Original Article

DOI: 10.4274/haseki.galenos.2025.21931
Med Bull Haseki 2025;63:33-39

Evaluation of Venous Thromboembolism in Multiple Myeloma and Its Impact on Mortality

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Abstract

Aim: Thromboembolism in multiple myeloma (MM) is a common complication and its relationship with increased mortality is unclear. We aimed to reveal the incidence of venous thromboembolism (VTE) in the first year of treatment for newly diagnosed MM patients, its effects on mortality, and to evaluate predictive models of VTE in our patients.

Methods: This study was conducted as a retrospective cohort study. A total of 150 consecutive adult patients who were newly diagnosed with and treated for MM were included in the study, conducted at our university hospital from January 2013 to June 2022. The study gathered information on patients' age, gender, type of disease, history of blood clots, surgeries and fractures, body mass index, lab and genetic test results at diagnosis before starting treatment for MM, initial treatment given, use of central venous catheters, blood clot events in the first year of treatment, when these events happened, how they were managed, outcomes of the blood clot events, whether they received preventive treatment for blood clots related to MM or other reasons, their status regarding autologous hematopoietic stem cell transplantation, and their survival.

Results: The incidence of VTE was 8% in the first year of treatment. The median VTE occurrence was 60 days. The mortality rate in the entire patient group was 48%. Median survival was 72 months in patients with a VTE event, while it was 58 months in patients without a VTE event. This difference was not found to be statistically significant (p=0.357). Being in the high-risk group of the IMPEDE VTE score was a statistically significant predictor of a VTE event (p=0.027) in univariate logistic regression analysis.

Conclusion: We showed that VTE events in the first year of treatment did not increase mortality. Except for high risk, the IMPEDE VTE score and the PRISM score models did not predict the risk of VTE in our group of patients.

Keywords: Multiple myeloma, venous thromboembolism, risk assessment, mortality

Introduction

Thromboembolism (TE) is one of the most common complications in multiple myeloma (MM), with a risk of more than 10%, especially in the first year of the diagnosis (1-3). The risk of venous TE (VTE) in patients with MM is 20 times higher than that in the general population (4). Underlying factors for TE are defined as patient-related, disease-related, and treatment-related (5). In recent years, some risk assessment models for VTE have been developed. The SAVED score was introduced and validated in 2019 using the Surveillance, Epidemiology, and End Results-Medicare data, and the IMPEDE VTE score was validated using the Veterans Health Administration database, respectively (6-8). Lastly, in 2022, the PRISM score, which consists of abnormal metaphase cytogenetics as a variable, was announced by Cleveland Clinic (9).

Although it is generally accepted that morbidity and mortality due to deep vein thrombosis (DVT) and pulmonary embolism (PE) are increased in MM, the effect of VTE on mortality is controversial. In particular, the results of single-center studies in recent years have shown that VTE has no effect on mortality (1-3,10,11).

Therefore, our study aimed to analyze the incidence of VTE events in newly diagnosed MM patients during the first year of treatment and their impact on survival. Additionally, we aimed to identify predisposing risk factors

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Received: 21.01.2025 **Accepted:** 08.04.2025 **Publication Date:** 29.04.2025

Cite this article as: Kirkizlar TA, Kirkizlar HO, Umit E, Demir AM. Evaluation of venous thromboembolism in multiple myeloma and its impact on mortality. Med Bull Haseki. 2025;63:33-39

for VTE and evaluate the role of the IMPEDE VTE and PRISM score models in predicting VTE risk.

Methods

Compliance with Ethical Standards

The study was approved by the Trakya University Faculty of Medicine Non-Interventional Scientific Research Ethics Committee (approval no.: 25/01 date: 26.12.2022) and was conducted in accordance with the Declaration of Helsinki.

