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ORIGINAL ARTICLE

Diagnostic Value of Coagulation Function Testing for Venous Thrombosis in Patients with Gastric Cancer

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SUMMARY

Background: **This study aimed to explore differences between thromboelastography (TEG) and conventional coagulation tests (CCTs) in evaluating coagulation function and analyze the diagnostic value of each indicator from these two methods in thrombosis among patients with gastric cancer.**
Methods: **We included 150 patients with gastric cancer and divided them into thrombus and non-thrombus groups. We obtained TEG (R, K, *α*-angle, and MA) and CCT (PT, APTT, Fib, D-D, and PLT) indicators and analyzed the ROC curve to determine the diagnostic value of each indicator in the occurrence of thrombosis.**
Results: **Compared with the control group, the gastric cancer group had decreased R and K and increased *α*-angle and MA. PT, FIB, D-D, and PLT in CCTs increased, while APTT slightly decreased, with statistically significant differences. The ROC results showed that R, K, *α*-angle, MA, PT, FIB, and D-D are closely related to the occurrence of thrombosis. The area under the curve for combined detection was 0.952 (95% CI: 0.913 - 0.990).**
Conclusions: **Both TEG and CCTs are of diagnostic value for venous thrombosis in patients with gastric cancer. These two methods should be used together for a better prediction of thrombosis in patients with gastric cancer.**
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INTRODUCTION

In 2020, 19.3 million new cases of cancer and approximately 10 million deaths resulting from cancer-related complications were reported worldwide. In the same year, 4.57 million new cases of cancer were identified in China. In addition, the number of cancer-related deaths has reached 3 million in the country. Gastric cancer alone accounts for 5.6% of total cancer cases worldwide, with a mortality rate of 7.7%. In China, gastric cancer accounts for 10.5% of the total cancer cases and 12.4% of cancer-related mortality. It ranks third in the incidence rate and mortality in the country [1].

Since the last century, the relationship between cancer and thrombosis has been attracting increasing attention in clinical settings. Tumor cells increase the coagulating ability of the blood. Consequently, the blood of patients with tumors is in the hypercoagulable state, leading to venous thrombosis in such patients. Various factors can affect the coagulation status of such patients, with tumors being the most important one. Some patients with malignant tumors exhibit a high coagulation state during their diagnosis and treatment [2,3]. Venous thromboembolism (VTE) is one of the most common and serious complications in the diagnosis and treatment of patients with tumors. The relationship is bidirectional: cancer increases the risk of VTE by 4 - 7 times and accounts for approximately 20% of all VTE cases [4,5]. This complication not only severely impacts patient survival and quality of life but also imposes a significant economic burden due to rising medical costs. Furthermore, the prognosis of patients with tumors is significantly worse and the mortality rate is significantly higher than it is for patients without tumors [6,7].

To monitor the coagulation function, clinical laboratories usually artificially divide the coagulation process into several pathways as follows: from the activation of thrombin to the formation of fibrin, such as endogenous and exogenous coagulation pathways, as well as common coagulation pathways. Clinical laboratories generally use prothrombin time (PT), activated partial thromboplastin time (APTT), plasma fibrinogen content (Fib), D-dimer (D-D), and platelet count as indicators for conventional coagulation function tests (CCTs).

Thromboelastography (TEG), developed by German scientist Dr. Harlert in 1945, was first applied clinically in the 1980s to monitor the coagulation function. It was initially used chiefly for selecting blood products for liver transplantation and for evaluating post-transfusion effects [8,9]. TEG is a diagnostic technique that can determine whether the balance between coagulation and anticoagulation is disrupted, providing a full picture of the coagulation process. Therefore, TEG can be employed to timely detect the hypercoagulable state of blood, predict the risk of thrombosis, and show fibrinolysis [10].

