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Original Article

Association between thrombelastography system and thromboembolic and bleeding events in Chinese aged people

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Abstract: Objectives: This study was designed to obtain the knowledge about TEG indexes distribution in Chinese aged people, as well as to test the hypothesis that previous TEG indexes are associated with the subsequent thromboembolic and bleeding events in the aged population. Methods: We conducted a two-year follow-up study in Chinese PLA General Hospital, Beijing, China. 403 aged people were enrolled in our study. They received TEG measurements at least once when they entered this study. We collected their demographical characteristics, clinical examination information and their outcome during their observational period. Structural equation modeling (SEM) was used to analyze the relationship between the four indexes from TEG and the outcome via a pathway of indicator. Results: We found that in the "model of bleeding" (adjusted by confounding of Anticoagulants), the model fit indices with chi-square/df = 9.555/7, CFI was 0.997, TLI was 0.994 and standardized root mean square residual (SRMR) was 0.034; while in the "model of thromboembolic events" (adjusted by confounding of Anticoagulants), the model fit indices with chi-square/df = 6.070/7, CFI was1.000, TLI was 1.002 and standardized root mean square residual (SRMR) was 0.000. The "model of thromboembolic events" showed that the four indexes (R, K, MA and ANGLE) were all significantly associated with thromboembolic events, while this significance was not found in the "model of bleeding". Conclusions: Previous TEG indexes are significantly associated with the subsequent thromboembolic events in the aged population. Future study can test this association and provide more information for the clinical use.

Keywords: Thrombelastography (TEG), thromboembolic event, bleeding, Chinese aged population, structural equation modeling (SEM)

Introduction

Cardiovascular disease (CVD) remains the biggest cause of deaths worldwide. More than 17 million people died from CVD in 2008, and the number will be up to almost 23.6 million by the year of 2030 [1]. In addition to causing significant mortality and morbidity, CVD is responsible for a very large portion of medical spending. CVD accounts for the most annual hospital discharges of the 10 leading diagnostic groups 96.2 million in 2006) [2]. Over the last two decades, 80% of CVD mortality occurred in low- and middle-income countries, suggesting that this disorder has become a leading threat to public health in most of the developing countries [3].

It has long been acknowledged that increasing age is one of the strongest risk factors for the development of CVD. The prevalence of CVD increases with age, from 15% in men and 9% in women aged 20-39 years to 79% in men and 85% in women aged 80+ years [2]. Thus, finding some indexes that can indicate subsequent thromboembolic and bleeding events in the elderly are of paramount importance from both the individual and societal perspectives to reduce the disease burden in coming decades.

Routine coagulation tests (eg., aPTT, PT, TT) indicate the time of fibrin formation through the intrinsic and extrinsic pathways of the coagulation cascade. However, their performance in plasma rather than whole blood limits their rel-

evance to overall dynamic clot formation in whole blood. And coagulation is a dynamic process in which many factors are involved. Routine coagulation tests provide limited information about the quality of clots because they identify only the first stage of clotting [4].

In contrast, thrombelastography (TEG; Haemoscope, USA) provides a comprehensive assessment of coagulation function instead of evaluating only discrete portions. By measuring the viscoelastic changes that occur during the hemostatic process, TEG gives a real-time functional evaluation of the coagulation cascade, beginning with initial platelet-fibrin interaction, through platelet aggregation, clot strengthening and fibrin cross-linkage and eventually clot lysis [5]. Since its first description in 1948 [6], the TEG has been successfully used in a diverse group of clinical settings [7]. The greatest use has been the application of TEG–guided transfusion of blood components in hepatic and more widely in cardiac surgery [8, 9]. Recent years have seen a renewed interest in the technology with applications for both pharmaceutical monitoring and patient screening being described [10].

Since TEG can detect hypercoagulable and hypocoagulable states, it is a potentially useful test for predicting abnormal bleeding and thromboembolic complications. Many studies designed to discuss the predictive value of single variable from TEG in postoperative or postpartum patients. However, most previous studies failed to demonstrate an association between four TEG variables and outcomes, lacked of a long-term observational time and few information about TEG in the elderly. Therefore, we designed a two-year follow-up study to obtain the knowledge about TEG variables distribution in Chinese aged population, as well as to test the hypothesis that previous TEG indexes are associated with the subsequent thromboembolic and bleeding events in the aged population.