Study Design

This study was conducted as a retrospective cohort study. A total of 150 consecutive adult patients who were newly diagnosed with and treated for MM were included in the study, conducted at our university hospital from January 2013 to June 2022. Patients with active synchronous malignancy, amyloid light-chain amyloidosis, known thrombotic disease, and thrombotic events before treatment initiation were excluded (Figure 1). All data were collected from the patients' medical files and electronic medical records. The data regarding patients' age, gender, subtype of the disease, history of VTE, surgery and fracture, body mass index (BMI), laboratory and genetic test results at diagnosis before starting MM treatment, initial induction treatment, use of central venous catheter, VTE event in the first year of treatment, timing of VTE, management and outcome of VTE event, receiving thromboprophylaxis related to MM or non-MM indications, the status of autologous hematopoietic stem cell transplantation (ASCT) and survival were collected. The diagnosis of MM was made according to International Myeloma Working Group (IMWG) criteria (12,13). Patients' laboratory tests included levels of total protein (g/dL), albumin (mg/L), lactate dehydrogenase (LDH) (U/L), urea (mg/dL), creatinine (mg/dL), beta 2 microglobulin (mg/L), D-dimer (mg/L), and C-reactive protein (mg/dL). For genetic tests, fluorescent in situ hybridization (FISH) and chromosomal cytogenetic analysis were used. Prognostic staging was made according to the International Staging System (ISS) and revised-ISS (R-ISS) based on the level of serum beta 2 microglobulin, albumin, LDH, and chromosomal abnormalities detected by FISH (14,15). Glomerular filtration rate was calculated with the Modification of Diet in Renal Disease formula (16). Treatment was chosen according to the reimbursement policy prevailing in the country during the study period. The dose of dexamethasone was adjusted according to the age and clinical condition of the patients. IMPEDE VTE and PRISM risk scores were calculated, and risk stratification was applied according to risk models (8,9). The diagnosis of deep venous thrombosis (DVT) was confirmed by the presence of an intraluminal thrombus detected via color Doppler ultrasonography. Pulmonary embolism was confirmed by identifying a total or partial intraluminal defect in a segmental, lobar, or main pulmonary artery via computed tomography angiography and/or a perfusion defect with normal ventilation via ventilation/perfusion scintigraphy in symptomatic patients. Patients were followed until the last follow-up date or death during the study period. All patients who received lenalidomide had thromboprophylaxis with acetylsalicylic acid (ASA) or low-molecular-weight heparin (LMWH) according to IMWG recommendations (6). Low molecular weight heparin was used in the treatment of VTE events and subsequently in thromboprophylaxis. However, due to heparin-induced thrombocytopenia, treatment and prophylaxis of VTE were provided with fondaparinux and rivaroxaban, respectively. Patient groups were compared based on the occurrence of VTE events in terms of demographic, clinical, laboratory, and mortality factors. Additionally, the predictors of VTE events were analyzed.

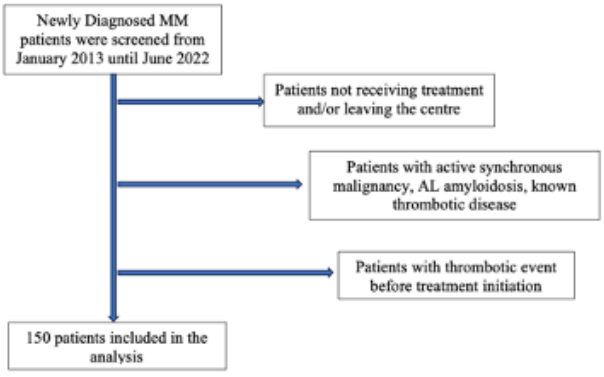

Figure 1. Flowchart of the study
MM: Multiple myeloma

Statistical Analysis

We used statistical package for the social sciences for all statistical analyses. For continuous variables, we determined the mean (±standard deviation) and median (with interquartile range 25-75) values. Categorical variables were shown as percentages. We used Mann-Whitney-Wilcoxon and t-tests for comparing continuous variables due to normal distribution, which is appropriate, and the χ^2 test or Fisher's exact test for comparing categorical variables, as appropriate. We used Kaplan-Meier analysis to determine the survival rates. We performed univariate and multivariate logistic regression analysis to identify predisposing factors for VTE. P-values less than 0.05 were regarded as statistically significant.

Results

One hundred and fifty patients were analyzed. The median age was 64 years, and 56% of patients were female. The most common heavy chain subtype of MM

was IgG (58.7%). Additionally, 18.6% of the patients had the light chain subtype of MM. 41.3% of the patients had ASCT during the study period. The most common initial induction treatment was the bortezomib, cyclophosphamide, and dexamethasone (VCD) protocol, accounting for 62.7%. The median BMI was 26.4 kg/m², and all patients were Caucasian. The median duration of follow-up was 36 months. The mortality rate was 48% during the follow-up.