MATERIALS AND METHODS

Inclusion and exclusion criteria

We enrolled 150 patients with gastric cancer who were treated in the Affiliated Cancer Hospital of Xinjiang Medical University from January 2021 through June 2022 and designated them as the gastric cancer group. We used the following criteria as inclusion criteria: 1) the complete blood coagulation function test data of the patients were available; 2) the patients were ≥ 18 years old; 3) all patients were diagnosed by routine pathology, with complete clinical pathology, laboratory, and imaging data, and were able to complete the follow-up; and 4) the patients did not have any mental health disorders in the past. We used the following criteria as exclusion criteria: 1) patients who were previously diagnosed with VTE or pulmonary embolism; 2) patients with blood-related diseases such as congenital coagulation factor deficiency; 3) patients with other primary tumors; 4) patients with severe abnormalities of the cardio-cerebrovascular, liver, and kidney functions, and hematopoietic system; 5) patients who took anticoagulants within one month of the beginning of the study; 6) patients with a different surgical history; and 7) patients who were pregnant, breastfeeding, or giving birth. All patients were confirmed to have gastric cancer based on histopathology tests. The pathological stages were performed according to the American Joint Commission on Cancer (AJCC) TNM staging (8th edition) criteria [11]. Venous ultrasound imaging was used to confirm DVT events. PE events were confirmed by computed tomography pulmonary angiogram. The patients were placed into two groups, thrombus and non-thrombus, according to whether venous thrombosis was detected.

Sample collection

The fasting blood samples of the patients were collected in the morning. The blood was drawn from their median cubital vein by using a disposable blood-collection needle and placed in two test tubes - one containing sodium citrate anticoagulant and the other containing EDTA-K2 anticoagulant. Each test tube had a volume of 2.7 mL. The test tubes were then gently flipped up and down to mix the blood with anticoagulants to make the samples non-hemolytic, clotting, and fatty. It was particularly important to note that the specimens were collected during the period after the surgery when no anticoagulants were administered.

TEG and CCTs

TEG curves and TEG indicators R, K, α-angle, and MA were obtained using the TEG®5000 coagulation monitoring system (Haemonetics, USA), by following the instrument instructions. The Sysmex CS5100 automatic coagulation analyzer was used to determine coagulation indicators, including PT, APTT, Fib, and D–D, by following the instrument instructions. PLT was conducted using the CAL8000 fully automated blood analyzer (Mindray, China).

Statistical analysis

The data were processed using the SPSS 26.0 software. The measurement data conformed to normal distribution and were represented as $\bar{x} \pm s$. A comparison between multiple groups was performed using one-way ANOVA. A pairwise comparison between multiple groups was conducted using the Bonferroni correction method. The comparison between the two groups (gastric cancer and control groups) was conducted through two independent sample t-tests or Fisher's exact probability method. Count data were expressed as frequency. $p < 0.05$ was considered significant.

Table 1. Comparison of age, gender, and ethnicity between the gastric cancer group and the control group.

Characteristics		Gastric cancer group (n = 150)	Control group (n = 150)	t/χ^2	p
Age (years)		61.25 ± 11.22	58.89 ± 14.80	1.552	0.122
Gender	male	82	69	2.253	0.133
	female	68	81		
Ethnicity	Han	84	92	0.88	0.348
	minority	66	58		

Table 2. Comparison of age, gender, and ethnicity between the thrombus group and the non-thrombus group.

Characters		Non-thrombus group (n = 121)	Thrombus group (n = 29)	t/χ^2	p
Age (years)		60.22 ± 11.66	64.66 ± 9.65	-1.895	0.06
Gender	male	62	20	2.966	0.085
	female	59	9		
Ethnicity	Han	69	15	0.267	0.606
	minority	52	14		
Infiltration degree	stage I	15	1	6.227	0.101
	stage II	26	4		
	stage III	20	10		
	stage IV	60	14		
Lymph node metastasis	no lymph node metastasis	44	8	0.769	0.372
	with lymph node metastasis	77	21		
Distant metastasis	no distant metastasis	91	21	0.096	0.756
	with distant metastasis	30	8		
Pathological types	neuroendocrine carcinoma	1	0	1.072	0.883
	adenocarcinoma	110	26		
	signet-ring cell carcinoma	6	2		
	adenocarcinoma + signet-ring cell carcinoma	4	1		

Table 3. Comparison of TEG and CCT parameters between the gastric cancer group and the control group.

