Hospital-related factors associated with venous thromboembolism incidence in pregnancy: a national survey in China

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Abstract

Objective: We aimed to investigate the venous thromboembolism (VTE) status in China, and identify the hospital organizational factors that affect VTE incidence. Design: Retrospective study. Setting: Online survey to evaluate hospital-related factors associated with VTE. Population or sample: Hospital-related general data, and those on system and strategy, diagnosis and treatment, and patient education were collected. Methods: T-tests and analyses of variance were performed to determine whether hospital-related factors were associated with VTE incidence. Main outcome measures: VTE incidence. Results: Totally, 113 hospitals were included. Of 770,828 deliveries, VTE was observed in 526: 423 cases with deep vein thrombosis (DVT), 103 with pulmonary embolism (PE), and three with maternal death due to VTE. Higher prevalence rates of DVT and PE were observed in tertiary hospitals (P<0.001), general hospitals (P=0.006), hospitals with a Cesarean section performance rate >50% or <30% (P<0.001). Women in hospitals with a higher Cesarean section performance rate (relative risk [RR]=1.6), and that did not have emergency transfer facilities (RR=10.6) or early mobilization implementation (RR=1.6) showed a significantly higher risk of DVT. Those in hospitals that did not use B ultrasound of the lower extremity vein (RR=1.4) and anticoagulants (RR=1.2), and did not implement early mobilization after vaginal (RR=1.3) and Cesarean section delivery (RR=1.1) had an increased PE risk. Conclusions: Large hospital-related variations were shown in the incidence of thromboembolism in pregnancy, significantly influenced by hospital-related characteristics and diagnostic competency. Improved patient education levels and VTE treatment availability are vital to reducing the VTE-related maternal mortality and morbidity risk.

1. Introduction

Thromboembolism in pregnancy is among the leading causes of maternal morbidity and mortality, worldwide [1-4]. In pregnant women, venous thromboembolism (VTE) presents as deep vein thrombosis (DVT) or pulmonary embolism (PE). It is well recognized that pregnancy increases the risk of thromboembolism under conditions of hypercoagulability, decreased mobility, and compression of the inferior vena cava and pelvic veins. In recent decades, VTE has become a leading cause of sudden death, accounting for 15-30% of all maternal deaths in the United States and other Western countries [5-6]. Therefore, VTE in pregnancy is an emerging health issue, and there is an urgent need to estimate its prevalence profile.

The reported incidence of thromboembolism in pregnancy greatly varies. Across different hospital settings, the rate of VTE diagnosis ranged from 1 in 500 to 2,000 pregnancies in the United States [7-8]. Hospital organizational factors such as VTE prevention, diagnosis and treatment potentially affect the disease's incidence in pregnant women. With the use of proper preventive mechanical prophylactic devices and anticoagulants for high-risk pregnant women, the rate of maternal death due to thromboembolic disease had declined from 14.8% in 2006 to 3.2% in 2014 [9-10]. Additionally, considering the fact that there is an overlap between the symptoms of VTE and pregnancy, the early detection of VTE and the method used for the same influence the related diagnoses. Second, the incidence of VTE varies across different patient backgrounds: Asian women show a lower risk of VTE and death from VTE than black women in the United

States [11-12]. Third, the incidence values varied across different epidemiological studies. In a retrospective case-control study in United Kingdom, the incidence of VTE was 0.85 per 1000 pregnancies [13], while in a population-based cohort study in the United States, the incidence was 2 per 1000 pregnancies [14]. Thus, the incidence of VTE in pregnancy is influenced by hospital-related variations due to differences in the healthcare settings, diagnosis competency, and patient heterogeneity.

Given the marked diversity of hospital settings across China, we hypothesize that the incidence of thromboembolism in pregnancy significantly varies in different hospitals. In order to investigate the status of VTE in China, and identify hospital organizational factors affecting its incidence, we performed a hospital-based point prevalence survey in 113 hospitals throughout China.

2. Methods

2.1. Data sources

This cross-sectional survey collected data on thromboembolism in pregnancy from January 1 to December 31, 2019. Participating hospitals included those across all levels that provided maternal healthcare services in mainland China. Based on the Chinese national network of women's and children's health, a survey request was sent to the chief of the Department of Obstetrics of each hospital. Hospitals that completed the survey and signed informed consent before February 29, 2020 were enrolled for the final analysis, and those with missing data were excluded. The Institutional Review Board of the Obstetrics and Gynecology Hospital of Fudan University approved the project, and written informed consent was obtained from each participating hospital before enrollment.