The median IMPEDE VTE score was 3, and 76% of patients were categorized as low-risk. Revised-International Staging System and PRISM scores could not be determined in 22 patients due to the lack of genetic tests. The median PRISM score was 0, and 61.7% of the patients were categorized as low-risk. Pre-treatment D-dimer value was present in 76 patients, and the median level was 0.93 mg/L. Patients' demographic, epidemiological, and clinical characteristics are shown in Table 1.

Deep venous thrombosis and/or PE occurred in 12 patients (8%) in the first year of treatment. The median day of VTE occurrence was 60 days. DVT occurred in the first 6 patients, while PE developed with or without DVT in the other 6 patients. One of the thrombosis events occurred in the upper extremity, with cephalic venous thrombosis. The remainder of the DVT events were in the lower extremity. One patient experienced a VTE event after central venous catheter insertion for stem cell mobilization prior to autologous transplantation in the eighth month of treatment. Two patients were in remission, while the remaining 10 patients had active disease when the VTE event occurred.

Seventeen patients received thromboprophylaxis. Five of the 17 patients received ASA or LMWH when using IMiDs, while the remaining 12 patients received ASA, clopidogrel, LMWH, rivaroxaban (2/12) or apixaban (1/12), regardless of the indication for MM, mostly for cardiac disease. Two of the patients (2/17) had VTE events during thromboprophylaxis. Sixty five patients (43.3%) received LMWH as enoxaparin sodium, tinzaparin sodium, or bemiparin sodium at the prophylactic dose during hospitalization for initial induction chemotherapy. These patients were not classified as having received thromboprophylaxis because thromboprophylaxis was limited.

In Table 2, the distribution of VTE events according to scores for predicting thrombosis risk and thromboprophylaxis status is shown.

In the comparison of the patient groups according to the occurrence of VTE events in the 1st year of treatment, the difference in PRISM risk classification between groups was statistically significant (p-value 0.021). Detailed analysis is shown in Table 3.

In Kaplan-Meier analysis, the median survival was 62 months (±6.41) in all patient groups. The median survival

Table 1. Characteristics of 150 newly diagnosed multiple myeloma patients

Median age (IQR)	64 years
Gender	Female: 56%
	Male: 44 %
Initial induction treatment	VAD: 17.3%
	VCD: 62.7%
	VRD: 3.3%
	VTD-PACE: 4%
	VELDEX: 12%
	MP: 0.7%
Subtype of disease	IgG κ: 44%
	IgG λ: 14.7%
	IgA κ: 12%
	IgA λ: 10%
	κ: 11.3%
	λ: 7.3%
	Non-secretory: 0.7%
Median total protein (NR: 6.6-8.3) (IQR)	8.40 g/dL
Median D-dimer (NR: 0-0.55) (76 pts) (IQR)	0.93 mg/L
Median glomerular filtration rate (IQR)	65.7 mL/min/1.73 m^2
Median C-reactive protein (NR: 0-0.5) (IQR)	0.55 mg/dL
VTE event in the 1st year of treatment	8%
Receiving thromboprophylaxis	11.3%
Median BMI (IQR)	26.40 kg/m2
Median IMPEDE score (IQR)	3
IMPEDE VTE risk	Low: 76%
	Intermediate: 20.7%
	High: 3.3%
Median PRISM score (128 pts) (IQR)	0
PRISM risk (128 pts)	Low: 61.7%
	Intermediate: 35.9 %
	High: 2.3%
ISS	Stage 1: 44.7%
	Stage 2: 26%
	Stage 3: 29.3%
R-ISS (128 pts)	Stage 1: 46.1%
	Stage 2: 39.1%
	Stage 3: 14.8%
ASCT	41.3%
Mortality rate during follow-up	48%
Median follow-up time (months) (IQR)	36

κ: Kappa light chain, λ: Lambda light chain
IQR: Interquartile range, VAD: Vincristine-doxorubicin and dexamethasone, VCD: Bortezomib-cyclophosphamide and dexamethasone, VRD: Bortezomib-lenalidomide and dexamethasone, VTD-PACE: Bortezomib, cisplatin, cyclophosphamide, dexamethasone, doxorubicin, etoposide and thalidomide, VELDEX: Bortezomib and dexamethasone, MP: Melphalan and prednisone, BMI: Body mass index, IMPEDE: Interventions to prevent deep venous thrombosis and embolism, PRISM: Preserved ratio impaired spirometry, ISS: International Staging System, R-ISS: Revised-International Staging System, ASCT: Autologous hematopoietic cell transplantation, NR: Normal range