Methods

Study setting

Our study was a two-year follow-up study. The institutional review board of Chinese PLA General Hospital approved this study. Chinese PLA General Hospital, located in Beijing, China, is the largest comprehensive level-3-Grade-A hospital in the army. It is well acknowledged as a modern medical institution with full range of medical service, health care, advanced medical education and powerful scientific research. It had a strong professional team of more than 3,600 staff members and received 2.5 million outpatients and over 80 thousand inpatients per year.

Selection of participants

Using the electronic medical record database of Chinese PLA General Hospital, we evaluated all elderly patients admitted between November 2007 and September 2011 who received TEG assessment. Patients who were younger than 65 years, lost before having clinical outcomes or full observational time, or incomplete medical records were excluded from this two-year follow-up study.

Data collection procedure

During the recruitment period, the results of TEG assessment would be recorded and the date of assessment would be considered as baseline time point of this study. Patients' demographical characteristics and thromboembolic disease history would also be recorded at baseline. Then we followed-up these patients, obtained their details of anti-platelet agent or anticoagulant usage, long-term bed rest information and observed them every time when they received hospital care or outpatient service to check whether they suffered thromboembolic or bleeding events (defined as follows). Once the subjects had clinical outcomes, we stopped following and wrote it down; Otherwise, the follow-up would be ended after the two-year observational period.

Definitions and outcomes

In our study, there were three outcomes of the subjects: thromboembolic events, bleeding events and normal. Thromboembolic events included MI, ischemic stroke, DVT, and PE. New onset MI was assessed using the Joint European Society of Cardiology/American College of Cardiology definition [11], electrocardiogram and troponin. DVT was diagnosed based on new clinical findings resulting in changes in treatment and positive venous duplex ultrasound scanning. PE was diagnosed based on clinical findings along with pulmonary computed tomography (CT) angiography.

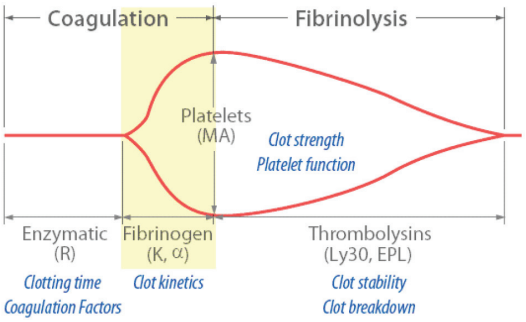

Figure 1. Diagrammatic representation of a TEG traces indicating the commonly reported variables.

Ischemic stroke was confirmed after clinical findings with head CT or nuclear magnetic resonance. The bleeding events included hematuria, GI bleeding, surgical wound bleeding, oral hemorrhage, nasal hemorrhage, purpuras and petechias, which were evaluated by direct observation, microscopic detection and occult blood test. Normal populations were defined as suffering neither of the two events mentioned above at the end of the observational period.

Laboratory setting and processing of specimens

All TEG specimens were run on Thromboelastograph Analyzer 5000 (Haemoscope Corp., IL). Blood was incubated at 37°C in a heated cup. Within the cup was suspended a pin connected to a detector system. This was a torsion wire in the case of TEG. The cup and pin were oscillated relative to each other through an angle of 4°45´. The movement was initiated from the cup. As fibrin formed between the cup and pin the transmitted rotation from the cup to pin was detected at the pin and a trace (**Figure 1**) generated at once with on-line analysis (TEG Analytical Software: Version 4.2.101 2006).

Staff laboratory technicians in the Chinese PLA General Hospital performed all the TEG and standard during the defined study period. They conducted TEG testing according to standard protocols and performed all the quality controls on the TEG analyzers every 8 hours.

Measurements

The r value (reaction time) (normal range, 2-8min) reflects the time for fibrin formation. This is the time taken from the beginning of the trace until it reaches an amplitude of 2 mm. R value is prolonged in the presence of factor deficiencies, systemic anticoagulation and thrombocytopenia. The k value (coagulation time) (normal range, 1-3min) represents the time taken for the amplitude to widen from 2 to 20 mm. K is dependent on fibrinogen and platelets. The alpha angle (normal range, 55-78 degrees) is the slope of the tracing that represents the rate of clot formation, increasing with hyperfibrinogenemia or increased platelet aggregation. The maximal amplitude (MA) (normal range, 51-69mm) is the greatest amplitude of the tracing and reflects platelet contribution to clot strength. High MA values correspond with states of platelet hypercoagulability.

