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ORIGINAL ARTICLE

Distribution of D-Dimer and FDP Test Results among South Koreans: Reference Laboratory Data from 2017 through 2023

Min J. Na [1, *], Jang M. Kim [2, *], Jae K. Kim [1]

[*] *These authors contributed equally to this study*
[1] *Department of Biomedical Laboratory Science, Dankook University College of Health Sciences, Chungnam, South Korea*
[2] *Department of Health Administration, College of Health Science, Dankook University, Cheonan, Republic of Korea*

SUMMARY

Background: **Thrombus formation and dissolution are important indicators for the diagnosis and prognosis of various diseases. D-dimer and fibrin degradation product (FDP) are key biomarkers reflecting this process. However, studies on the distribution and characteristics of these biomarkers by age and gender in Koreans are lacking. The aim of this study was to utilize test data from EONE Laboratories, a large contract research institute, from 2017 through 2023 to analyze the age- and gender-specific distribution of D-dimer and FDP levels, changes in testing demand during the COVID-19 pandemic, and correlation between the tests, thereby providing basic data for a diagnosis strategy for thrombosis.**
Methods: **Data from EONE Laboratories collected between 2017 and 2023 were analyzed. After excluding individuals aged < 20 years, 11,483 adult cases with recorded gender and age were included. Microsoft Excel 2010, jamovi, and SPSS Statistics were used to compare testing trends by year, distribution by age and gender, and positive test rates.**
Results: **In total, 11,483 out of 169,921 D-dimer and FDP test results were analyzed. The number of annual inspections exhibited a significant pattern, with a considerable increase of 153.7% between 2018 and 2019. Women aged 30 - 39 years had higher levels of D-dimer and FDP; a decrease was observed in those in their 40s, and an increase was observed in older individuals, forming a U-shaped curve. For men, the test results showed a steady increase with age. A significant correlation was found between D-dimer and FDP test results ($\chi^2 = 3836.57$, $p < 0.001$).**
Conclusions: **D-dimer and FDP test results in South Koreans varied by age and gender. The COVID-19 pandemic significantly increased testing demand. These findings offer useful insights for diagnosing and treating thrombotic diseases.**
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Correspondence:
Jae Kyung Kim
Department of Biomedical Laboratory Science
Dankook University College of Health Sciences
No. 119, Dandae-ro, Dongnam-gu, Cheonan-si
Chungnam 31116
South Korea
Phone: + 82 415501451
Fax: + 82 415597934
Email: nerowolf2@dankook.ac.kr

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KEYWORDS

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INTRODUCTION

Thrombus formation and lysis play important diagnostic and prognostic roles in various clinical situations. D-dimer and fibrin degradation products (FDPs), important clinical markers of these processes, are utilized in conditions such as thrombosis, pre-occlusion, cardiovascular disease, recovery after major surgery, and cancer [1, 2].

D-dimer is a protein fragment produced when platelets are broken down, the level of which increases during clot formation and lysis. This can help diagnose or rule out conditions such as thrombosis, deep vein thrombosis (DVT), and pulmonary embolism (PE). D-dimer levels can rapidly increase in acute conditions, facilitating immediate diagnosis in emergencies [3]. In addition, FDPs are protein fragments produced during fibrin degradation and play a role in the coagulation and fibrinolysis processes [4]. FDP testing is often used in combination with D-dimer testing to assess specific aspects of clot formation and lysis, thereby providing complementary information [2]. These tests are not only important for diagnosing thrombotic diseases but also for identifying potential complications in patients with COVID-19, such as thrombosis and other coagulation disorders. FDP and D-dimer are central biomarkers in the coagulation-fibrinolysis cascade. However, despite the importance of such markers, systematic studies on the distribution and characteristics of D-dimer and FDP test results according to age and gender in South Koreans are lacking. Understanding the trends in their distribution and variation is essential for establishing clinical diagnosis and treatment strategies for thrombotic diseases. In South Korea, the incidence of thrombotic diseases such as venous thromboembolism (VTE), PE, and DVT is increasing. For example, the number of patients with VTE has increased significantly from 12,064 in 2009 to 22,039 in 2016, emphasizing the importance of determining the distribution of major biomarkers, such as FDP and D-dimer, for the effective diagnosis and management of thrombotic diseases [5].