Characters	Gastric cancer group (n = 150)	Control group (n = 150)	T	p
R (5 - 10 minutes)	4.10 ± 0.38	6.60 ± 0.88	-31.844	0.000
K (1 - 3 minutes)	1.22 ± 0.38	1.99 ± 0.35	-18.338	0.000
α-angle (53 - 72)	71.97 ± 4.99	62.12 ± 4.31	18.274	0.000
MA (50 - 70mm)	64.17 ± 7.38	58.02 ± 3.58	9.171	0.000
PT (10 - 14 seconds)	11.80 ± 0.89	11.60 ± 0.61	2.246	0.026
APTT (20 - 40 seconds)	26.63 ± 2.40	27.13 ± 1.82	-2.081	0.038
Fib (2 - 4g/L)	2.99 ± 0.78	2.55 ± 0.35	6.258	0.000
D-D (0 - 0.55mg/L)	1.02 ± 1.02	0.35 ± 0.25	7.860	0.000
PLT (100 - 300 × 10^9/L)	269.96 ± 88.43	244.33 ± 53.28	3.040	0.003

Table 4. Results for relevant factors in logistic regression for gastric cancer patients.

	B	S.E.	Wald	p	OR	95% CI
***R* (minutes)**	**-1.276**	**0.622**	**4.201**	**0.040**	**0.279**	**0.082 - 0.946**
***K* (minutes)**	**-4.473**	**1.13**	**15.674**	**0.000**	**0.011**	**0.001 - 0.104**
α-Angle	**0.186**	**0.055**	**11.328**	**0.001**	**1.204**	**1.081 - 1.342**
MA (mm)	**0.384**	**0.068**	**32.087**	**0.000**	**1.468**	**1.285 - 1.677**
PT (seconds)	**0.452**	**0.213**	**4.518**	**0.034**	**1.572**	**1.036 - 2.386**
APTT (seconds)	**-0.045**	**0.087**	**0.272**	**0.602**	**0.956**	**0.806 - 1.133**
Fib (g/L)	**0.555**	**0.268**	**4.296**	**0.038**	**1.743**	**1.031 - 2.946**
D-D (mg/L)	**0.721**	**0.207**	**12.127**	**0.000**	**2.057**	**1.371 - 3.086**
PLT ($\times 10^9$/L)	**0.002**	**0.002**	**0.819**	**0.365**	**1.002**	**0.998 - 1.007**

Table 5. Prediction value of different indexes on thrombosis for patients with gastric cancer.

	Area under curve	Sensitivity	Specificity	Optimal threshold	p	95% CI	Youden index
***R* (minutes)**	**0.648**	**0.897**	**0.512**	**4.2**	**0.013**	**0.554 - 0.742**	**0.409**
***K* (minutes)**	**0.779**	**0.862**	**0.612**	**1.2**	**0.000**	**0.699 - 0.858**	**0.474**
α-Angle	**0.729**	**0.690**	**0.727**	**74.5**	**0.000**	**0.623 - 0.835**	**0.417**
MA (mm)	**0.931**	**0.862**	**0.909**	**69.4**	**0.000**	**0.881 - 0.981**	**0.771**
PT (seconds)	**0.613**	**0.724**	**0.286**	**11.6**	**0.058**	**0.498 - 0.729**	**0.286**
Fib (g/L)	**0.602**	**0.517**	**0.777**	**3.42**	**0.088**	**0.468 - 0.737**	**0.294**
D-D (mg/L)	**0.582**	**0.379**	**0.934**	**2.09**	**0.172**	**0.439 - 0.724**	**0.313**
Combination	**0.952**	**0.828**	**0.950**	**-**	**0.000**	**0.913 - 0.990**	**0.778**

RESULTS

Analysis of general information

The gastric cancer group comprised 150 patients, and the control group had 150 healthy individuals. No statistically significant difference was observed between the two groups regarding age, gender, or ethnicity ($p > 0.05$) (Table 1). The patients in the gastric cancer group were divided into two groups, thrombus and non-thrombus, based on the presence or absence of venous thrombosis, respectively, during the diagnosis and treatment. The non-thrombus group had 121 patients, while the thrombus group had 29 patients. No statistically significant difference regarding age, gender, ethnic group, degree of invasion, lymph node metastasis, distant metastasis, and pathological types was observed among the members of the non-thrombus group ($p > 0.05$) (Table 2). In contrast to the control group, the gastric cancer group showed a reduction in the *R*- and *K*-values; an increase in the α-angle and MA values; an increase in the PT, Fib, D-D, and PLT values; and a slight decrease in APTT (Table 3). We conducted a logistic regression analysis on TEG and CCT indicators and identified R, K, α-angle, MA, PT, Fib, and D-D as statistically significant ($p < 0.05$). We believe that they can be considered risk factors for thrombosis in patients with gastric cancer (Table 4).