Table 2. VTE event and thromboprophylaxis status according to IMPEDE VTE and PRISM risk scores						
Risk score	**Low**		**Intermediate**		**High**	
	VTE event	**TP**	**VTE event**	**TP**	**VTE event**	**TP**
IMPEDE VTE	7%	11.4%	6.45%	9.68%	40%	20%
PRISM	8.8%	11.4%	-	10.9%	33.3%	66.6%

VTE: Venous thromboembolism, TP: Thromboprophylaxis (Percentages were calculated according to the number of patients in risk score categories), IMPEDE: Interventions to prevent deep venous thrombosis and embolism, PRISM: Preserved ratio impaired spirometry

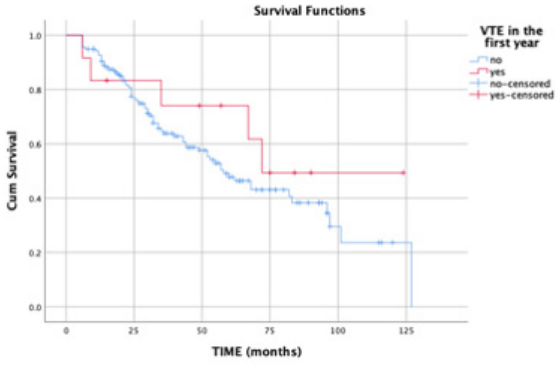

Figure 2. Kaplan-Meier analysis according to the status of VTE event at first year of treatment
VTE: Venous thromboembolism

Table 3. Comparison of the patient groups with VTE event and without VTE event in the 1st year of treatment			
Variables	**With VTE event (n=12 pts)**	**Without VTE event (n=138 pts)**	**p-value**
Age (years) (Mean)	65.08 (±11.10)	63.38 (±10.99)	0.655*
Gender	Male: 58.3%	Male: 42.8%	
	Female: 41.7%	Female: 57.25%	0.459[x]
Initial induction treatment	VAD: 25%	VAD: 16%	
	VCD: 66.7%	VCD: 62.3%	
	VRD: 0	VRD: 3.65%	
	VTD-PACE: 0	VTD-PACE: 0	
	VELDEX: 0	VELDEX: 13%	
	MP: 8.3%	MP: 4.35%	0.152[y]
Subtype of MM	IgG κ: 58.3%	IgG κ: 42.8%	
	IgG λ: 16.7%	IgG λ: 14.5%	
	IgA κ: 16.7%	IgA κ: 11.6%	
	IgA λ: 0	IgA λ: 10.9%	
	κ: 0	κ: 12.3%	
	λ: 8.3%	λ: 7.2%	
	Non-secretory: 0	Non-secretory: 0.7%	0.683[y]
Mean total protein (g/dL)	8.80 (±2.16)	8.35 (±1.52)	0.606*
Mean D-dimer (mg/L) (76 pts)	1.64 (±1.04)	1.71 (±2.04)	0.248*
Mean GFR (mL/min/1.73 m^2)	73.8 (±38.18)	66.56 (±34.18)	0.467*

Table 3. Continued			
Variables	**With VTE event (n=12 pts)**	**Without VTE event (n=138 pts)**	**p-value**
Mean C-reactive protein (mg/dL)	2.95 (±3.52)	1.61 (±2.73)	0.060*
Receiving thromboprophylaxis	16.7%	10.9%	0.628[x]
Mean BMI (kg/m^2)	28.49 (±3.78)	27.38 (±5.79)	0.284*
Mean IMPEDE score	4.17 (±2.20)	3.24 (±1.85)	0.154*
IMPEDE VTE risk	Low: 66.6%	Low: 76.8%	
	Intermediate: 16.7%	Intermediate: 21%	
	High: 16.7%	High: 2.2%	0.082[y]
Mean PRISM score	1 (±2.82)	1.02 (±1.59)	0.210*
PRISM risk (128 pts)	Low: 87.5%	Low: 60%	
	Intermediate: 0	Intermediate: 38.3%	
	High: 12.5%	High: 1.7%	0.021[y]
ISS	Stage 1: 44.2%	Stage 1: 44.2%	
	Stage 2: 33.3%	Stage 2: 25.4%	
	Satge 3: 16.7%	Stage 3: 30.4%	0.597[y]
R-ISS (128 pts)	Stage 1: 62.5%	Stage 1: 45%	
	Stage 2: 37.5%	Stage 2: 39.2%	
	Stage 3: 0	Stage 3: 15.8%	0.551[y]
ASCT	41.7%	41.3%	1.000[x]
Deaths during the follow-up	41.7%	48.6%	0.876[x]
Mean duration of follow-up (months)	56.92 (±35.89)	43.33 (±28.87)	0.207*

