg/L increase)	0.976
Fibrinogen (per mg/dL increase)	1.000

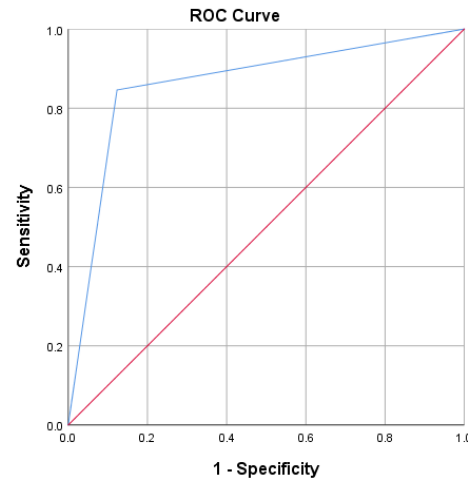


FIG 2: Receiver operating characteristic (ROC) curve demonstrating the diagnostic performance of wearable-based alerts for detection of recurrent deep vein thrombosis.

Quality of Life and Recurrence

Patients who experienced recurrent DVT reported substantially poorer disease-specific quality of life compared with those without recurrence. The mean VEINES-QOL score was markedly lower in patients with recurrence (43.72 ± 6.48) than in those who remained recurrence-free (72.03 ± 7.02), indicating significant worsening of symptoms, functional limitations, and overall well-being following recurrence (Table 7).

Table 7. VEINES-QOL by Recurrence Status

Recurrence	Mean ± SD
No	72.03 ± 7.02
Yes	43.72 ± 6.48

Diagnostic Performance of Wearable Alerts

Wearable-based alerts demonstrated excellent diagnostic performance for the detection of recurrent DVT. The area under the ROC curve was 0.862 (95% CI: 0.788–0.935), indicating strong discriminative ability to differentiate patients with and without recurrence (fig 2). The high sensitivity of 84.6% suggests that the majority of recurrent events were correctly identified, while the specificity of 87.7% indicates a low rate of false-positive alerts. Together, these findings support the potential clinical utility of wearable alerts as an effective point-of-care monitoring tool for early identification of recurrent DVT in routine practice (table 8).

Table 8. ROC Analysis for Wearable Alerts

Metric	Value
AUC	0.862 (95% CI: 0.788–0.935)
Sensitivity	84.6%
Specificity	87.7%

Discussion

The study found that approximately one-quarter of patients developed recurrent DVT in a group of patients who had proximal lower-limb DVT treated at a tertiary care hospital, which showed that current anticoagulant treatments still fail to prevent DVT recurrence. The recurrence rate which the study found matches the recurrence rates which large observational studies and registry-based research report for high-risk groups throughout their long-term observation periods [10,11]. The present study group developed their unprovoked DVT because this type of DVT creates more permanent thrombotic risk than other types of DVT.

The current study found that no baseline clinical variable predicted recurrent DVT while previous research showed that age and obesity and previous thrombotic events functioned as key risk factors for DVT recurrence [12,13]. The Wells score showed borderline association to clinical aggregation because

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it forecasts DVT recurrence but its predictive power dies at long-term DVT prediction through existing clinical assessment methods. Multivariable models in prospective cohorts showed that they could only partially forecast recurrence because their prediction results exhibited poor performance for normal medical operations [14].

The study found that D-dimer and C-reactive protein and fibrinogen measurements from the start of the study showed no connection to DVT recurrence. The findings support previous research which shows that single biomarker tests conducted during acute thrombosis only provide limited value for predicting future DVT cases according to open-access cohort studies which studied this relationship. [15,16]. Serial or post-treatment biomarker assessment has been proposed as a more informative approach; however, its feasibility in resource-limited settings remains uncertain. The present findings reinforce the concept that static laboratory values at diagnosis are insufficient for durable risk stratification.

Although recurrence rates were numerically higher among patients with moderate and poor anticoagulant adherence, the association did not reach statistical significance. Real-world studies showed similar results because adherence was not sufficient to explain the observed recurrence patterns which were determined by biological and anatomical and inflammatory causes that existed beneath the surface [17]. The study found that bleeding events occurred infrequently and showed no significant differences between adherence groups which supports the findings of open-access observational studies that show modern anticoagulant regimens have safe bleeding risks when doctors prescribe them correctly [18]. The research results demonstrate that sustained anticoagulation treatment remains safe while the research needs additional strategies which should be developed to monitor adherence beyond existing methods.

The study discovered that patients who experienced recurrent DVT showed significant decline in their disease-specific quality of life. The VEINES-QOL scores showed substantial differences between recurrence and nonrecurrence groups which matched earlier prospective studies that proved recurrent thrombotic events lead to ongoing symptoms and functional limitations and psychosocial distress [19,20]. The results show that recurrence functions as a clinical endpoint which affects long-term patient

outcomes therefore preventive methods and early detection systems need to be implemented.

The wearable-based alert system showed exceptional diagnostic performance through its ability to achieve high AUC results while maintaining equal detection rates for both true positive and false positive cases. The results of the study establish a positive comparison with current research from open-access digital health studies which examine the effectiveness of remote monitoring systems that track vascular and thrombotic disorders [21,22]. Continuous wearable monitoring provides better early detection of physiological changes which indicate disease recurrence compared to traditional follow-up methods that use scheduled visits and patient-reported symptoms. The technologies support main medical procedures in situations where standard imaging tests need extensive resources because they alert clinicians to conduct essential verification tests at proper times.

The study results demonstrate that traditional baseline predictors and biomarkers provide minimal predictive power for DVT recurrence while repeated events create a serious detrimental effect on life quality. The ability of wearable monitoring systems to deliver precise diagnostic results demonstrates how dynamic real-time monitoring has become the preferred method for detecting recurrences. The implementation of these technologies in tertiary care facilities will enhance results that focus on patient needs while creating more efficient treatment patterns which will benefit low- and middle-income countries.

Strengths and Limitations

Strengths of this study include its prospective design, complete follow-up, integration of patient-reported outcomes, and real-world evaluation of point-of-care monitoring. Limitations include the single-center design, modest sample size, and reliance on baseline biomarker measurements rather than serial assessment.

Future Directions

Future studies should focus on multicenter, larger-scale prospective cohorts to validate the diagnostic utility and generalizability of wearable-based monitoring for recurrent deep vein thrombosis across diverse populations. Longitudinal assessment incorporating serial biomarker measurements, imaging findings, and continuous digital health data may improve risk stratification beyond single baseline evaluations. Randomized controlled trials are warranted to

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determine whether integration of wearable surveillance into routine care can reduce recurrence, improve quality of life, and optimize healthcare utilization. In addition, cost-effectiveness analyses and implementation research in resource-limited settings will be essential to support broader clinical adoption.

Conclusion

Recurrent deep vein thrombosis remained common in this tertiary care cohort and was not reliably predicted by baseline clinical variables or single biomarker measurements. Recurrence was associated with substantial impairment in disease-specific quality of life. Wearable-based point-of-care monitoring demonstrated high diagnostic accuracy for detecting recurrent events, supporting its role as a useful adjunct to conventional follow-up for early identification of recurrence in routine clinical practice.

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