The COVID-19 pandemic (2019 - 2023) increased thrombotic risk globally, which led to a rise in the clinical use of D-dimer and FDP testing [6-8]. Research from China, Spain, and Italy has also shown that D-dimer levels increased significantly during the COVID-19 pandemic [9-11]. In South Korea, D-dimer testing has been utilized in patients with suspected COVID-19-related thrombosis, and several domestic and international studies have demonstrated its clinical usefulness in diagnosing deep vein thrombosis and pulmonary thromboembolism among patients with COVID-19 infection [12-14]. However, no comprehensive studies have evaluated age- and gender-specific trends in D-dimer and FDP levels in South Koreans or systematically assessed the impact of the COVID-19 pandemic on test utilization.

The aim of this study was to analyze D-dimer and FDP test results from January 2017 through December 2023. We used data from EONE Laboratories to compare differences by age and gender and provide fundamental insights into thrombotic disease diagnostics in South Korea. By systematically analyzing these coagulation markers, the results of this study will enhance the understanding of thrombosis-related biomarkers in the Korean population and provide essential data for improving thrombosis diagnosis and management strategies.

MATERIALS AND METHODS

Target population and data collection

We obtained and analyzed the results of D-dimer and FDP tests commissioned by EONE Laboratories (Incheon, South Korea), a Korean reference laboratory. We collected the results of D-dimer and FDP tests conducted by EONE Laboratories between January 2017 and December 2023 from the database and obtained 169,921 data points. We excluded data from those aged < 18 years (n = 2,941) and those aged between 18 and 19 years (n = 21). In addition, we excluded records with missing gender and age information (n = 5,715) and cases in which the D-dimer and FDP tests were performed separately (n = 149,761). The final analysis data set included data from 11,483 patients aged ≥ 20 years in whom D-dimer and FDP tests were performed simultaneously. Individual overlaps within the data were not considered. Data were analyzed backward to assess yearly testing trends, gender and age distributions, and correlations between concurrent D-dimer and FDP test results (Figure 1).

Ethical approval

This study was approved by the Clinical Trials Ethics Committee of EONE Laboratories (no. 128477-202406-BR286), and it complied with the principles of the Declaration of Helsinki. We retrospectively analyzed the results of existing tests, and no consent was required because personal patient information was not included.

Materials

The anticoagulant tube (BD Vacutainer, Becton Dickinson, Franklin Lakes, NJ, USA) used contained 0.3 mL of 3.2% sodium citrate. A ratio of 0.109 mol/L citric acid to blood was maintained at 1:9. The collected blood was centrifuged at 2,000 - 2,500 g for 15 minutes. After centrifugation, the plasma was separated using a pipette, ensuring that the buffy coat was not disturbed, and transferred into a separate tube for analysis. Plasma samples were either analyzed immediately or stored at -80°C until analysis to preserve sample integrity.

Analyses

The D-dimer test used the STA-LIATESTD-DI (Diagnostica Stago, Asnieres, France) reagent and the FDP test used the NanopiaP-FDP (SEKISUI MEDICAL Co., Ltd., Tokyo, Japan) reagent. Both tests are commercially available assays and were performed using the STA R MAX (Diagnostica Stago, Asnieres, France) instrument. D-dimer and FDP tests used an immunoturbidity method to measure changes in turbidity caused by antigen-antibody reactions with latex reagents using a spectrophotometer. The concentrations were determined using a calibration curve.

Quality control for D-dimer testing was performed using STA-Liatest Control N+P (Diagnostica Stago, Asnieres, France), and quality control for FDP testing was performed using NanopiaP-FDP Control (SEKISUI

Table 1. Annual test count trends.

Year	n	Trend	%
2017	680	increasing trend	-
2018	850	increasing trend	25.0% increase
2019	2,156	increasing trend	153.7% increase
2020	2,473	increasing trend	14.7% increase
2021	3,047	increasing trend	23.2% increase
2022	1,407	decreasing trend	53.8% decrease
2023	870	decreasing trend	38.2% decrease

n - total concurrent tests, % - percentage change.

