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Management and 1-year outcomes of first-episode venous thromboembolism in patients over 75: a prospective observational study

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Abstract

Background

Venous thromboembolism (VTE) is highly prevalent in the elderly, yet optimal anticoagulation strategies beyond the acute phase remain uncertain, particularly due to the high risk of bleeding. This study aimed to evaluate real-world anticoagulant management and clinical outcomes in elderly patients after a first episode of VTE.

Methods

We conducted a prospective observational study including patients aged > 75 years with a first VTE event who completed at least 3 months of anticoagulation. Patients were followed for 12 months after the acute phase. Outcomes included VTE recurrence, bleeding events, all-cause mortality, and a composite endpoint of these events. Patients were stratified according to continuation or discontinuation of anticoagulation.

Results

A total of 177 patients (mean age 83 years, 63.3% female) were included. At 3 months, 69.5% of patients remained on anticoagulation, decreasing to 54% at 12 months. VTE recurrence occurred in 3 patients (1.7%), all in the continuation group. 13 CRNMB events (7.3%) and nine deaths (5.1%) were recorded. Discontinuation of anticoagulation was associated with a significantly lower risk of the composite outcome (RR 0.24, 95% CI 0.08–0.68) and CRNMB (RR 0.21, 95% CI 0.01–0.88), without a significant increase in VTE recurrence or mortality. Recurrences were observed only in patients with active cancer.

Conclusion

In this elderly cohort, discontinuation of anticoagulation after the acute phase was associated with reduced bleeding and composite outcomes, without an increase in thrombotic risk. These findings support an individualized approach to anticoagulation in older patients, although larger studies are needed to confirm optimal treatment duration and dosing strategies.

Background

Venous thromboembolism (VTE) is the third most common cardiovascular disease and represents a condition of particular relevance in the elderly population, with an incidence reaching up to 500 cases per 100,000 person-years among individuals aged over 75–80 years [1–2]. Anticoagulant management after a first episode of VTE is supported by robust evidence during the initial 3–6 months [3], with current recommendations favoring the use of direct oral anticoagulants (DOACs) [4], including dose reduction according to specific criteria such as renal impairment, low body weight, or age > 80 years [5]. Therapeutic decisions are generally guided by discontinuation of anticoagulation in cases of VTE provoked by a major transient risk factor and continuation of therapy in unprovoked VTE or in events

associated with minor or persistent risk factors (e.g., active cancer) [6]. However, within the risk–benefit balance, bleeding risk is more difficult to predict than the risk of VTE recurrence, yet it is of comparable clinical relevance, particularly in the elderly [7–8]. Patients of advanced age, who are often frail and multimorbid, represent a significant therapeutic challenge due to the coexistence of multiple age-related conditions [9]. Notably, patients aged > 75 years remain underrepresented in the literature, both in pivotal DOAC registration trials and in studies evaluating extended anticoagulation for VTE, accounting for only approximately 11–13% of the total enrolled population [10]. In the setting of cancer-associated thrombosis, extended anticoagulation beyond six months is generally recommended in patients with active malignancy, such as those with metastatic disease or ongoing anticancer therapy. However, the strength of this recommendation remains limited due to the scarcity of evidence from randomized clinical trials [11–12]. Therefore, the aim of this study was to describe real-world anticoagulant management in patients aged ≥ 75 years after a first episode of VTE, based on routine outpatient clinical practice.

Methods

This prospective, non-interventional, single-center observational study evaluated patients aged > 75 years referred to the outpatient clinics of the Angiology Unit of Padua (tertiary-level university hospital) who experienced a first episode of VTE and had completed anticoagulant therapy for the acute phase (first 3 months). Baseline characteristics were collected for all patients, including comorbidities, cardiovascular risk factors, medication history, and frailty assessment. Patients with active cancer and an estimated life expectancy > 6 months were included. Study participants subsequently underwent clinical follow-up for 12 months after completion of the acute phase. Patients were excluded in cases of recurrent VTE, hospitalization for other reasons, refusal to provide informed consent, life expectancy < 6 months, the presence of another indication for anticoagulation, or the need for inferior vena cava filter placement. Each thrombotic event was classified according to the site of involvement as pulmonary embolism (PE) or deep vein thrombosis (DVT) of the lower limbs (proximal or distal). VTE events were further categorized as provoked or unprovoked based on the presence of major transient risk factors. Patients were followed for 12 months from the index event. Follow-up visits were scheduled at 3, 6, and 12 months. At each visit, patients underwent clinical evaluation and venous duplex ultrasonography of the affected venous district. The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Padua University Hospital (cod. URC: AOP 3250 – cod CET-ACEV 5906/AO/24). All patients provided written informed consent.