Statistical analysis

Statistical analysis on characteristic of study populations across groups was performed by one-way analysis of variance for continuous data and chi-square for categorical data. All statistical tests were two tailed with $p<0.05$ set as significant. SAS software (SAS institute Inc., Cary, North Carolina) was used for analysis.

Structural equation modeling (SEM) was used to analyze the association between baseline TEG indexes and subsequence outcomes. SEM is a very general, very powerful multivariate analysis technique. The strength of this approach is that it quantifies the amount of variance in indicators due to the latent construct versus error or unreliability. Accounting for error variance creates factors that are mathematically perfectly reliable, which increases the statistical power of the overall analysis. SEM also allows researchers to test complex relationships between multiple factors and indicators at once. In addition, the fit of one model can also be compared with the fit of alternative models to determine which one best reflects the data. Mplus 6.0 and logistic SEM were also employed for the analyses of structural equation modeling.

Results

Demographic and baseline data

A total of 403 aged people met our inclusion criteria and participated in this study. Of these, 92.6% was male and 7.4% was female. The average of their age was 83.0 years old. We found 25 (6.2%) of them were end up with bleeding and 78 (19.4%) of them were end up

Table 1. Demographic and clinical characteristic of study subjects between different outcome groups

Variable		outcome			
		Normal	Bleeding	Thromboembolic	X^2 or F (P)
Number		300	25	78	
Age, mean (sd)		82.2 (7.4)	86.9 (7.7)	84.9 (5.7)	8.467 (0.0003)
Gender					0.3622 (0.8344)
Male (%)		279 (93.0)	23 (92.0)	71 (91.0)	
Female (%)		21 (7.0)	2 (8.0)	7 (9.0)	
Long-term bed rest[#]					105.894 (<0.0001)
No (%)		281 (93.7)	6 (24.0)	52 (66.7)	
Yes (%)		19 (6.3)	19 (76.0)	26 (33.3)	
Anticoagulants[*]					3.698 (0.157)
No (%)		59 (19.7)	2 (8.0)	10 (12.8)	
Yes (%)		241 (80.3)	23 (92.0)	68 (87.2)	
thromboembolic disease history[&]					15.8972 (0.0004)
No (%)		202 (67.3)	18 (72.0)	34 (43.6)	
Yes (%)		98 (32.7)	7 (28.0)	44 (56.4)	
type 2 diabetes history					3.0487 (0.2178)
No (%)		164 (54.67)	18 (72.0)	46 (58.97)	
Yes (%)		136 (45.33)	7 (28.0)	32 (41.03)	
hypertension history					10.1413 (0.0063)
No (%)		73 (24.33)	12 (48.00)	29 (37.18)	
Yes (%)		227 (75.67)	13 (52.00)	49 (62.82)	
angina pectoris history					7.2414 (0.0268)
No (%)		80 (26.67)	10 (40.00)	32 (41.03)	
Yes (%)		220 (73.33)	15 (60.00)	46 (58.97)	
atrial fibrillation history					3.5015 (0.1736)
No (%)		266 (88.67)	19 (76.00)	69 (88.46)	
Yes (%)		34 (11.33)	6 (24.00)	9 (11.54)	
arrhythmia history					2.2137 (0.3306)
No (%)		207 (69.00)	19 (76.00)	60 (76.92)	
Yes (%)		93 (31.00)	6 (24.00)	18 (23.08)	
baseline TEG	R, mean (sd)	6.8 (2.0)	7.3 (2.3)	6.3 (1.6)	3.592 (0.0284)
	K, mean (sd)	1.9 (0.8)	2.0 (0.7)	1.7 (0.6)	2.981 (0.0519)
	MA, mean (sd)	60.2 (5.7)	59.8 (7.7)	61.7 (6.9)	2.055 (0.1294)
	ANGLE, mean (sd)	59.1 (10.4)	61.7 (8.4)	62.2 (8.8)	3.295 (0.0381)

[#]The patients who stayed in bed more than one year in our study can be defined as "long-term bed rest". [*]The patients who took anticoagulants during most of our study time could be defined as "yes" in the variable of "anticoagulants". The anticoagulants included aspirin, ticlopidine, clopidogrel, prasugrel, eptifibatide, tirofiban, abciximab, warfarin, heparin, low- molecular weight heparin. [&]Thromboembolic disease history included old myocardial infarction and old lacunar cerebral infarction.