2.2. Data collection

The participating hospitals completed the survey forms, and all data were uploaded. This thromboembolism survey was designed to evaluate the hospital related factors of VTE within Donabedian's framework [15-16]. It covered the following aspects: basic information on the obstetrician who filled the survey, hospital-related characteristics, hospital system and strategy, diagnosis and treatment in the hospital, and patient education. The chief of the Department of Obstetrics or senior physicians in each hospital submitted the survey questionnaire and VTE case report. Trained staff members, assigned for data quality control, telephoned the point of contact in the case of any queries.

The primary outcome of this survey was the number of cases and incidence of DVT, PE, and maternal death due to VTE. Hospital-related factors predominantly included: general information (hospital type, hospital characteristics, annual delivery, Cesarean section rate), hospital system and strategy (VTE management system, risk assessment scale, emergency transfer/consultation), diagnostic and treatment methods used in the hospital (D-dimer test, ultrasound of the lower extremity vein, computed tomography pulmonary angiography (CTPA), anticoagulants, and elastic stockings/compression devices), and patient education (education on health, and early mobilization and timing).

2.3. Statistical analysis

We used numbers and percentage to describe the incidence of DVT, PE, and maternal death due to VTE. Differences in the hospital-related characteristics were examined using $\chi 2$ tests. The association of hospital-related characteristics with DVT, PE, and maternal death due to VTE was analyzed by a T-test and analysis of variance (ANOVA). Statistical analyses were performed using SPSS version 26.0. Multiple imputation was considered appropriate as the number of missing values was low and could be predicted from the observed variables. One hundred simulated imputed datasets, each with 50 iterations, were generated and analyzed.

3. Results

3.1 General parameters of the enrolled hospitals

A total of 113 hospitals submitted the survey before February 29, 2020, and were included in the final analysis (Table 1). The baseline characteristics of the included and excluded hospitals were of no significance. The

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survey was completed and submitted by the chief of the Department of Obstetrics or senior physicians in each hospital; 80% of them were older than 40 years, 75% were associated physicians or above, and 53% had a Master's degree or above. Of the 113 enrolled hospitals, 79% (89) were tertiary hospitals, 20% (23) were secondary hospitals, and one was a primary hospital. As for the hospital-related characteristics, 63% (71) of the hospitals were general hospitals, and 37% (42) were specialized hospitals. The total number of deliveries in 2019 was 770,828, and the average Cesarean section rate was 42% (324,155).

3.2 Incidence of deep vein thrombosis, pulmonary embolism, and maternal death due to venous thromboembolism

Of the 770,828 deliveries, 526 VTE cases were noted. The proportion of DVT cases was 423, and its prevalence was 54.9 per 100,000 live births (95% confidence interval [CI]: 54.6, 55.1). For PE, the number of cases was 103, and its prevalence was 13.4 per 100,000 live births (95% CI: 13.3, 13.4). In addition, three cases of maternal death due to VTE were documented, and the rate of maternal death caused by VTE was 0.4 per 100,000 live births.

3.3 Association between hospital-related factors and deep vein thrombosis

In terms of the association with DVT, a higher rate of DVT was observed in general hospitals (P=0.006), and hospitals with a Cesarean section rate >50% or <30% (P<0.001). Unsurprisingly, hospitals with sufficient diagnostic methods, such as D-dimer tests, ultrasound of the lower extremity, and CTPA showed a higher DVT rate, while those with the use of anticoagulants and elastic stockings or compression devices in treatment showed a lower rate (P<0.001) (Fig 1). More importantly, hospitals with higher Cesarean section rates were at a higher risk of DVT (RR=1.6), and those that implemented early mobilization after vaginal delivery (relative risk [RR]=1.9) and Cesarean section (RR=1.8) showed a significantly lower rate (Table 2).

