

A Study on Risk Factors for Venous Thromboembolism and the Requirement of Thromboprophylaxis in Pregnancy and Postpartum Period in a Tertiary Care Centre in South Asian Country: A Cross Sectional Study

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Abstract

Introduction: Thrombosis is a major cause of maternal death worldwide. During pregnancy, the risk of venous thromboembolism (VTE) increases fourfold to five-fold and contributes towards maternal morbidity and mortality. Sri Lanka does not have a proper assessment tool to detect and manage it in the antenatal care. **Objectives:** To identify risks factors for VTE among pregnant mothers, postpartum mothers according to RCOG (Royal College of Obstetricians) risk categorization and to assess the requirement of thromboprophylaxis. **Method:** A cross sectional study was conducted at the antenatal clinics and obstetrics and gynaecology wards (ward 2, 5, 8) of De Soysa Hospital for Women in 2021. Obstetric thromboprophylaxis risk assessment tool recommended by the RCOG was used for the risk assessment of pregnant mothers during the antenatal and postpartum period. **Results:** In antenatal period, obesity (BMI > 35), age more than 35 years and parity more than 3 were the commonest risk factors. Out of 404 mothers, 67.33% did not have any risk factors. Among others, 18.56%, 0.40%, 2.72%, 0.99% had a score of 1, 2, 3 and 4 respectively. Patients with intermediate (0.99%) and high risk (2.72%) were commenced on thromboprophylaxis from 28 weeks. The low-risk category was not started on any treatment (28.96%, n = 97). Approximately 96% of mothers did not require any thromboprophylaxis during an-

tenatal period. Another 404 postnatal mothers were recruited for the study group. Elective caesarean section and caesarean section during labour were the main risks identified other than pre-existing antenatal risks. 39.95 % of mothers did not have any risk factors and 37.22% of mothers had a score of 1. **Conclusions:** VTE risk assessment tool can be implemented at national level to detect patients at risk of VTE and improve maternal care.

Keywords

Venous Thromboembolism, Postpartum, Thromboprophylaxis, Cross-Sectional Study, Maternal Morbidity and Mortality

1. Introduction

Thrombosis is a major cause of maternal death worldwide. During pregnancy, the risk of venous thromboembolism (VTE) increases fourfold to five-fold [1]. The overall incidence is 0.7 to 1.7 per 1000 deliveries [1]. The highest risk of VTE is in the first 3 months postpartum when the risk is increased 20 to 80-fold, and postpartum pulmonary embolism (PE) occurs in approximately 0.45 of 1000 deliveries [1] [2]. In women of reproductive age, more than half of all VTE are related to pregnancy [1].

All three components of Virchow's triad: venous stasis, hypercoagulability and vessel wall damage, are present in pregnancy [3]. The venous thromboembolism (VTE) includes deep vein thrombosis (DVT), pulmonary embolism and cerebral venous sinus thrombosis. Venous thromboembolism (VTE) remains one of the main direct causes of maternal death in the UK. The subjective clinical assessment of deep venous thrombosis (DVT) and pulmonary embolism (PE) is unreliable in pregnancy and only a minority of women with clinically suspected VTE have the diagnosis confirmed when objective testing is employed [4].

Though venous thromboembolism (VTE) is a serious maternal complication, Universal thromboprophylaxis may not be cost effective or safe because of the risk for allergy and bleeding. Routine thromboprophylaxis is only recommended for women considered as high risk for VTE on the basis of their risk factors.

However, there is disagreement and inconsistency regarding the characteristics that put women at higher risk of developing a first VTE during pregnancy or postpartum combined with a lack of data about the relative effect of those risk factors with respect to the absolute risk for VTE. Therefore, a proper assessment of risk factors of VTE and early identification of pregnant women who are in need of thromboprophylaxis based on the risk assessment is vital in the overall management of the pregnancy.