Table 2. Characteristics of TEG indexes

	mean	sd	min	max	median
R	6.741	1.9648	2.5	21.8	6.600
K	1.895	0.7383	0.8	8.8	1.800
MA	60.460	6.1277	27.5	78.4	60.700
ANGLE	59.893	10.0910	15.1	79.7	61.600

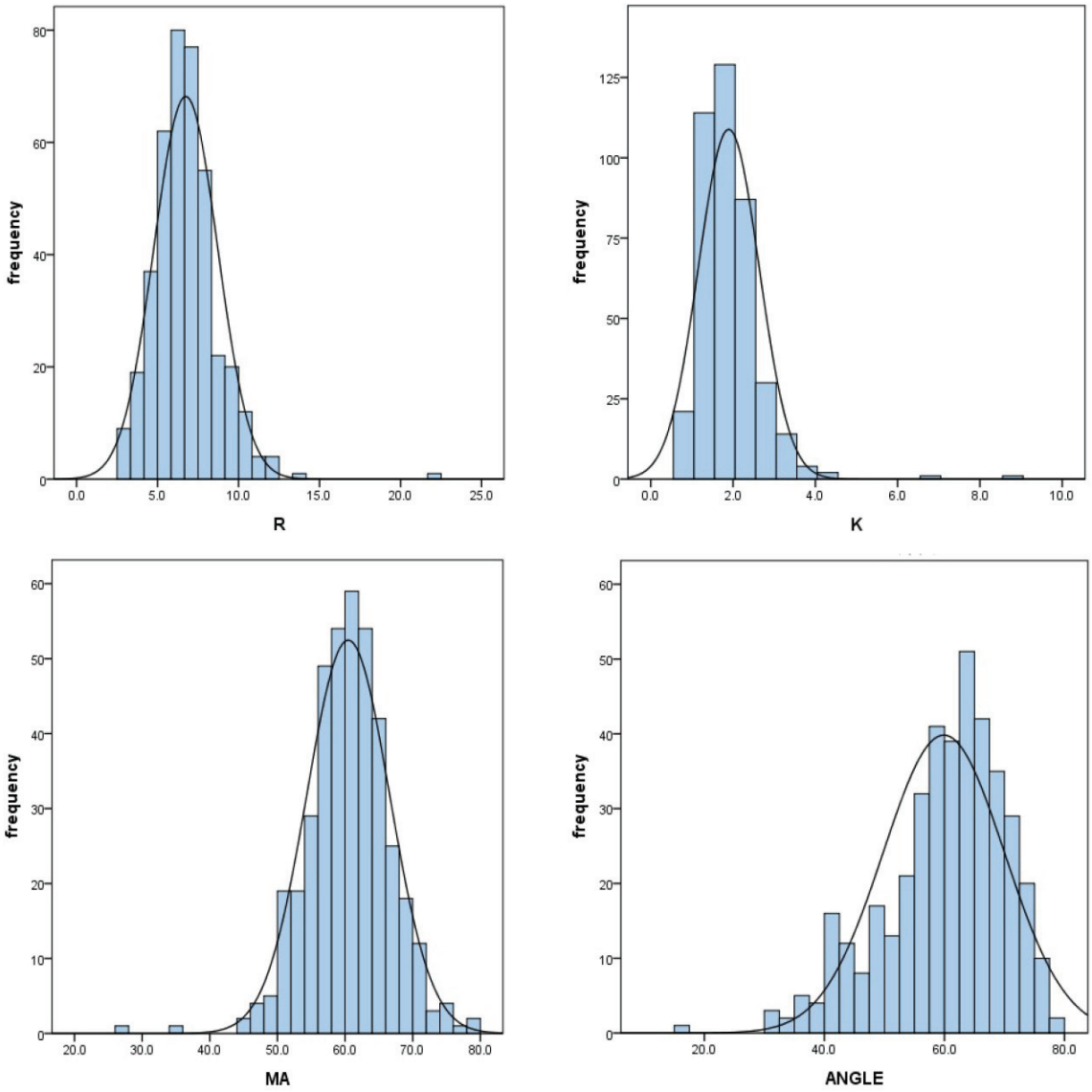

Figure 2. The distribution of four TEG indexes in Chinese aged population.