Outcomes

The primary objective was to assess VTE recurrence, bleeding events and all-cause mortality within 12 months after the acute phase, as well as a composite endpoint including these outcomes. Recurrent VTE was defined as a new, objectively confirmed episode of DVT or PE occurring after the index event, based on imaging criteria (compression ultrasonography, computed tomography pulmonary angiography, or ventilation–perfusion scan). Major bleeding was defined according to the criteria of the International

Society on Thrombosis and Haemostasis as bleeding that was fatal, occurred in a critical site and/or was associated with a decrease in hemoglobin level of ≥ 2 g/dL or required transfusion of ≥ 2 units of packed red blood cells. Clinically relevant non-major bleeding (CRNMB) was defined as any overt bleeding not meeting the criteria for major bleeding but requiring medical intervention. Secondary objectives included evaluation of therapeutic strategies adopted in clinical practice, assessment of bleeding risk factors, and overall mortality at 18 months from the index event. For outcome assessment, the cohort was stratified according to continuation or discontinuation of anticoagulation. Discontinuation was recorded at 3, 6, or 12 months after the acute event. Among patients who continued therapy, those receiving full-dose anticoagulation were distinguished from those receiving reduced-dose regimens.

Statistical Analysis Descriptive statistics were used to summarize baseline demographic and clinical characteristics. Continuous variables are reported as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate based on data distribution. Categorical variables are presented as counts and percentages. Comparisons between groups (continuation vs discontinuation of anticoagulation) were performed using the Student's t-test or Mann–Whitney U test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables, as appropriate. The association between anticoagulation strategy and clinical outcomes was assessed by calculating relative risks (RRs) with corresponding 95% confidence intervals (CIs). RRs were derived from contingency tables comparing event rates between groups. In the presence of zero events in one group, a continuity correction was applied. All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant. Statistical analyses were performed using SPSS Statistics (version 27.0, IBM Corp., Armonk, NY, USA).

Results

A total of 275 patients aged > 75 years with a first episode of VTE were enrolled between July 2022 and December 2024. Of these, 46 were excluded due to recurrent VTE and 11 due to hospitalization for other reasons, resulting in a final cohort of 218 patients. At the 3-month evaluation, 41 patients were excluded as they no longer met inclusion criteria; therefore, 177 patients were included in the follow-up analysis. Baseline characteristics are summarized in Table 1. Patients were stratified by anticoagulation status (Stop AC vs AC), and baseline characteristics were well balanced between groups.. The cohort consisted predominantly of women (63.3%), with a mean age of 83 years. The most common comorbidities were arterial hypertension, dyslipidemia, peripheral artery disease, and chronic kidney disease. The index event was PE in 22 patients (12.4%) and DVT in 155 (87.6%), of which 59.2% were proximal and 40.8% distal (Table 2). Active cancer was present in 41.7% of patients. Provoked VTE accounted for 67.8% of cases, whereas 32.2% were unprovoked. During the acute phase, 86% of patients were treated with DOAC (Table 3). Among them, 87 patients (49.1%) continued DOAC therapy (full or reduced dose), whereas 90 patients (50.9%) discontinued treatment. After 12 months of follow-up, anemia was significantly more frequent among patients who discontinued anticoagulation. During follow-up, VTE recurrence occurred in 3 patients (1.7%). A total of 13 bleeding events occurred: no major bleeding, 13

clinically relevant non-major bleeding (CRNMB) events (7.3%) were recorded. Nine deaths unrelated to VTE (5.1%) were observed (Table 4). Among patients who continued anticoagulation, 3 VTE recurrences occurred, whereas no recurrences were observed in those who discontinued therapy. Additionally, 10 CRNMB events (relative risk [RR] 0.21, 95% confidence interval [CI] 0.01–0.88) and 6 deaths were recorded in the continuation group. The composite outcome showed a significant reduction in the discontinuation group (RR 0.24, 95% CI 0.08–0.68). Regarding treatment patterns, 69.5% of patients remained on anticoagulation at 3 months, decreasing to 54% at 12 months. Among those continuing therapy, only 50% were on full-dose treatment at 3 months. At 6 months, more than 70% had transitioned to reduced-dose regimens. At the final follow-up, only 21% remained on full-dose therapy, whereas 77% were receiving reduced-dose DOACs, either according to label recommendations or off-label.