3.4 Association between hospital-related factors and pulmonary embolism

Of the 113 participating hospitals, a higher prevalence of PE was observed in the tertiary hospitals (P<0.001), general hospitals (P=0.006), and those with a Cesarean section rate >50% or <30% (P<0.001). Unsurprisingly, hospitals with adequate diagnostic/treatment strategies showed a higher PE rate (P<0.001) (Fig 2). Hospitals not using B ultrasound of the lower extremity vein (RR=1.4) and anticoagulants (RR=1.2) were at a higher risk of PE than those using them. Patients with early mobilization after vaginal delivery (RR=1.3) and Cesarean section (RR=1.1) showed a significantly increased PE incidence (Table 3).

4. Discussion

4.1 Main findings

In this hospital-based point prevalence survey conducted across 113 hospitals in China, we found significant hospital-related variations in the incidence of thromboembolism in pregnancy. Hospital-related factors, including the preventive system and strategy employed, diagnosis and treatment availability, and patient education significantly affected the prevalence of DVT, PE, and maternal death due to VTE. Therefore, further efforts must focus on strengthening the existing preventive strategies, improving diagnosis and treatment availability, and promoting the level of patient education in order to reduce the VTE-related maternal mortality and mobility.

4.2 Strengths and limitations

The main strength of this study was that it is the first nation-wide hospital-based survey to evaluate the VTE status in China that accounted for potential healthcare quality-related factors within hospitals, including their structure, process, and preventive and treatment strategies for VTE. Additionally, this survey covered alternative hospital-related factors that can be improved upon for the elimination of VTE risk. Thus, the findings are practical and indicate potential for clinical implementation. In addition, a T-test and ANOVA were used in the analysis of the association between VTE in pregnancy and hospital-related factors.

4.3 Interpretation

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In this hospital-based VTE survey, the incidence of VTE has covered in a nation-wide range. Based on the existing literature, the VTE prevalence was focused on targeted high-risk populations or on the regional rate. Moreover, due to the increasing application rate of diagnostic methods, the incidence was expected to be elevated. Therefore, it is necessary to investigate the status of VTE in China. In this study, we found that the average prevalence of DVT and PE was 54.9 and 13.4 per 100,000 live births, respectively, consistent with previous reports in the United States and European countries.

More importantly, the enhancement of hospital resource availability and patient education quality is beneficial in reducing the risk of VTE. We found that the presence of established preventive strategies, including the hospital management system and risk assessment, as well as emergency transfer were associated with a lower incidence of DVT and PE. Sufficient patient education levels were significantly associated with a lower risk of VTE in pregnancy, and were widely implemented in more than 80% of the hospitals. There is a need for the provision of detailed health-related education, especially in terms of early mobilization both after vaginal delivery and Cesarean section. These organizational and health promotion factors are adequately modifiable, and should be highlighted in other healthcare settings.

The presence of sufficient screening and diagnostic methods is expected to be correlated to a higher reported incidence of DVT and PE. D-dimer testing and ultrasound of the lower extremity vein were commonly performed and available in more than 90% of the enrolled hospitals in China. CTPA was available in 80% of the enrolled hospitals; however, emergent cases did not have access to the other 20% hospitals. In addition, the use of elastic stockings, compression devices, and anticoagulants, which were critical for effective VTE prevention and treatment, was not observed in all the hospitals. Therefore, a greater degree of attention should be paid to the promotion of the utilization of CTPA, elastic stockings, compression devices, and anticoagulants for the further elimination of the risk of VTE in pregnancy and the related maternal mortality.

This study has some limitations. First, the hospitals participating in this survey were mainly tertiary and secondary hospitals, and only one primary hospital was enrolled. The VTE status in primary hospitals requires further investigation. Second, this survey was based on a questionnaire, and the presence of potential reporting bias should be considered. This survey was completed by the department chief or senior physicians from the Department of Obstetrics from each hospital, which ensured the quality of the survey to some extent. In addition, trained staff members were assigned for data quality control, and they could telephone the point of contact if there existed any queries.

5. Conclusions

In conclusion, large hospital-related variations in the incidence of thromboembolism in pregnancy were indicated in China. This hospital-based point survey demonstrated that the varied incidence of DVT, PE, and maternal death due to VTE was significantly influenced by hospital-related characteristics and the related diagnostic competency. Additionally, efforts should be driven towards the improvement of patient education levels and VTE treatment availability to reduce the risk of VTE-related maternal mortality and mobility.