with thromboembolic events. 300 (74.4%) participants did not suffer any thromboembolic or bleeding events. According to their clinical outcomes, we divided the people into three groups: normal group, bleeding group and thromboembolic group. The differences between the three groups were compared by analysis of variance in relation to the age, the four indexes and chi-square test was used for gender, long-term bed rest, medicine and disease history variables. As indicated in **Table 1**, there were significant differences between the three groups in age, long-term bed rest, hypertension history, angina pectoris history and thromboembolic disease history variables. What's more, there were also difference between groups in the three TEG indexes, R, K and ANGLE.

The distribution of TEG indexes in Chinese aged population

After the test of normality, the four TEG indexes obey to the normal distribution in Chinese aged population. The details of the distribution were showed below (**Figure 2** and **Table 2**).

Structural equation modeling

Since each of the four TEG variables has correlation with others and it just reflects partial of hemostatic process, we decided to use struc-

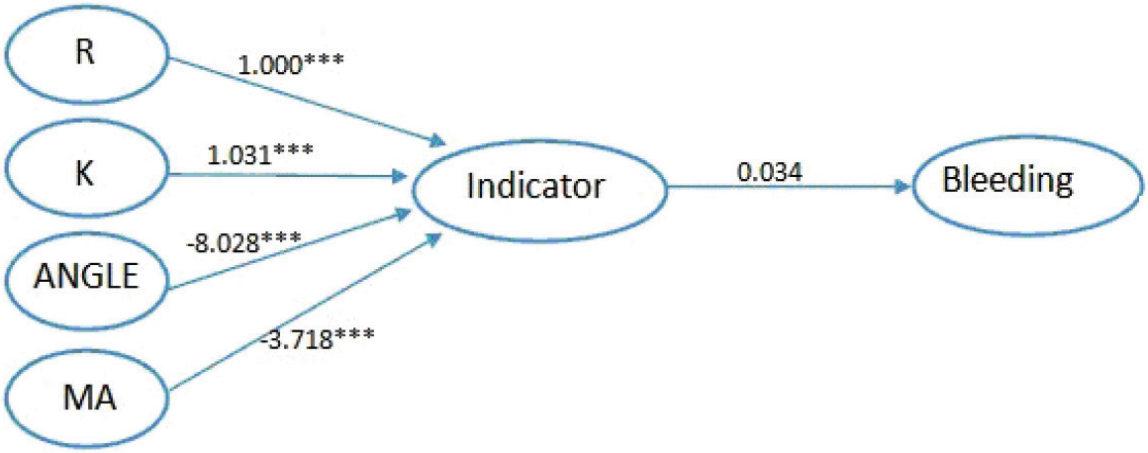

Figure 3. Model 1 Relationship between the four indexes and bleeding. ***All paths are statistically significant (P<0.001).