Table 1
Baseline characteristics of the study population

Age Y, mean ± SD	**Total (N = 177)**	**Stop AC (N = 87)**	**AC (N = 90)**	***p-value***
	83 ± 1	**83 ± 1**	**77 ± 1**	**0.31**
Male	65 (36.7)	33 (37.6)	33 (36.3)	0.26
Hypertension	123 (69.5)	63 (72.4)	60 (66.7)	0.26
Dyslipidemia	94 (53.1)	51 (58.6)	43 (47.8)	0.18
Peripheral arterial disease	55 (31.1)	31 (35.6)	24 (26.7)	0.41
Diabetes	25 (14.1)	12 (13.8)	13 (14.4)	0.46
Chronic ischemic heart disease	18 (10.2)	14 (16.1)	4 (4.4)	0.12
Previous stroke	14 (7.9)	10 (11.5)	4 (4.4)	0.46
Chronic kidney disease	45 (25.4)	25 (28.7)	20 (22.2)	0.22
Anemia < 10 g/L	19 (10.7)	26 (29.7)	5 (5.6)	0.02
Liver disease (AST/ALT > 4)	4 (2.2)	3 (3.4)	1 (1.1)	0.3

Table 2
Classification of VTE Events and Provoking Factors (assessed at the end of the acute phase)

VTE type	**Total (N = 177)**	**AC stop (N = 75)**	**AC (N = 102)**
	DVT: 155 (87.6)	**DVT: 71 (94.7)**	**DVT: 84 (82.4)**
	PE/DVT: 22 (12.4)	**PE/DVT: 4 (5.3)**	**PE/DVT: 18 (17.6)**
Provoked VTE	120 (67.8)	54 (72.0)	66 (64.7)
Post trauma	46 (38.3)	22 (40.7)	24 (36.4)
Post surgery	31 (25.8)	15 (27.8)	16 (24.2)
Acute infection	27 (22.5)	12 (22.2)	15 (14.7)
CRT	10 (8.3)	6 (8.0)	4 (3.9)
Active cancer	50 (41.7)	20 (26.6)	31 (47.0)
Gastrointestinal	12 (29.3)	2 (20.0)	10 (32.3)
Lung	12 (29.3)	3 (30.0)	9 (29.0)
Hematological	10 (24.4)	2 (20.0)	8 (25.8)
Breast	7 (17.1)	1 (10.0)	6 (19.4)
Other	2 (< 5%)	1 (10.0)	2 (7.0)

Abbreviation: AC anticoagulation, DVT deep vein thrombosis, PE pulmonary embolism, CRT catheter related thrombosis

Table 3
Treatment Modality, Pharmacological Agent, and Dosage

Anticoagulant	**Overall N (%)**	**Stop AC N (%)**	**AC N (%)**
DOAC (overall)	153 (86.4)	66 (75.9)	87 (96.7)
Apixaban	54 (30.5)	21 (24.1)	33 (36.7)
└ *Reduced dose*	27 (50)	10 (47.6)	17 (51.5)
Edoxaban	71 (40.1)	34 (39.1)	37 (41.1)
└ *Reduced dose*	9 (12.7)	4 (11.8)	5 (13.5)
Rivaroxaban	32 (18.1)	12 (13.8)	20 (22.2)
└ *Reduced dose*	4 (12.5)	1 (8.3)	2 (15.0)
LMWH	24 (13.6)	9 (10.3)	15 (16.7)

Abbreviation: DOAC direct oral anticoagulation, AC anticoagulation, LMWH low molecular weight heparin

Table 4
Clinical outcomes according to anticoagulation strategy

Outcome	Total (%)	Stop AC n/N (%)	AC n/N (%)	RR (95% CI)	*p-value*
Composite outcome	23/177 (13.0)	4/87 (4.6)	17/90 (18.9)	0.24 (0.08–0.68)	0.006
VTE recurrence	3/177 (1.7)	0/87 (0.0)	3/90 (3.3)	-	-
Bleeding (Major and CRNMB)	13/177 (7.3)	2/87 (2.3)	10/90 (11.1)	0.21 (0.01–0.88)	0.03
Death	9/177 (5.1)	2/87 (2.3)	6/90 (6.7)	0.33 (0.06–1.81)	0.28

Abbreviation: AC anticoagulation, RR relative risk, VTE venous thromboembolism, CRNMB clinical relevant non major bleeding