In order to assess the risk of VTE the UK has developed the Royal College of obstetricians and gynaecologists (RCOG) VTE risk assessment guidelines at the booking visit, each antenatal admission and postpartum, and then according to

the risk factors they classify the pregnant mothers into high risk, intermediate risk and low risk [5].

In Sri Lanka according to 2011-2013 statistics reported cases of deaths due to deep vein thrombosis and pulmonary embolism were 2, 3 and 3 respectively [6]. Although the contribution of VTE for the maternal morbidity and mortality statistics is significant we haven't yet developed a proper VTE risk assessment tool or a detailed plan of follow up in antenatal clinics or in the ward for risk classification.

Many antenatal thromboembolic events occur in the first trimester and therefore prophylaxis, if given, should begin early in pregnancy [7]. The risk for VTE increases with gestational age, the highest risk period for VTE, and pulmonary embolism in particular, is during the postpartum period [1] [8] [9] [10].

Risk factors for venous thromboembolism in pregnancy can be categorized into pre-existing, obstetrics and new onset risk categories. Pre-existing risk factors can be previous history of venous thromboembolism, inherited or acquired thrombophilia and medical comorbidities such as heart or lung disease, cancer SLE. Age, parity, smoking, gross varicose veins and paraplegia also categorized as pre-existing risk factors. Obstetrics risk factors include multiple pregnancy, assisted reproductive therapy Pre-eclampsia Caesarean section and postpartum haemorrhage requiring transfusion [8].

Two well recognized significant risk factors for VTE in pregnancy are thrombophilia and previous VTE. Inherited thrombophilia is found in 20% - 50% of pregnancy-related VTE [11]. Women aged over 35 years, obesity and caesarean section contribute most substantially to the rates of VTE because of their high (and increasing) prevalence [12]. Obesity warrants particular consideration as a risk factor because of its high prevalence within the population [13] [14] [15] [16].

The objectives of this study are to assess the prevalence of risk factors for VTE in pregnancy and immediate postpartum period; to assess the requirement of thromboprophylaxis in pregnant women with risk factors for VTE during the antenatal period and to assess the requirement of thromboprophylaxis in immediate postpartum period with risk factors for VTE.

2. Methods

The study was carried out as a hospital based cross sectional study. The study was conducted in the Antenatal clinics and in the obstetrics and gynaecology wards (ward 2, 5, 8) of De Soysa Hospital for Women in 2021. All the pregnant women who attended the antenatal clinic at their booking visit and the women who get admitted to the antenatal wards bypassing the clinic and the women during their immediate postpartum period within one week following the delivery were recruited as study participants. No specific exclusion criteria were defined in the study. Obstetric thromboprophylaxis risk assessment tool recommended by the RCOG was used for the risk assessment of pregnant women during the antenatal and postnatal period. The women were given a score and

categorized into three groups as low, intermediate and high-risk groups. The following risk factors were analysed and a score was given to each woman based on the presence of risk factors and were subsequently categorized according to the risk score as shown in **Table 1**.

Data collection was done using an interviewer-administered questionnaire. Prevalence of risk factors of thromboembolism in pregnancy has not been properly evaluated up to now in Sri Lanka, so there is no current data for prevalence. Sample size was calculated with a precision of 5% and confidence interval of 95% and with 5% for non-responders the final calculation came down to 403. The outcome measures were according to RCOG risk assessment score of above-mentioned risk factors. Pregnant mothers and postpartum mothers were categorized into the following categories: high risk: if total score ≥ 4 antenatally, thromboprophylaxis was considered from the first trimester; intermediate risk: if a total score of 3 antenatally then thromboprophylaxis was considered from 28 weeks. Low risk: fewer than three risk factors were advised on mobilization and avoidance of dehydration. If the total score ≥ 2 postnatally, thromboprophylaxis was considered for at least 10 days. Questionnaires were pre-coded for the convenience of data entry. SPSS 18.0 was used to perform the data analysis. Mean and standard deviations were to describe continuous variables and percentages and standard deviations was used to describe categorical variables.