The ROC curve analysis showed areas under *R*, *K*, α-angle, MA, PT, Fib, and D-D curve. For more information, please see Table 5 and Figure 1. The ROC curve shows that *R*, *K*, α-angle, MA, PT, Fib, and D-D are closely related to the occurrence of thrombus. It can also be seen from the results that when a single index was used to predict thrombosis, the AUC of K, α-angle, and MA in TEG were all greater than 0.7. In contrast, in CCTs, MA was 0.931, while PT, Fib, and D-D were only approximately 0.6. Hence, the diagnostic value of TEG was higher than that of CCTs. The area under the curve of combined detection (i.e. when both TEG and CCTs were used) was 0.952 (95% CI: 0.913 - 0.990), the sensitivity was 0.828, and the specificity was 0.950. The diagnostic value of combined detection was significantly higher than that obtained using TEG and CCTs alone, suggesting that combined detection can improve the predictive value of thrombosis and can be used for clinical application.

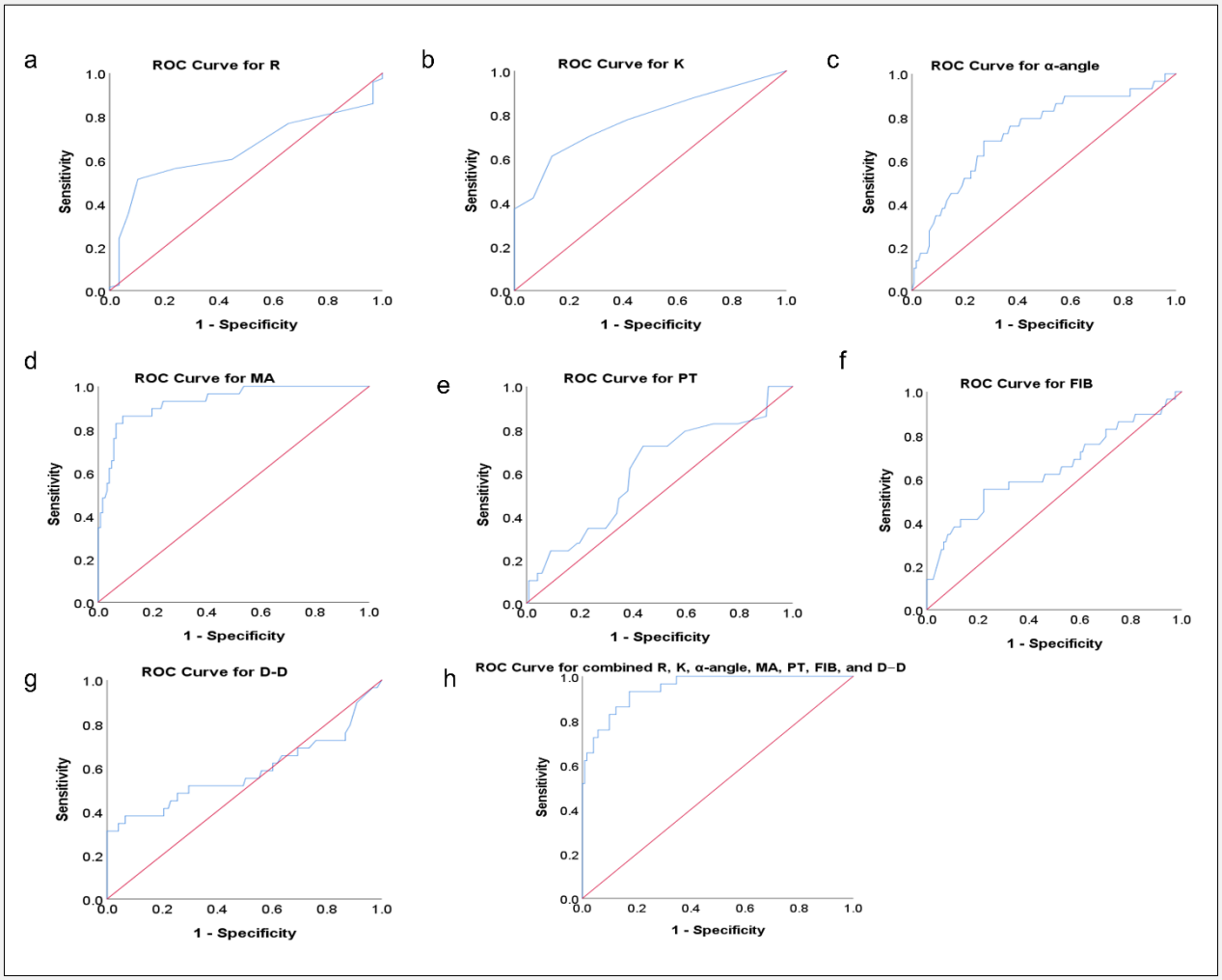

Figure 1. Receiver operating characteristic (ROC) curves for predicting thrombosis.

ROC curves for a - R, b - *K*, c - *α*-angle, d - MA, e - PT, f - Fib, g – D-D, and h - combined *R*, *K*, *α*-angle, MA, PT, Fib, and D-D.

DISCUSSION

Coagulation function in most cancer patients is affected by various factors, including both direct and indirect effects of tumor cells. In addition, these cytokines directly act on vascular endothelial cells and platelets, thereby disrupting the balance of the normal coagulation system in the human body [12]. Patients in the pre-thrombotic state often exhibit no obvious symptoms. Therefore, it is crucial to evaluate the coagulation status of patients with tumors using coagulation function-related tests for the timely detection of the hypercoagulable state of the blood and for prompt clinical intervention to improve the quality of life and survival period of such patients [13,14]. In addition, routine monitoring of the coagulation function in patients with gastric cancer should be conducted, and a reference range for relevant coagulation indicators should be established for preventing DVT complications and evaluating the prognosis of these patients [15].