Table 2. Cross-table and chi-squared test results of D-dimer and FDP.

			FDP		Total	χ^2/p
			negative	positive		
D-dimer	negative	count (%)	4,354 (60.3)	84 (2.0)	4,438 (38.6)	3,836.57/0.001
		expected count	2,792.3	1,645.7	4,438.0	
	positive	count (%)	2,871 (39.7)	4,174 (98.0)	7,045 (61.4)	
		expected count	4,432.7	2,612.3	7,045.0	
Total		count (%)	7,225 (100.0)	4,258 (100.0)	11,483 (100.0)	
		expected count	7,225.0	4,258.0	11,483.0	

$p < 0.005$.
FDP - fibrin degradation product.

MEDICAL Co., Ltd., Tokyo, Japan). All tests were performed according to the manufacturers' instructions, and the results were analyzed retrospectively.

Statistical analyses

Microsoft Excel 2010 (Microsoft, Redmond, WA, USA) was used to organize the data and perform preliminary analysis. To analyze changes in the number of inspections by year, we summarized the collected data by year. We calculated the rate of increase or decrease compared with the previous year to confirm the annual increase rate. Analysis of test results by age and gender was assessed for statistical significance using a *t*-test with jamovi (version 2.4.11, Jamovi, Sydney, Australia). Comparisons of the positive rates of D-dimer and FDP test results were evaluated using the chi-squared test. SPSS Statistics (version 29.0, IBM Corp., Armonk, NY, USA) was used for all analyses. The significance level was set at $p < 0.05$.

RESULTS

Study population and data selection

In this study, D-dimer and FDP tests were conducted on 169,921 individuals between 2017 and 2023. Pediatric cases for those aged < 18 years (n = 2,941) were excluded, as were those aged 18 - 19 years (n = 21), owing to the small number of cases, which could reduce the reliability of the analysis. Therefore, the analysis was performed on adult men and women aged ≥ 20 years; thus, 166,980 patients were included. We also excluded cases with missing gender and age information (n = 5,715) and cases with only FDP or D-dimer testing (n = 149,761). Therefore, the final analysis included 11,483 cases in which FDP and D-dimer tests were performed simultaneously.

Analysis of annual test counts

The annual number of D-dimer and FDP tests increased consistently from 2017 to 2021, with a 153.7% rise observed between 2018 and 2019. This upward trend con-