There were no major ethical issues with this research project. The study did not alter any patient management protocols and the subjects did not undergo any additional invasive investigations in view of the study project. When the need for thromboprophylaxis was identified the treatment was started without any delay. There will be no additional costs to the study subjects and there will be no payments or reimbursements planned. Written informed consent was obtained from all study participants at the recruitment and they had the right to withdraw from follow up without any consequences to their clinical management. Ethical approval for the study will be obtained from the ethics review committee of the Faculty of Medicine, University of Colombo, permission was obtained from the Director of De Soysa Hospital for Women. All details regarding each participant will be kept confidential under locked and key. Data will be discarded after 2 years duration.

3. Results

A total of 404 antenatal mothers were recruited. The percentage age distribution for the following age groups was 31%, 0.01% and 14.11% respectively. Nineteen antenatal risk factors were assessed, among them thirteen risk factors were present in at least in one woman. A summary of the prevalence of risk factors of thromboembolism and their percentages in the antenatal period is shown in **Table 2**.

There was a case of thrombophilia with Antiphospholipid syndrome and the patient was referred to haematology team and started on thromboprophylaxis from the beginning of pregnancy and continued up to 6 weeks postpartum.

Table 1. Scoring of risk factors according to the RCOG guideline.

Pre-existing risk factors	Score
Previous VTE (except a single event related to major surgery)	4
Previous VTE provoked by major surgery	3
Known high-risk thrombophilia	3
Medical comorbidities cancer, heart failure; active systemic lupus erythematosus, inflammatory polyarthropathy or inflammatory bowel disease; nephrotic syndrome; type I diabetes mellitus with nephropathy; sickle cell disease; current intravenous drug user	3
Family history of unprovoked or oestrogen-related VTE in first-degree relative	1
Known low-risk thrombophilia (no VTE)	1
Age (> 35 years)	1
Obesity (BMI > 30/>40)	1/2
Parity \geq 3	1
Smoker	1
Gross varicose veins	1
Obstetric risk factors	
Pre-eclampsia in current pregnancy	1
ART/IVF (antenatal only)	1
Multiple pregnancy	1
Caesarean section in labour	2
Elective caesarean section	2
Mid-cavity or rotational operative delivery	1
Prolonged labour (>24 hours)	1
PPH (>1 L or transfusion)	1
Preterm birth < 37 + 0 weeks in current pregnancy	1
Stillbirth in current pregnancy	1
Transient risk factors	
Any surgical procedure in pregnancy or puerperium except immediate repair of the perineum	3
Hyperemesis	3
Ovarian Hyperstimulation Syndrome (first trimester only)	4
Current systemic infection	1
Immobility, dehydration	1

A case of inflammatory bowel disease was recognized. As she did not have any other risk factors her total score was 3, which warranted thromboprophylaxis from 28 weeks.

Out of 404 antenatal mothers 14.11 % (n = 57) of them were aged above 35 years. Obesity was noted in 10.89% (BMI > 30 = 10.64, BMI > 40 = 0.25%) of

Table 2. Summary of prevalence of risk factors of thromboembolism in the antenatal period.

	Frequency	Percentage
Previous VTE (except a single event related to major surgery)	0	0
Previous VTE provoked by major surgery	0	0
Known high-risk thrombophilia	1	0.25
Medical comorbidities	1	0.25
Family history of unprovoked or oestrogen-related VTE in first-degree relative	0	0
Known low-risk thrombophilia (no VTE)	0	0
Age (>35 years)	57	14.11
Obesity (BMI > 30)	43	10.64
Obesity (BMI > 40)	1	0.25
Parity ≥ 3	57	14.11
Smoker	0	0
Pre-eclampsia in current pregnancy	5	1.2
ART/IVF (antenatal only)	3	0.74
Multiple pregnancy	4	0.99
Any surgical procedure in pregnancy or puerperium except immediate repair of the perineum,	0	0
Hyperemesis	4	0.99
Ovarian Hyperstimulation Syndrome (first trimester only)	2	0.50
Current systemic infection	0	0
Immobility	1	0.25