This study explored differences in TEG and CCTs in patients with gastric cancer. TEG and conventional coagulation function testing operate on different principles. Hence, we suggest that the two testing methods should be used together to predict venous thrombosis, in order to improve the accuracy of the test results. We

analyzed the TEG test results and found that, compared with the control group, the *R*- and *K*-values of the gastric cancer group significantly decreased, while their MA value and *α*-angle significantly increased. The difference was statistically significant. In addition, we found that, compared with the control group, the gastric cancer group exhibited increased values for PT, FIB, D-D, and PLT and slightly decreased values for APTT. Patients with gastric cancer exhibited more significant changes in their blood hypercoagulability indicators and a more pronounced hypercoagulable state compared to the healthy control populations. However, we found prolonged PT in the gastric cancer group in routine CCTs, implying that the blood of such patients is hypocoagulable. This result is in contrast to the overall assessment, perhaps because the hypercoagulable state of blood in patients with gastric cancer is caused more by the hyperactivity of the extrinsic coagulation pathway. Compared with traditional CCTs, TEG uses whole blood as the test sample and tracks the entire process from the activation of the coagulation system, the formation of fibrin, to the formation of blood clots, excluding the role of blood vessels. Thus, TEG allows for a more comprehensive expression of the entire coagulation state and can be used to monitor the complete coagulation process of patients [16].