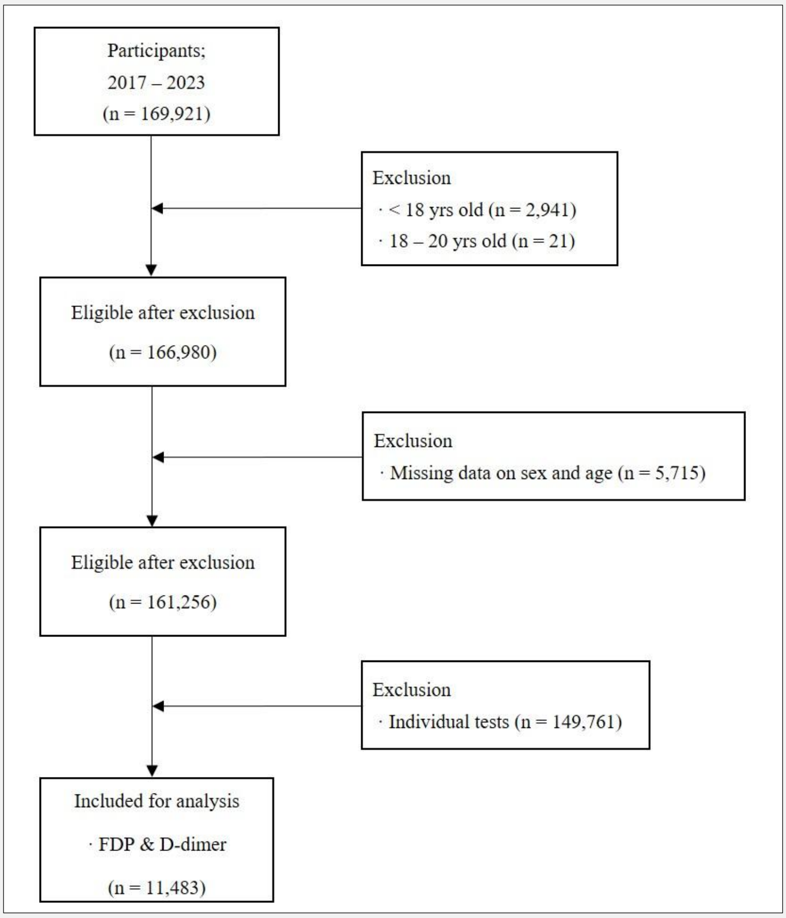


Figure 1. Study sample enrollment process.
FDP - fibrin degradation product, n - number of individuals assessed.

tinued, reaching the highest number of tests in 2021. However, a notable decline followed in the subsequent years, with the number of tests decreasing by 53.8% in 2022 compared with the previous year and an additional 38.2% reduction recorded in 2023 (Figure 2; Table 1). These year-to-year changes suggest that the clinical demand for thrombosis-related testing was influenced by the progression and stabilization of the COVID-19 pandemic.

Annual trends in FDP and D-dimer levels by gender and age

For women, between the ages of 30 and 39, FDP and D-dimer levels increased and were higher than those in the other age groups. However, in the 40 - 49-year-old age group, FDP and D-dimer levels decreased significantly, and a subsequent increase was observed with a further increase in age. We found that these trends continued in older age groups, with FDP and D-dimer levels gradually increasing in women aged > 50 years.

Men showed a different pattern from women. According to the data, men showed a trend of steadily increasing FDP and D-dimer levels with increasing age.

Analysis of D-dimer and FDP by age and gender

A comparison of FDP levels between men and women by age group showed a general increasing trend with age. FDP levels were significantly higher in women than in men in the 30 - 39 ($p = 0.019$) and 70 - 79 ($p = 0.018$) age groups, whereas in the 50 - 59 age group, men had significantly higher FDP levels than women ($p = 0.045$). In contrast, no significant differences were observed between men and women in the 20 - 29, 40 - 49, 60 - 69, and ≥ 80 age groups ($p > 0.05$) (Figure 3). A comparison of mean D-dimer levels between men and women by age group showed a general increasing trend with age. D-dimer levels were significantly higher in women than in men in the 30 - 39 ($p = 0.006$) and 70 - 79 ($p = 0.002$) age groups, whereas in the 50 - 59 ($p = 0.007$) and 60 - 69 ($p = 0.012$) age groups, men had sig-