mothers. There were four cases of multiple pregnancies (0.99%) and three cases of pregnancies following IVF (0.74%) in the study group. The numbers of cases with hyperemesis gravidarum were four (0.99%) while ovarian hyper stimulation syndrome accounted for two cases (0.99%). There was a case of high-risk thrombophilia and one case of SLE which were entered into the coexisting medical co-morbidities category. Previous VTE provoked by major surgery, known cases of low-risk thrombophilia (no VTE) were not observed in this study group.

The VTE risk score of all of these women in the antenatal period is shown in **Table 3**. Category of high-risk group, who required thromboprophylaxis from first trimester was 0.99% (n = 4). The intermediate risk group accounted for 2.72% (n = 11) and thromboprophylaxis was started on them from 28 weeks of gestation. The low-risk category did not require any major interventions (28.96%, n = 97) but they were advised on mobilization and to avoid dehydration. Approximately 96% of women in this study group did not require any thromboprophylaxis during the antenatal period.

Table 3. VTE risk score in antenatal women.

Value (Risk Score)	Frequency	Percentage
0	272	67.33
1	75	18.56
2	42	10.40
3	11	2.72
4	4	0.99

Total of twenty-three risk factors and their percentages were assessed in post-natal women (n = 404) as shown in **Table 4**. Out of them ten risk factors were present in at least in one woman. The number mothers aged above 35 years were fifty (12.37%). Out of that 82 % of them had additional risk factors which required thromboprophylaxis. The prevalence of class 1 obesity was 12.12% (n = 49). Out of that 59% of them had additional risk factors. Out of total number 15.34% (n = 62) of mothers had this risk factor. Six cases of pre-eclampsia were detected and all of them delivered immediately due to maternal risk by emergency caesarean sections and all of them required thromboprophylaxis for next 10 days duration. Twenty-one cases of caesarean sections while in the labour were identified in the study group.

The VTE risk score of these women is shown in **Table 5**. Most of them did not have additional risk factors (**Table 5**). But due to the high score (score of 2) all of them required thromboprophylaxis for the initial 10 days of postpartum period.

Total number of caesarean sections was 103. Score of 1 was given to this category. There were 3.31% (N = 13) of PPH cases (> 1 L or transfusion) were detected. There may be an under reporting of this risk factor group as there was no proper documentation of estimated blood loss in PPH.

The number of preterm deliveries was 27 (6.68%). Out of them 40% of the cases were iatrogenic due to the presence of maternal medical comorbidities including diabetes mellitus and pre-eclampsia. There were five cases (1.23%) of systemic infection in the postpartum period. Three were due to lower respiratory tract infection, one was due to urinary tract infection and the other due to surgical site infection. There were no cases of immobility in the postpartum study group.

The percentage of women who were on thromboprophylaxis in the antenatal period was 1.74% (n = 07) and all of them required postnatal thromboprophylaxis for another 6 weeks' duration.

4. Discussion

The introduction of VTE risk assessment to clinical practice was difficult at the beginning, as it became an additional burden to the routine practice. After few introductory sessions and addition of a printed risk assessment tool to the antenatal clinic record, the process became more convenient.

Table 4. Summary of prevalence of risk factors of thromboembolism in postpartum period.

