Research Article

Risk Assessment of Venous Thromboembolism in Pregnancy and Adequate Prophylaxis: An Observational Study

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Abstract: Background: Globally, Venous Thromboembolism (VTE), which includes pulmonary embolism and deep vein thrombosis, is a major cause of maternal morbidity and mortality. A hypercoagulable state is brought on by pregnancy, and risk is further increased by obesity, cesarean sections, and thrombophilia.

Objective: The purpose of this study was to determine the risk factors for VTE in pregnant women and the effectiveness of thromboprophylaxis in accordance with the recommendations of the Royal College of Obstetricians and Gynecologists (RCOG)

Materials and Methods: A prospective observational study was conducted over nine month period started from November 20, 2023 to August 20, 2024 in the Department of Obstetrics and Gynaecology, LCMD/DSH Hospital, Karachi. Non-probability convenience sampling was used to recruit 246 first-trimester pregnant women. Each participant was given a VTE risk score using the RCOG method after clinical, obstetric, and demographic information was gathered. To find predictors of prophylactic use, chi-square and logistic regression tests were used in statistical analyses

Result: The mean age of participants was 28.9 ± 5 years. Cesarean section was the most frequent mode of delivery (69.8%), and obesity (BMI > 30 kg/m²) was present in 13.2%. Based on RCOG scoring, 34.3% were high-risk, 44.9% moderate-risk, and 20.4% low-risk for VTE. Only 28.2% received thromboprophylaxis. Obesity (OR = 6.56; $p < 0.001$), high-risk score (OR = 8.41; $p < 0.001$), and cesarean delivery (OR = 2.58; $p = 0.01$) were significant predictors of prophylaxis use.

Conclusion: A substantial proportion of pregnant women were at moderate to high risk for VTE, yet prophylaxis use was suboptimal. Incorporating structured RCOG-based risk assessment and improving adherence to thromboprophylaxis guidelines could significantly reduce VTE-related maternal morbidity and mortality.

Keywords: Venous thromboembolism, Pregnancy, Thromboprophylaxis, Risk assessment, Cesarean section, Obesity.

INTRODUCTION

Venous Thromboembolism (VTE) composed of deep vein thrombosis (DVT) and pulmonary embolism (PE) is a major cause of morbidity and mortality in the world [1]. Pregnancy is a known hypercoagulable condition, and the probability of getting VTE in antepartum period is five times higher and up to 60 times during postpartum period than age-matched non-pregnant women [2]. This increased risk is further espoused by the increasing maternal age, the upsurge in obesity and the tendency to avoid normal delivery at Caesarean section [3].

In spite of the improved diagnostic and treatment methods used, VTE remains a cause of maternal death especially in developed nations. VTE in the United States contributes to the maternal mortality rate in the country at around 10 percent and PE is the leading cause [4]. The maternal mortality rate as a result of VTE is estimated to be 1.5 per 100, 000 pregnancies in the United Kingdom as the European countries [5, 6]. One of the largest retrospective studies which consisted of over 72, 000 deliveries estimated the incidence of DVT as 0.71 per 1000 births of which 0.5% were in the antenatal period and 0.21 in the post-partum care [7, 8]. Interestingly, the risk is more severe within the first six weeks after childbirth, which is taken as the most susceptible [9]. The incidence and presentation of VTE are different depending on vascular health, ethnicity, as well as population-based risk factors. It has been observed in women, who have either a personal or family history of VTE, thrombophilia, assisted reproductive practices, and in women, who complain of having one or more comorbidities like diabetes and hypertension. Racial and ethnic inequalities are still present as well, with the African American women being reported to have an extremely higher risk in comparison to the White Caucasian women [10, 11]. Since, VTE may have fatal outcomes and can be difficult to diagnose, it is particularly essential to be able to recognize and prevent it. As unattended, about a quarter of the number of cases of DVT may lead to PE, which means urgency in recognizing and addressing the disease. Luckily, proper risk

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assessment and prophylaxis of VTE are largely preventable in the presence of proper professional bodies namely: the Royal College of Obstetricians and Gynecologists (RCOG), American College of Obstetricians and Gynecologists (ACOG), and the Working Group in Women Health of the Society of Thrombosis and Hemostasis (GTH). They also suggest prophylaxis anticoagulation in high-risk women with confirmed scoring systems [12, 13].

Although global information may be availed, it has been discovered that there is scanty local literature on the occurrence and risk factors of VTE in pregnancy in our society. The actual burden of disease is underreported which is probably because of inadequate surveillance and awareness [14]. Hence, the rationale of the study is to investigate the risk factors of having VTE among our obstetric population and to highlight the need to have regular risk assessment and proper prophylaxis to curb maternal morbidity and mortality and based on the observed gaps in local data regarding VTE risk assessment and the effectiveness of thromboprophylaxis, we hypothesize that multiple maternal risk factors significantly contribute to VTE occurrence, and that appropriate prophylactic measures can reduce this risk.