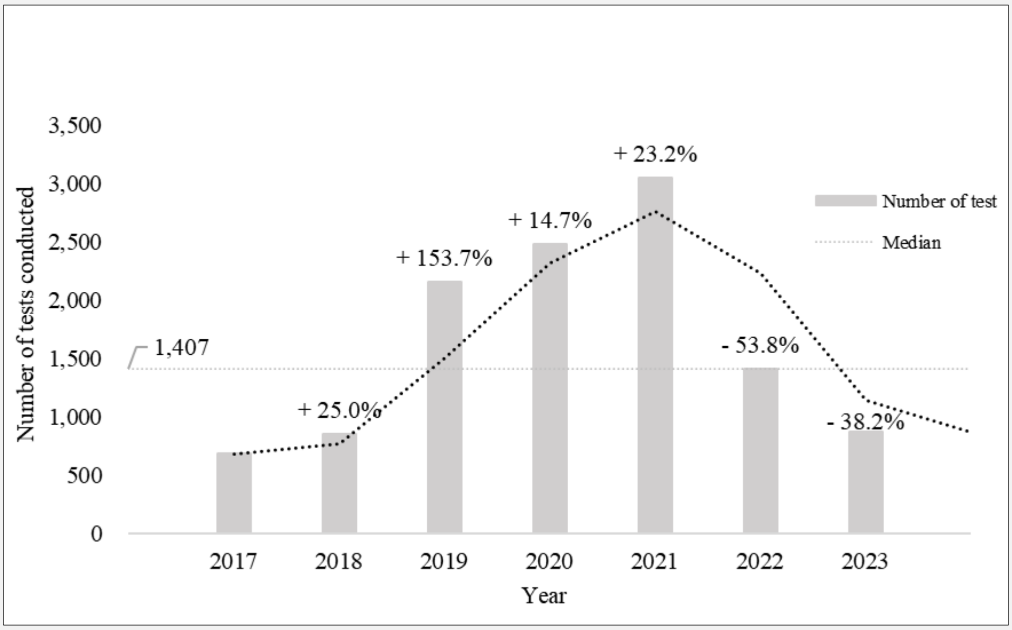
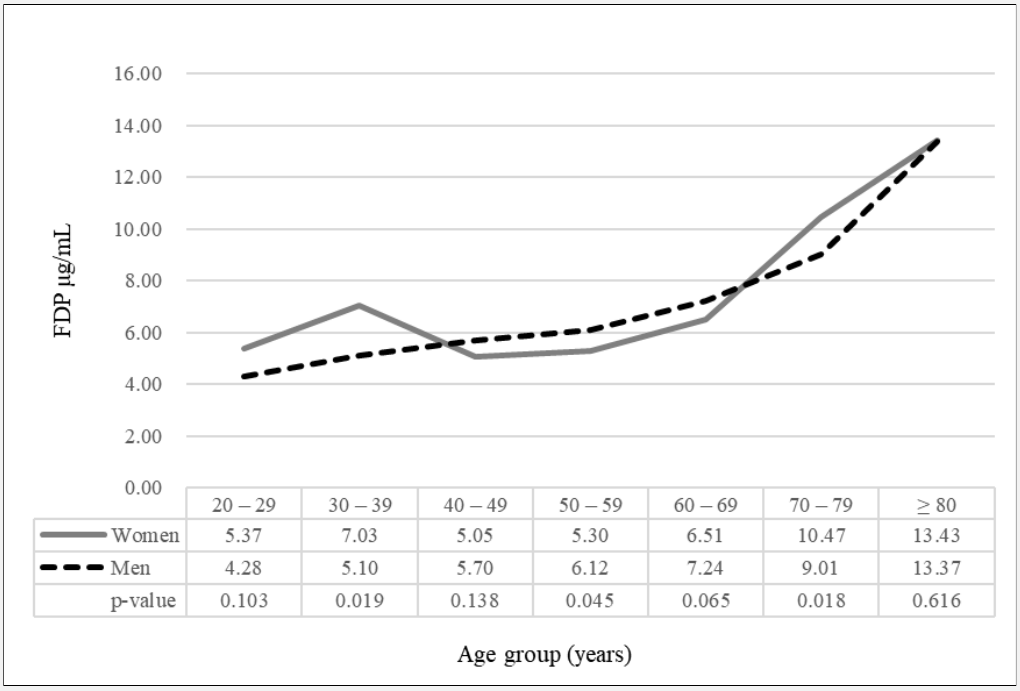


Figure 2. Annual test count trends (2017 - 2023).



	20 – 29	30 – 39	40 – 49	50 – 59	60 – 69	70 – 79	≥ 80
Women	5.37	7.03	5.05	5.30	6.51	10.47	13.43
Men	4.28	5.10	5.70	6.12	7.24	9.01	13.37
p-value	0.103	0.019	0.138	0.045	0.065	0.018	0.616

Figure 3. Comparison of FDP levels by age and gender.
FDP - fibrin degradation product.