The diagnostic value of thrombus was evaluated by TEG and CCT indexes for the two groups of patients. The logistic regression analysis showed that *R*, *K*, *α*-angle, MA, PT, FIB, and D-D were statistically significant risk factors for venous thrombosis. The receiver operating characteristic (ROC) results showed that the prediction levels of *R*, PT, Fib, and D-D for patients with gastric cancer were poor (AUC 0.5 - 0.6); those of *K* and *α*-angle for venous thrombosis were general (AUC 0.7 - 0.8); and those of MA for venous thrombosis were good (AUC 0.9 - 1). The MA value can be used to determine the strength and hardness of blood clots and is used to understand the overall clotting ability of blood. The reduction of the MA value is mainly used to calculate the number and function of platelets. The MA value is a comprehensive index that reflects the effects of all components involved in the formation of blood clots, such as platelet number and function, fibrinogen, fibrin, the functional state of platelet GPIIb/IIIa receptor, and the activity of factor XIII [17]. When all indicators were detected simultaneously, the area under the curve of the combined detection became 0.952 (95% CI: 0.913 - 0.99). Each indicator made up for the lack of sensitivity and specificity. Consequently, the area under the ROC of the predictor, which had the largest area under the curve, improved and became significantly higher than that achieved when only one method was used for the detection. The MA value plays a crucial role in the formation of blood clots. Although it has very high sensitivity, its specificity was slightly lower than combined detection, and the possibility of false positives and the sensitivity of combined detection were higher than those achieved when only one method was used for the detection. Hence, the combined detection method could allow for a better prediction of the risk of thrombosis. Hence, it can be suggested that when the combined detection indicators of TEG and CCTs reach the threshold, a double lower limb arteriovenous Doppler ultrasound examination should be conducted as soon as possible to diagnose thrombosis. In contrast, for low-risk patients, if there is no obvious indication, the aforementioned ultrasound examination can be skipped for the time being. Compared with the vascular Doppler ultrasound examination, the indicators included in the predictive factors allow convenient detection. Consequently, the patient action can be left out.

In summary, both methods (TEG and CCTs) can be used to assess the coagulation function of patients. TEG can detect the coagulation and fibrinolysis functions. In CCTs, the corresponding reagents are added to the isolated plasma. Each CCT indicator only reflects a part of the entire coagulation process, which limits the predictive ability of receiver operating characteristics in predicting the venous thrombosis stage in patients.

Numerous studies have discussed the clinical significance of TEG in patients with malignant tumors. TEG has shown that many patients with malignant tumors exhibit a high coagulation status, although traditional CCTs do not show any abnormality in the indicators. In such patients, changes in APTT, PT, D-dimer, Fib, and other CCT indicators are often not obvious [17,18]. Notably, TEG can detect coagulation abnormalities that cannot be detected by routine CCTs. Therefore, clinical workers should refer to clinical symptoms, along with the patient diagnosis and treatment history, to comprehensively analyze the coagulation status of the patient. The comprehensive test results help doctors reasonably choose blood products to improve the coagulation function, use drugs for anticoagulant treatment, timely improve the coagulation function, and reduce the risk of thrombosis in patients [19,20].

Our study has also several limitations: We included only those patients with gastric cancer who did not have any other disease to avoid interference with our results. Hence, the scope of this study is relatively limited. Future studies should be conducted using a larger survey scope across multiple regions and disciplines to better analyze the coagulation function of patients with gastric cancer. If we can collaborate with multiple institutions for research, establish a broad reference range for conducting TEG along with CCTs, and collect more epidemiological and laboratory monitoring data, we may be able to identify and study more risk factors for the timely detection of venous thrombosis in patients with gastric cancer.

Establishing the relationship between the coagulation system and malignant tumors can help in developing more risk-assessment models for such patients [21,22]. This not only has a clinical value in predicting the occurrence of venous thrombosis complications in patients, but also in predicting the prognosis of patients. Consequently, doctors can better understand the coagu-

lation status of patients and carry out the corresponding symptomatic treatment, which will improve the survival period of such patients.

Patients with gastric cancer exhibit a more pronounced blood hypercoagulability status than those in healthy controls. *R*-value, *K*-value, *α*-angle, MA, PT, Fib, and D-D are closely related to the occurrence of venous thrombosis. TEG and CCTs can be used together for a more comprehensive evaluation of the blood hypercoagulability status of patients with gastric cancer, detect abnormal blood coagulation function in time, and better predict the risk of venous thromboembolism. These findings could not only enhance the early identification of gastric cancer-related VTE but also contribute to providing new strategies to improve long-term survival for patients.

Ethical Approval Statement:

This study was approved by the Medical Ethics Committee of the Affiliated Cancer Hospital of Xinjiang Medical University (K-2024013). All methods were carried out in accordance with the Declaration of Helsinki.

Consent to Participate:

Patients were not required to give informed consent to the study, because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

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Data Availability Statement:

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of Interest:

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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