Disclosure of interests:

The authors have no conflicts of interest to disclose. All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest.

Contribution to authorship:

Dr. Zhou and Dr. Li had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Zhou and Li.

Acquisition, analysis, or interpretation of data: All authors.

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Details of ethics approval:

The Institutional Review Board of the Obstetrics and Gynecology Hospital of Fudan University approved the project, and written informed consent was obtained from each participating hospital before enrollment (kyy2020-124, March 27th 2020).

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Figure legends:

Fig 1. Hospital-related factors associated with DVT incidence.

Fig 2. Hospital-related factors associated with PE incidence.

Table 1. Basic characteristics of hospital factor of 113 responding hospitals in China.

Hospital factors	**Responding hospital No. (%)**	**Annual delivery No. (%)**
Hospital type		
Type of hospital		
Tertiary hospitals	89(78.9) *	680658(88.3) *
Secondary hospitals	23(20.4)	88270(11.5)
Primary hospitals	1(0.9)	1900(0.2)
Characteristics of hospital		
General hospitals	71(62.8) *	286717(37.2) *
Specialized hospitals	42(37.2)	484111(62.8)
Cesarean rate		
0-30%	17(15.0) *	41818(5.4) *
30%-50%	69(61.1)	570625(74.0)
>50%	27(23.9)	158385(20.5)
System and strategy		
VTE management system		
Yes	97(85.8) *	670076(86.9) *
No	16(14.2)	100752(13.1)
VTE risk assessment scale		
Yes	85(75.2) *	592703(76.9) *
No	28(24.8)	178125(23.1)
Emergency transfer/consultation		
Yes	109(96.5) *	751778(97.5) *
No	4(3.5)	19050(2.5)
Diagnosis and treatment		
D-dimer		
Yes	112(99.1) *	760568(98.7) *
No	1(0.9)	10260(1.3)
B ultrasound of lower extremity vein		
Yes	104(92.0) *	717367(93.1) *
No	9(8.0)	53461(6.9)
CTPA		
Yes	91(80.5) *	644735(83.6) *
No	22(19.5)	126093(16.4)
Anticoagulants		
Yes	92(81.4) *	665850(86.4) *

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No	21(18.6)	104978(13.6)
Elastic stockings/compression device		
Yes	99(87.6) *	657828(85.3) *
No	14(12.4)	113001(14.7)
Patient education		
Health education		
Yes	92(81.4) *	577280(74.9) *
No	21(18.6)	193548(25.1)
Early mobilization		
Yes	108(95.6) *	748332(97.1) *
No	5(4.4)	22496(2.9)
Mobilization after vaginal delivery		
The same day	102(90.3) *	728593(94.5) *
One day after or later	11(9.7)	42235(5.5)
Mobilization after Cesarean section		
The same day or one day after	98(86.7) *	722911(93.8) *
Two days or later	15(13.3)	47917(6.2)
Total	113(100.0)	770828(100.0)

*P value<0.001.

Table 2. Analyses of hospital factors affecting the incidence of DVT.

Hospital factors	**Incidence, per 100,000 live births (95%CI)**	**RR**	**P value**
Hospital type			
Type of hospital			
Tertiary hospitals	14.4(14.3, 14.5)	Ref	<0.001
Secondary hospitals	5.7(5.5, 5.9)	0.4	
Primary hospitals	0.0(0.0, 0.0)	0.0	
Characteristics of hospital			
General hospitals	26.5(26.3, 26.7)	Ref	<0.001
Specialized hospitals	5.6(5.6, 5.6)	0.2	
Cesarean rate			
0-30%	26.3(25.9, 26.7)	Ref	<0.001
30%-50%	9.6(9.6, 9.7)	0.4	
>50%	23.4(23.1, 23.6)	0.9	
System and strategy			
VTE management system			
Yes	14.5(14.4, 14.6)	Ref	<0.001
No	6.0(5.8, 6.1)	0.4	
VTE risk assessment scale			
Yes	15.5(15.4, 15.6)	Ref	<0.001
No	6.2(6.1, 6.2)	0.4	
Emergency transfer/consultation			
Yes	13.7(13.6, 13.8)	Ref	<0.001
No	0.0(0.0, 0.0)	0.0	
Diagnosis and treatment			