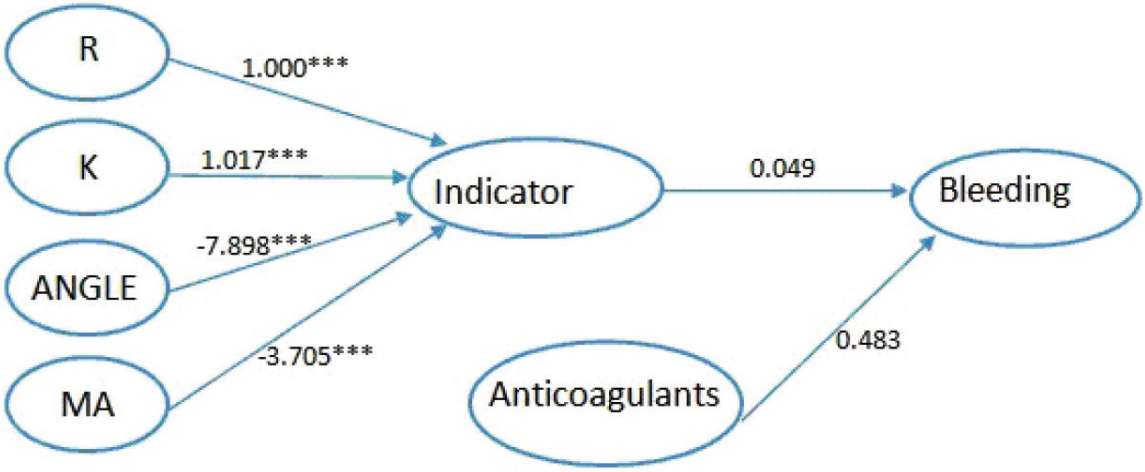

Figure 4. Model 2 Relationship between four indexes and bleeding adjusted by confounding of Anticoagulants. ***All paths are statistically significant (P<0.001).

tural equation modeling to control their correlation and put them together to make a comprehensive evaluation.

The pathway from the four indexes to outcome was further analyzed by SEM modeling. Model 1 focused on the outcome of bleeding. We integrated the information provided by the four indexes, controlled their own correlations and built the model in order to find the association between the four indexes and the outcome of bleeding. In **Figure 3**, it could be seen that the four indexes all significantly built a great contribution to the indicator. The estimated level through R was 1.000 (P<0.001), 1.031 (P<0.001) through K, -8.028 (P<0.001) through ANGLE and -3.718 (P<0.001) through MA. The model fit indices with chi-square/df = 4.759/3, CFI was 0.998, TLI was 0.994 and standardized root mean square residual (SRMR) was 0.042, indicating an excellent model fit (**Table 3**). In consideration of the age and anticoagulant variables might have an effect on the outcome, we added the variable into our model step by step to find a better model. Finally, we added the anticoagulant variable into our model to build the model 2. In **Figure 4**, the model fit indices with chi-square/df = 9.555/7, CFI was 0.997, TLI was 0.994 and standardized root mean square residual (SRMR) was 0.034. Model 2 suggested that all indexes in TEG had significant effects on the variable of indicator.

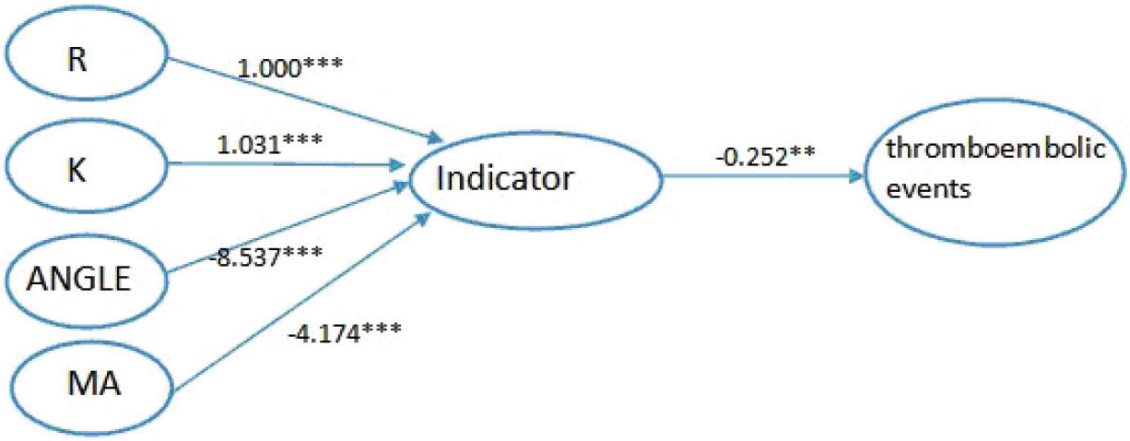

Figure 5. Model 3 Relationship between four indexes and thromboembolic events. ***All paths are statistically significant (P<0.001), **P<0.01.