*Mann-Whitney U test, [x]: χ^2 test, y: Fisher's exact test, κ: Kappa light chain, λ: Lambda light chain
VTE: Venous thromboembolism, VAD: Vincristine-doxorubicin and dexamethasone, VCD: Bortezomib-cyclophosphamide and dexamethasone, VRD: Bortezomib-lenalidomide and dexamethasone, VTD-PACE: Bortezomib, cisplatin, cyclophosphamide, dexamethasone, doxorubicin, etoposide and thalidomide, VELDEX: Bortezomib and dexamethasone, MP: Melphalan and prednisone, GFR: Glomerular filtration rate, BMI: Body mass index, ISS: International Staging System, R-ISS: Revised International Staging System, ASCT: Autologous hematopoietic cell transplantation

was 72 months in patients with a VTE event in the first year of treatment and 58 months in patients without a VTE event. This difference was not found to be statistically significant (p-value 0.357) (Figure 2). Cumulative survival rate was 94% (±2%) at 12 months in the group without

a VTE event, while it was 83% (±8%) at 12 months in the group with a VTE event in the first year of treatment. None of the deaths were attributed to VTE.

Regarding predictors of VTE, univariate logistic regression analysis showed that being in the high-risk IMPEDE VTE categorization was a predictor of an 8.8-fold increased risk of VTE (p-value 0.027). None of the variables was found to be predictive of VTE risk in the multivariate logistic regression analysis.

Discussion

Multiple myeloma patients have an increased risk of VTE, especially in the first six months of diagnosis (4). VTE risk assessment should be carefully conducted at diagnosis to include patient, disease, and treatment factors, and the need for thromboprophylaxis should be revealed. In recent years, some risk assessment models have been developed and validated, although there is no recommendation for thromboprophylaxis (7-9,17).

The incidence of VTE was reported to be between 6.5% and over 10% within the first year in newly diagnosed MM (NDMM) patient groups in various studies, where the thromboprophylaxis ranged between 22% and 99% in patient groups (1-3,10,11,18). A recent retrospective study at Mayo Clinic reported an 11.7% incidence of VTE within the first year of diagnosis for NDMM patients using triplet or quadruplet lenalidomide-based induction regimens (19). In the studies from Asia and Mexico, where immunomodulatory drugs (IMIDs) were used in more than half of the patients' initial treatment, the incidence of VTE ranged between 10% and 15% (1-3). The median timing of VTE was reported to range from 66 days to 3.5 months, and the most common site of VTE was lower extremity DVT, with a rate of >50% in the studies (1,3,10,11). In our patient group, the median time of VTE occurrence and the site of VTE were compatible with the literature. However, the incidence of VTE was slightly lower than the literature at a rate of 8%, despite the low rate of thromboprophylaxis at 11.3% in the entire patient group. Although the use of doxorubicin, which is a risk factor for thrombosis in induction therapy, was common in our study group, the use of IMID was very limited. Besides that, more than 90% of the patients in our study were on VCD, vincristine-doxorubicin and dexamethasone (VAD), or bortezomib and dexamethasone (VELDEX) regimens, with over 60% receiving the VCD regimen for induction treatment. None of the patients with VTE received IMIDs-based induction therapy, while all patients who had IMIDs in induction therapy were in the non-VTE group. We could not show a statistically significant difference between groups with and without VTE when comparing groups based on induction treatments. This lower VTE rate may be related to our standard clinic practice of hospitalizating patients and administrating thromboprophylaxis with LMWH during the first cycle of induction chemotherapy, regardless of the clinical status and the high thromboprophylaxis compliance in the use of subsequent lenalidomide treatment.