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D-dimer			
Yes	13.5(13.5, 13.6)	Ref	<0.001
No	0.0(0.0, 0.0)	0.0	
B ultrasound of lower extremity vein			
Yes	13.0(12.9, 13.1)	Ref	<0.001
No	18.7(18.4, 19.1)	1.4	
CTPA			
Yes	13.8(13.7, 13.9)	Ref	<0.001
No	11.1(11.0, 11.2)	0.8	
Anticoagulants			
Yes	13.1(13.0, 13.2)	Ref	<0.001
No	15.2(15.0, 15.4)	1.2	
Elastic stockings/compression device			
Yes	14.6(14.5, 14.7)	Ref	<0.000
No	6.2(6.0, 6.4)	0.4	
Patient education			
Health education			
Yes	17.2(17.0, 17.3)	Ref	<0.001
No	2.0(2.0, 2.1)	0.1	
Early mobilization			
Yes	13.8(13.7, 13.9)	Ref	<0.001
No	0.0(0.0, 0.0)	0.0	
Mobilization after vaginal delivery			
The same day	13.2(13.1, 13.3)	Ref	<0.001
One day after or later	16.6(16.2, 17.0)	1.3	
Mobilization after Cesarean section			
The same day or one day after	14.6(14.2, 15.0)	Ref	<0.001
Two days or later	16.6(16.2, 17.0)	1.1	
Total	13.4(13.3, 13.4)		

RR: relative risk.

Table 3. Analyses of hospital factors affecting the incidence of PE.

Hospital factors	**Incidence, per 100,000 live births (95%CI)**	**RR**	**P value**
Hospital type			
Type of hospital			
Tertiary hospitals	14.4(14.3, 14.5)	Ref	<0.001
Secondary hospitals	5.7(5.5, 5.9)	0.4	
Primary hospitals	0.0(0.0, 0.0)	0.0	
Characteristics of hospital			
General hospitals	26.5(26.3, 26.7)	Ref	<0.001
Specialized hospitals	5.6(5.6, 5.6)	0.2	
Cesarean rate			
0-30%	26.3(25.9, 26.7)	Ref	<0.001
30%-50%	9.6(9.6, 9.7)	0.4	
>50%	23.4(23.1, 23.6)	0.9	
System and strategy			
VTE management system			
Yes	14.5(14.4, 14.6)	Ref	<0.001
No	6.0(5.8, 6.1)	0.4	

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VTE risk assessment scale			
Yes	15.5(15.4, 15.6)	Ref	<0.001
No	6.2(6.1, 6.2)	0.4	
Emergency transfer/consultation			
Yes	13.7(13.6, 13.8)	Ref	<0.001
No	0.0(0.0, 0.0)	0.0	
Diagnosis and treatment			
D-dimer			
Yes	13.5(13.5, 13.6)	Ref	<0.001
No	0.0(0.0, 0.0)	0.0	
B ultrasound of lower extremity vein			
Yes	13.0(12.9, 13.1)	Ref	<0.001
No	18.7(18.4, 19.1)	1.4	
CTPA			
Yes	13.8(13.7, 13.9)	Ref	<0.001
No	11.1(11.0, 11.2)	0.8	
Anticoagulants			
Yes	13.1(13.0, 13.2)	Ref	<0.001
No	15.2(15.0, 15.4)	1.2	
Elastic stockings/compression device			
Yes	14.6(14.5, 14.7)	Ref	<0.000
No	6.2(6.0, 6.4)	0.4	
Patient education			
Health education			
Yes	17.2(17.0, 17.3)	Ref	<0.001
No	2.0(2.0, 2.1)	0.1	
Early mobilization			
Yes	13.8(13.7, 13.9)	Ref	<0.001
No	0.0(0.0, 0.0)	0.0	
Mobilization after vaginal delivery			
The same day	13.2(13.1, 13.3)	Ref	<0.001
One day after or later	16.6(16.2, 17.0)	1.3	
Mobilization after Cesarean section			
The same day or one day after	14.6(14.2, 15.0)	Ref	<0.001
Two days or later	16.6(16.2, 17.0)	1.1	
Total	13.4(13.3, 13.4)		

RR: relative risk.

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