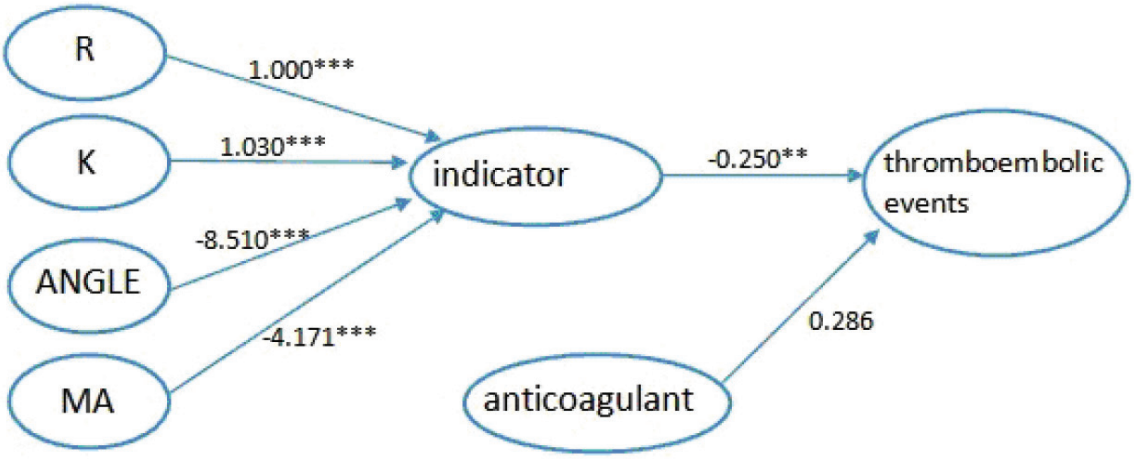

Figure 6. Model 4 Relationship between four indexes and thromboembolic events adjusted by confounding of Anticoagulants. ***All paths are statistically significant (P<0.001), **P<0.01.

But when synthesized them in one variable (indicator), there showed no significant association between them (**Table 4**).

Further, we focused on the outcome of thromboembolic events to build another model. We used the same method as above. Firstly, we constructed the model 3 to show the relationship between the four indexes and the outcome, thromboembolic events. As showed in **Figure 5**, the estimated level through R was 1.000 (P<0.001), 1.031 (P<0.001) through K, -8.537 (P<0.001) through ANGLE and -4.174 (P<0.001) through MA. The model fit indices with chi-square/df = 2.922/3, CFI was 1.000, TLI was 1.000 and standardized root mean square residual (SRMR) was 0.000 (**Table 5**).

Next, we added the variables mentioned before to get a better model. The last, we got the model 4 with anticoagulants variable added. In **Figure 6**, it could be seen that indicator was significantly related to thromboembolic events (estimate=-0.250; t ratio=-3.013; P value= 0.003).The model fit indices with chi-square/df = 6.070/7, CFI was 1.000, TLI was 1.002 and standardized root mean square residual (SRMR) was 0.000, indicating an excellent model fit and a significant relationship between indicator and thromboembolic events (**Table 6**).

Discussion

TEG provides a comprehensive evaluation of the viscoelastic properties of blood, generating

Table 3. Path way from four indexes to bleeding

Path	Estimate	SE	T ratio	*P*-value
R-indicator	1.000	0.000		
K-indicator	1.031	0.109	9.441	<0.001
ANGLE- indicator	-8.028	0.772	-10.632	<0.001
MA-indicator	-3.718	0.181	-20.552	<0.001
Indicator-bleeding	0.034	0.107	0.319	0.750

Table 4. Path way from four indexes to bleeding adjusted by confounding of Anticoagulants

Path	Estimate	SE	T ratio	*P*-value
R-indicator	1.000	0.000		
K-indicator d	1.017	0.106	9.576	<0.001
ANGLE-indicator	-7.898	0.751	-10.518	<0.001
MA-indicator	-3.705	0.182	-20.308	<0.001
Indicator-bleeding	0.049	0.104	0.472	0.637
anticogulants-bleeding	0.483	0.330	1.462	0.144

Table 5. Path way from four indexes to thromboembolic events

Path	Estimate	SE	T ratio	*P*-value
R-indicator	1.000	0.000		
K-indicator	1.031	0.095	10.816	<0.001
ANGLE-indicator	-8.537	0.822	-10.385	<0.001
MA-indicator	-4.174	0.175	-23.829	<0.001
Indicator- thromboembolic events	-0.252	0.084	-3.012	0.003