In the studies, there was no difference between groups with and without TE regarding subtype of disease, ISS, R-ISS, M protein level, creatinine level, paraprotein type, and renal failure like ours (10,19).

Most patients in our study group were classified as low-risk according to IMPEDE VTE and PRISM score models, with no intermediate-risk patients in the VTE event group. The IMPEDE VTE and PRISM risk scores did not differentiate the VTE risk well enough. We think that this situation could be related to the decreased use of IMIDs in the induction treatment, while the use of doxorubicin was more common. The high-risk classification of the IMPEDE VTE risk score was found to be a VTE predictor in our patient group, probably because doxorubicin is a strong variable in this model. The PRISM risk score could not predict a VTE event, probably due to limited use of IMID in induction treatment, which is a very strong variable in this risk assessment model. In addition, all the patients except one who were treated with had dexamethasone. Dexamethasone dose, a variable in the IMPEDE VTE risk score, was "low" due to adjustments related to fragility and age in our clinical practice (8). Ethnicity is also a variable in both score models. In the study with a group of Chinese patients, IMPEDE VTE was found to be a predictor of VTE, while in our study, where all patients were of Caucasian race, it was not a predictor of VTE, except in cases classified as high-risk (20). In the study from Malaysia, IMPEDE VTE was not an independent factor for thrombosis in multivariate analysis, while the study from Mexico reported that the IMPEDE VTE score was efficient in discriminating between high- and intermediate-risk patients (1,2).

The impact of VTE on mortality has been unclear in previous studies. In a population-based study that was conducted between 1987 and 2005, the group with a VTE event had a higher mortality rate than the group without VTE at 1.5, and 10 years (hazard ratio 2.9, 1.6, and 1.6, respectively). However, the occurrence of VTE was not associated with inferior survival at 6-month mortality (21). In the other study, the median survival was 32.5 months, and the mortality rate was 27.2% within 1 year. VTE was found to be a factor that increases mortality with a 67% relative risk at 6 months (11). Barrett et al. (18) reported the mortality odds ratio as 3.3 in patients with a VTE event compared to the age-matched control group. The occurrence of VTE was found to be an independent risk factor for early death, although there were no VTE-related deaths in the study. In the study of lenalidomide-based

induction regimens in newly diagnosed MM patients, TE was reported as a predictive factor for mortality according to univariate and multivariate analysis (19). In contrast to these previous studies, occurring thrombosis was not found to impact survival (2,3). The 3-year overall survival was 60% and 63% in the groups with and without thrombosis, respectively, at a p-value of 0.6 (3). In our study, the median survival time was 62 months and the mortality rate was 48% in the cohort during the follow-up. Surprisingly, the median survival was longer (72 months) in patients with a VTE event than in patients without one (58 months), a difference that was not statistically significant. This difference might be due to better monitoring and treatment of VTE events, careful prevention measures, and different treatment choices based on the specific type of event in the VTE group.

Study Limitations

The study, retrospectively designed, has limitations due to the limited use of IMIDs in initial induction therapy and the small number of patients.

Conclusion

This study showed that VTE status does not affect survival. In addition, only the high-risk category of the IMPEDE VTE risk score predicted VTE events. We believe that the new VTE risk score models are evolving. However, the utility of the models in daily practice, the lack of thromboprophylaxis recommendations, and compliance with recommendations are currently unresolved issues.

Ethics

Ethics Committee Approval: This study was approved by the Trakya University Faculty of Medicine Non-Interventional Scientific Research Ethics Committee (date: 26.12.2022, approval no.: 25/01).

Informed Consent: All the patients or first-degree relatives have signed informed consent.

Footnotes

Authorship Contributions

Surgical and Medical Practices: T.A.K., H.O.K., E.U., A.M.D., Concept: T.A.K., H.O.K., Design: T.A.K., H.O.K., E.U., A.M.D., Data Collection or Processing: T.A.K., H.O.K., E.U., Analysis or Interpretation: T.A.K., H.O.K., E.U., Literature Search: T.A.K., H.O.K., A.M.D., Writing: T.A.K., H.O.K., E.U., A.M.D.

Conflict of Interest: No conflicts of interest were declared by the authors.

Financial Disclosure: This study received no financial support.

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