Discussion

In this prospective cohort of elderly patients (aged > 75 years) with a first episode of VTE, our findings provide relevant insights into the real-world management of anticoagulation beyond the acute phase and its clinical implications.The main results of the study indicate that discontinuation of anticoagulation after the initial treatment phase was common; furthermore, stopping DOAC therapy was associated with a significantly lower risk of the composite outcome and clinically relevant non-major bleeding, without a significant increase in VTE recurrence or mortality, although the number of events was low. The management of anticoagulation in elderly patients remains particularly challenging due to the delicate balance between thrombotic and bleeding risks [13–14]. In our cohort, nearly half of the patients discontinued DOAC therapy after the acute phase, reflecting a pragmatic, individualized approach that likely takes into account frailty, comorbidities, and bleeding risk. This is further supported by the observation that anemia was more frequent among patients who discontinued anticoagulation at 12 months, suggesting that clinical deterioration or perceived higher bleeding risk may have influenced therapeutic decisions. One of the most relevant findings is the significantly lower risk of the composite outcome among patients who discontinued DOAC therapy (RR 0.24, 95% CI 0.08–0.68). This reduction appears to be primarily driven by a lower incidence of bleeding events, as also reflected by the significantly reduced risk of CRNMB (RR 0.21). These data highlight the substantial impact of bleeding complications in this population and reinforce the importance of bleeding risk assessment in long-term management strategies [8–15]. Importantly, discontinuation of anticoagulation was not associated with a statistically significant increase in VTE recurrence. Although all recurrence events occurred in the group that continued DOAC therapy, this finding should be interpreted with caution due to the very low number of events and the resulting wide confidence intervals. It is plausible that selection bias played a role, with higher-risk patients being preferentially maintained on anticoagulation. Notably, all cases of VTE recurrence in our cohort occurred among patients with active malignancy undergoing chemotherapy

or those requiring surgical intervention. These clinical scenarios often necessitate interruptions of anticoagulant therapy in order to reduce periprocedural bleeding or to manage chemotherapy-induced thrombocytopenia [16]. Such mandatory treatment gaps likely compromised the maintenance of a stable therapeutic range, potentially explaining why recurrences were confined to this specific high-risk subgroup. These findings underscore that in the 'oldest-old' population, the presence of active cancer and the need for invasive procedures represent major drivers of thrombotic failure [12]. Therefore, the apparent lack of increased thrombotic risk in the discontinuation group should not be overinterpreted. Mortality rates were similar between groups, with no signal suggesting harm associated with discontinuation of anticoagulation. All deaths were unrelated to VTE, underscoring the competing risk of non-thrombotic causes in this elderly population [17]. This aspect is particularly relevant, as it may attenuate the net clinical benefit of prolonged anticoagulation. Another key observation of our study is the progressive shift toward reduced-dose DOAC regimens over time. While approximately half of the patients were on full-dose anticoagulation at 3 months, the majority transitioned to reduced doses by 6 and 12 months, with only 21% remaining on full-dose therapy at the final follow-up. This trend reflects current clinical practice, where dose reduction is frequently adopted to mitigate bleeding risk, even beyond formal label indications [18–19]. However, the clinical impact of such strategies remains insufficiently supported by robust evidence, particularly in very elderly populations [20]. Our findings are consistent with the growing body of literature suggesting that shorter or less intensive anticoagulation strategies may be appropriate in selected high-risk populations, especially when bleeding risk outweighs thrombotic risk [7–9–17]. However, randomized controlled trials specifically addressing anticoagulation duration and dosing in elderly patients are still lacking. Several limitations should be acknowledged. First, the observational design of the study introduces the possibility of residual confounding and selection bias. Second, the relatively small sample size and low number of events limit statistical power, particularly for thrombotic outcomes. Third, the lack of time-to-event analysis in the current evaluation may underestimate differences between groups. Finally, treatment decisions were not standardized and were left to physician discretion, reflecting real-world practice but reducing internal validity.

In conclusion, in this cohort of elderly patients with VTE, discontinuation of DOAC therapy after the acute phase was associated with a lower risk of bleeding and composite outcomes, without a clear increase in thrombotic events or mortality. These findings support a tailored approach to anticoagulation in older patients, emphasizing individualized risk assessment. Further randomized studies are needed to better define the optimal duration and dosing of anticoagulant therapy in this vulnerable population.

Declarations

Author Contribution

D.C. and G.T. conceived the studyD.C., G.T. and A.P. developed the methodology. D.C., G.T, F.C and F. B performed the statistical analysis. D.C. wrote the original manuscript draft. P.P and G.A. supervised the project"

Data Availability

Davide Ceccato reports was provided by University of Padua. Davide Ceccato reports a relationship with University of Padua that includes: employment and non-financial support. Davide Ceccato has patent licensed to cod. URC: AOP 3250 – cod CET-ACEV 5906/AO/24. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

AUTHOR CONTRIBUTIONS D.C. conceptualized and conducted the statistical analysis and wrote the original draft. D.C. and F.C provided support in the statistical analysis by independently repeating the primary analysis. G.T. performed the literature search. F.B. and A.P. intervened to resolve any discordance regarding study eligibility. G.T, A.P. F.B. and P.P. critically reviewed the manuscript. D.C and G.T. was responsible for resource provision and critically reviewed the manuscript. D.C. supported conceptualization, was responsible for supervision, and critically reviewed the manuscript.

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