Table 6. Path way from four indexes to thromboembolic events adjusted by confounding of Anticoagulants

Path	Estimate	SE	T ratio	*P*-value
R-indicator	1.000	0.000		
K-indicator	1.030	0.096	10.728	<0.001
ANGLE-indicator	-8.510	0.814	-10.458	<0.001
MA-indicator	-4.171	0.176	-23.651	<0.001
indicator-thromboembolic events	-0.250	0.083	-3.013	0.003
anticoagulants-thromboembolic events	0.286	0.202	1.416	0.157

a complete analysis of the clotting mechanisms from thrombin activation to fibrinolysis. Our study included 403 aged people who were followed over a two-year period, which is the first time to demonstrate a significantly statistical association between four TEG indexes, R, K, ANGLE and MA, and thromboembolic and bleeding events in the aged population.

Theoretically, hypercoagulability has been implicated in the pathogenesis of thrombotic complications, including MI, DVT, PE, ischemic stroke, and vascular graft thrombosis. Despite the limitation that TEG cannot specify the mechanism for hypercoagulable states, it has shown a promising ability to detect known or established hypercoagulable states during pregnancy and postpartum [12-14] or during the presence of cancer [15]. It has been increasingly used in the assessment of postoperative hypercoagulability for a variety of surgical procedures including neurosurgery [16], orthopedic surgery [17] and abdominal surgery [18, 19]. Furthermore, TEG assays can assess coagulopathy, platelet dysfunction, and hyperfibrinolysis at an early posttraumatic stage and

suggest more effective interventions [20]. Wilson performed TEG every other day in 250 patients having undergone proximal femoral fracture repair and showed that patients suffering from postoperative DVT had a significantly higher level of hypercoagulability as measured by TEG than did those who did not suffer DVT [19]. A study by Traverso included 100 patients undergoing selective abdominal surgery, and in the patients randomized to receive no postoperative heparin thromboprophylaxis, TEG MA value showed the ability to predict the occurrence of DVT with a sensitivity of 72.2% and specificity of 69% [21]. McGrath concluded that TEG MA predicted postoperative thrombotic complications including MI more significantly than the traditional Goldman risk score [22]. However, the accuracy of TEG in predicting thromboembolic events is still in doubt in some studies [19, 23, 24]. In our study, we documented 36 of the 403 study aged (8.93%) as exhibiting a hypercoagulable state or borderline TEG results. A total of 11 patients (13.8%) who suffered a thromboembolic event (MI, *n*=5; DVT, *n*=3; Cerebrovascular Accident, *n*=3) were predicted by prior TEG hypercoagulability as manifested by increased MA. 65 patients with normal TEG MA value had an thromboembolic event (MI, *n*=25; DVT, *n*=23; PE, *n*=1; cerebrovascular accident, *n*=16). Therefore, only used MA to detect subsequence thromboembolic events was not appropriate, the structural equation modeling showed that four TEG variables were all associated with thromboembolic events.

There are limitations in our study. Firstly, as this is a medical record database study, although we have tried our best to collect the comprehensive data available for us, maybe still some potential variables are been neglected. Another limitation is that this study was conducted in one hospital with the sample size of 403 subjects. Our conclusion should be tested in future multicenter, prospective, longitudinal studies.

In conclusion, in this study, we used structural equation modeling to show the association between Thrombelastography System and Thromboembolic and Bleeding Events in Chinese Aged People. For the first time, as far as we know, we have demonstrated this significantly statistical association. Besides, this study can make contribution and point out the direction of future studies.

We are interested in developing subsequent study to validate a predictive model of thrombotic and bleeding events based on TEG indexes in the aged people. More investigations are necessary to assess the utility of TEG to monitor thromboprophylactic treatment and define optimal treatment strategies for the aged population to improve the safety and efficacy of antithrombotic strategies in the aged population. In summary, TEG is nonetheless a valuable tool for assessing the occurrence of thromboembolic events in the aged people.

Conflict of interests

We certify that none of the authors has any financial (e.g., employment, consultancies, honoraria, stock ownership or options, grants, contracts, patents, or royalties) or scientific involvement or conflicts of interest with any organizations or materials discussed in the manuscript.

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