Risk Factor	Frequency	Percentage
Previous VTE (except a single event related to major surgery)	0	0
Previous VTE provoked by major surgery	0	0
Known high-risk thrombophilia	0	0
Medical comorbidities	0	0
Family history of unprovoked or oestrogen-related VTE in first-degree relative	0	0
Known low-risk thrombophilia (no VTE)	0	0
Age (>35 years)	50	12.37
Obesity (BMI > 30)	49	12.12
Obesity (BMI > 40)	0	0
Parity ≥ 3	62	15.34
Smoker	0	0
Pre-eclampsia in current pregnancy	6	1.5
Multiple pregnancy	3	0.74
Caesarean section in labour	21	5.19
Elective caesarean section	103	25.49
Mid-cavity or rotational operative delivery	0	0
Prolonged labour (>24 hours)	0	0
PPH (>1 litre or transfusion)	13	3.21
Preterm birth < 37 + 0 weeks in current pregnancy	27	6.68
Any surgical procedure in pregnancy or puerperium except immediate repair of the perineum,	0	0
Current systemic infection	5	1.23
Immobility, dehydration	0	0

Table 5. VTE risk score in post-natal mothers.

Value (Risk Score)	Frequency	Percentage
0	161	39.95
1	150	37.22
2	74	18.36
3	11	2.73
4	06	1.49
5	01	0.25

Despite of the acceptance of the tool among patients they were reluctant at the beginning to commence on thromboprophylaxis and discussions with obstetric

and haematology team were of value to persuade these women.

Though the mortality and morbidity associated with VTE is very high, the prevalence of risk factors was very low in the antenatal population. The requirement of enoxaparin as prophylactic treatment was very low (3.71%). When considering the cost for enoxaparin, total economic burden was very minimum as it was required only for less than 4% of antenatal population.

The mothers who had risk factors but did not require prophylaxis were about 28.96%. They were advised on avoidance of immobilization and dehydration. All of them were educated on risk of VTE and pulmonary embolism and also depending on their identified risk factors further advices including advices on weight reduction and referral to the nutritionist were offered.

Though the processes of labour and its own complications invariably increases the VTE risk some women who were in the low-risk category group in the antenatal period became high risk at postnatal period. Though the identification of mothers who at risk was easy at postpartum period due to their hospital stay, the initiation of thromboprophylaxis was very difficult. Around 45% of mothers were reluctant to start on treatment with enoxaparin. Of them 40% of them worried about breast-feeding another 30% said it was difficult.

In the group of post-natal mothers 77.17%, 22% and 1.7% required no, ten days and six weeks of thromboprophylaxis respectively. When considering the risk prevalence for both antenatal and postnatal period, prevalence of antenatal risk factors is very low and requirement of enoxaparin is less than 3%. But during the postpartum period prevalence of risk factors was higher and the requirement of thromboprophylaxis was about 22%. But most of them required it only for next 10 days.

The major limitations of this study are that majority of women in the study group were from the urban population, so their lifestyle, dietary pattern which may impact VTE risk may be different from the general populations. Most of the antenatal and postnatal mothers in this study were Sinhalese. Inclusion of other ethnic groups should be increased to improve the predictive validity. A research which involves multiple centres with inclusion of all the ethnicities and all geographical areas will help to overcome this problem. The questionnaire and the risk tool only collected the information on the predetermined risk factors. It is more useful to gather additional information on identifying more aetiologies. There might be other possible risk factors involved in VTE that is not included in this tool, so frequent re-evaluation and updating the risk assessment tool is important. The antenatal risk assessment is relatively easy, but postnatal assessment is relatively time consuming, in which all intrapartum data has to be traced and if the data is inadequate risk scoring is difficult such as estimation of prolonged labour more than 24 hours, estimation of blood loss at postpartum haemorrhage. Initiation of antenatal thromboprophylaxis also easy as maternal support is very high during this period. But during the postpartum period most of the mothers are busy with their new babies and their concern is very low regarding new treatment. Education of mothers during the antenatal period is necessary to

increase the compliance during the post-natal period. The main target of this study is to describe the risk prevalence among pregnant mothers and risk stratification in order to commence treatment.

5. Conclusion

Though the prevalence of VTE and its related complication are very low, occurrence of such event increases both maternal morbidity and mortality. So early identification and prevention have critical importance. Convenient, non-invasive and less expensive screening tool would be an ideal option for a country like us.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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