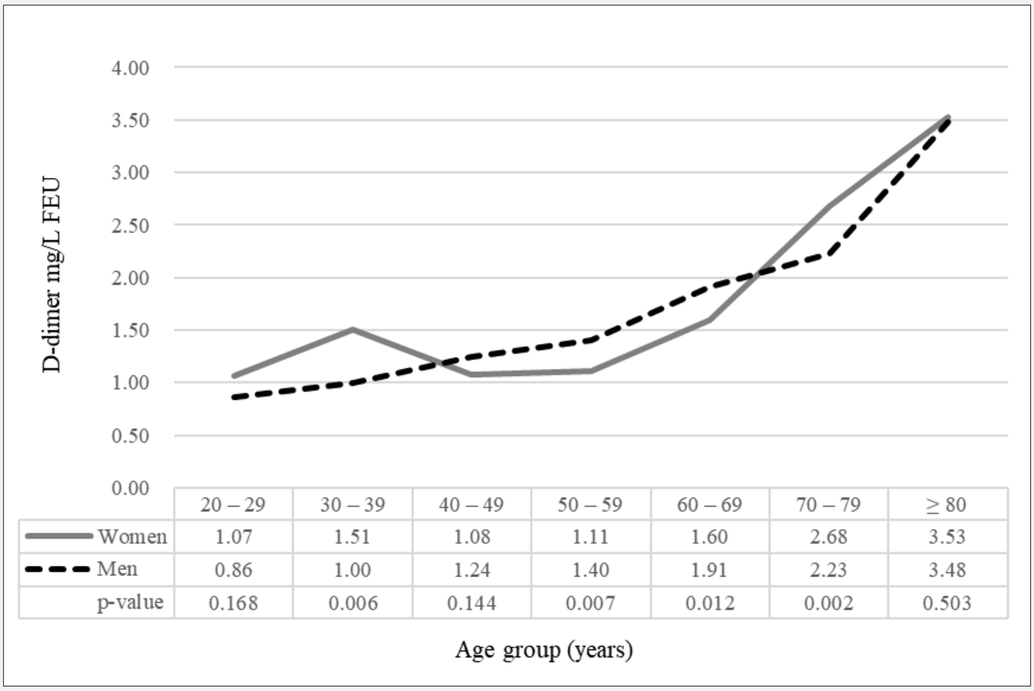


Figure 4. Comparison of D-dimer levels by age and gender.

nificantly higher D-dimer levels than women. In contrast, no significant differences were observed between men and women in the 20 - 29, 40 - 49, and ≥ 80 age groups ($p > 0.05$) (Figure 4).

Comparison of D-dimer and FDP test positivity rates

The observed frequencies were 4,174 cases with both positive tests, 2,871 cases with D-dimer positive and FDP negative, 84 cases with D-dimer negative and FDP positive, and 4,354 cases with both negative tests. The expected frequencies, assuming independence, were 2,612.3, 4,432.7, 1,645.7, and 2,792.3, respectively. The chi-squared statistic was 3,836.57, and the p-value was less than 0.001, indicating a significant correlation between D-dimer levels and FDP results ($\chi^2 = 3,836.57$, $p < 0.001$) (Table 2). This suggests that the FDP and D-dimer values are significantly correlated, supporting the validity of using both markers in clinical diagnosis.

DISCUSSION

This study analyzed the results of 11,483 adult patients who underwent D-dimer and FDP tests simultaneously between 2017 and 2023. It investigated changes in the number of tests per year, differences in test results by gender and age group, and positive test results in the South Korean population.

The incidence of thrombosis in South Korea has been increasing annually [5], as has the number of D-dimer and FDP tests. Between 2018 and 2019, the number of tests increased significantly by 153.7%, indicating a substantial shift in testing patterns. Moreover, the COVID-19 pandemic has had a global impact on healthcare systems and diagnostic patterns [14], with the infection itself being linked to an increased risk of thrombosis and various coagulation disorders [15,16]. D-dimer and FDP tests are useful biomarkers for thrombosis [17]. As a result, a surge in demand for D-dimer and FDP testing during the pandemic, owing to the increased number of patients visiting medical institutions with COVID-19 symptoms, has been reported [6]. Similarly, this study also observed a temporary increase in testing rates during the pandemic period. Although the COVID-19 pandemic caused a temporary surge in testing, the overall demand for thrombosis-related testing in South Korea has shown a continued upward trend, suggesting both a pandemic-related impact and sustained increase in the baseline incidence of thrombosis.

We observed that women in the 30 - 39 years age group had significantly higher FDP and D-dimer levels. This level was significantly higher than that in other age groups and decreased in those in their 40s. A previous study has confirmed the differences in FDP and D-dimer levels between pregnant and non-pregnant women [18]. In addition, women in the 30 - 39 age group had higher D-dimer ($p = 0.006$) and FDP ($p = 0.019$) levels than men in the same age group. Some studies have shown that these increases and decreases are affected by various factors, such as hormonal changes, pregnancy, oral contraceptive use, and lifestyle [19,20].

Women aged > 50 years showed a tendency for gradually increasing FDP and D-dimer levels with age. This trend is consistent with the finding that FDP and D-dimer levels gradually increase with age in the South Korean population [21]. Moreover, the FDP and D-dimer levels continued to increase with age in both men and women. One of the major factors that increases FDP and D-dimer levels with age is the increased incidence of thrombosis. Older individuals have a higher risk of thrombosis associated with cardiovascular disease, peripheral vascular disease, and other coagulation disorders [22,23]. In addition to the increased incidence of thrombosis, elevated FDP and D-dimer levels with age may be linked to physiological changes not associated with direct thrombogenesis. Studies have shown that age-related inflammatory responses, decreased renal function, and the prevalence of chronic diseases may affect the levels of these markers [20,24].

Men in the 50 - 59 years age group had higher D-dimer ($p = 0.007$) and FDP ($p = 0.045$) levels than women, and men in the 60 - 69 years age group had higher D-dimer levels than women ($p = 0.012$). Conversely, women in the 70 - 79 years age group had higher D-dimer ($p = 0.002$) and FDP ($p = 0.018$) levels than men. These differences in the patterns of increasing D-dimer and FDP levels according to age group and gender are thought to have been influenced by various factors, including hormonal changes, cardiovascular risk factors, physiological differences, and lifestyle.

In this study, the correlation between the tests and their usefulness for diagnosing thrombosis were evaluated by comparing the results of the D-dimer and FDP tests. A significant correlation was observed between the test results ($\chi^2 = 3{,}836.57$, $p < 0.001$). According to a previous study, these high concordance rates suggest that both tests provide reliable and consistent results [1]. In our study, 4,174 cases (36.3%) of both tests were positive, and 4,354 cases (38.0%) of both tests were negative, indicating consistent results in 74.3% of all cases. These correlations emphasize the usefulness of using both tests for the early diagnosis of thrombosis and for establishing appropriate treatment plans [25,26]. Therefore, we believe that conducting both D-dimer and FDP tests simultaneously enables efficient use of medical resources by reducing unnecessary additional tests and providing accurate diagnoses. The use of these complementary tests improves diagnostic accuracy and plays an important role in patient management [27]. The significant concordance between D-dimer and FDP test results observed in this study suggests that these tests may play complementary roles in the diagnosis of thrombosis.

In total, 2,871 cases (25.0%) were found in which the D-dimer test was positive but the FDP test was negative, suggesting the possibility that the D-dimer test could detect a broader spectrum of thrombotic states [28]. Previous studies have shown a strong correlation between these markers, with low D-dimer values observed in some patients. A similar pattern was observed in this study; in 84 patients (0.7%), the D-dimer test result was negative but the FDP result was positive. One study has shown that this rare discrepancy could be attributed to the action of non-plasmin proteases or the presence of uncoagulated fibrinogen residues in the blood sample [29].

This study has some limitations. Data on the COVID-19 infection status, thrombotic symptoms, personal medical history, and medical records were not collected. This study focused only on D-dimer and FDP results based on gender and age; hence, it may be limited to directly associating these markers with specific diseases. In future studies, it will be necessary to include this data to enable a more comprehensive analysis across various population groups. Moreover, more longitudinal studies are required to track the variability of these markers. These limitations can be resolved by investigating their association with various diseases and performing multivariate analyses.

In conclusion, this study analyzed D-dimer and FDP test results from 11,483 adults in South Korea between 2017 and 2023 and identified age- and gender-related variations. Women in their 30s exhibited distinctly elevated levels, and both markers increased steadily with age in men and women over 50. A temporary surge in testing volume was observed during the COVID-19 pandemic, but the overall trend suggests a long-term rise in testing demand, likely reflecting a sustained increase in thrombotic disease incidence. A strong correlation between D-dimer and FDP results supports the complementary diagnostic value of using both markers in clinical practice. These findings contribute important population-based data on coagulation biomarkers and underscore the need for age- and gender-specific interpretations of thrombosis diagnoses. This study may inform on personalized diagnostic strategies and improve the clinical management of thrombotic diseases.

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Declaration of Interest:
The authors declare no financial conflicts of interest.

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