The purpose of this study was to determine the multiple risk factors of venous thromboembolism (VTE) in pregnancy and the post-partum stage of the obstetric population in the area, and to determine suitability of prophylaxis against pregnant and postpartum women.

MATERIALS AND METHODS

The proposed study is a prospective observational study conducted in the Department of Obstetrics and Gynecology, Liaquat College of Medicine & Dentistry/Dar ul Sehat, Hospital, Karachi, Pakistan. The study duration was of nine months starts from November 20, 2023 to August 20, 2024 after having approval from the Institutional Review Board (IRB) bearing number (Ref. No. IRB/M-000074/23, Dated: November 13, 2023).

In the study, non-probability convenience sampling is used. The sample size is calculated using the sample size calculator Openepi version 3 software. The desired sample size is calculated to be 246, using a 95% confidence level, 3.2 % margin of error, and an expected prevalence of VTE of 0.071%.

All pregnant women presenting in the first trimester (from conception up to 14 weeks of gestation) were included. Women with a pre-existing diagnosis of DVT and the women already on anticoagulant therapy (e.g., heparin, LMWH) were excluded.

All eligible pregnant women attending the antenatal booking clinic during their first trimester were invited to participate. Informed consent was obtained, and the purpose of the study explained in detail. Participants were enrolled consecutively, and a structured proforma is completed by a trained nurse. The proforma is divided into two parts: Part A: Demographic and Clinical Data containing Age, parity, residence, occupation, Previous mode of delivery, History of miscarriage, dilatation and evacuation (D&E), or cesarean section, Complications in current pregnancy, Mode of delivery and birth outcome, Use of heparin or low molecular weight heparin (LMWH) Part B: VTE Risk Assessment Tool form The Royal College of Obstetricians and Gynecologists (RCOG) Risk factors will be assessed, scored, and the corresponding management plan is documented. This form is attached to the patient's antenatal record at first visit, and reassessed at delivery and postpartum follow-up (1 week). If any additional risk factors develop during pregnancy (e.g., hyperemesis, prolonged bed rest, hypertensive disorders), the form is updated

Participants are followed through the antenatal period until delivery and postpartum. Outcomes recorded included: Mode of delivery (MOD): spontaneous, induced labor (IOL), or cesarean, Amniotic fluid leakage, antepartum/postpartum hemorrhage and neonatal outcomes: birth weight, sex of the baby, and NICU admissions, Participants are the classified into low, medium, or high-risk groups based on the RCOG risk assessment and prophylaxis given is observed

STATISTICAL ANALYSIS

SPSS version 23 was used for statistical analysis. Relevant descriptive statistics, frequency and percentage was obtained for presentation of qualitative variables like, residence, patient and husband occupation, mode of delivery. Quantitative variable like age, no. of children, gestational age and risk score for VTE is presented by mean standard deviation. Chi-square tests were used to examine associations with risk factors, and t-tests were used to analyze continuous variables. Exploratory multivariate binary logistic regression was also performed and reported.

RESULT

A total of 246 patients were included in the study. The mean age was 28.9 ± 5 years (18–42 years). Among the participants, 58 (23.6%) were primigravida, 149 (60.5%) were multigravida, and 39 (15.8%) were grand multipara with parity greater than five. The mean gravidity was 2.9 ± 1.7 [1-8]. A history of miscarriage was observed in 79 patients (32.2%). Of these, 48 (19.6%) had experienced a single miscarriage, 24 (9.8 %) had two miscarriages while recurrent miscarriages (more than three) were reported in 7 cases (2.9%). The mean BMI of the study population was 25.0 ± 3.3 (18–33 kg/m²). Obesity (BMI >30 kg/m²) was identified in 32 patients (13.1%), while 213 (86.9%) were non obese BMI Regarding the mode of delivery, cesarean section was the most common, performed in 171 cases (69.8%). Normal vaginal delivery occurred in 64 patients (26.1%), and instrumental vaginal delivery was the least frequent, observed in 10 cases (4.1%). Singleton pregnancies were predominant, with 241 (98.3%) cases, while only 4 (1.7%) involved multiple gestations. Low-risk thrombophilia was identified in 29 patients (11.8%). The mean VTE risk score was 2.3 ± 2.01. While observing new born birth weight 28(11.4%) had <2.5 kg weight, 208 (82.3%) were of 2.5-4 kg and 11 (4.5%) were of > 4 kg weight (Table **1**).

Table 1. Baseline Characteristics of the Study Population.

Variable	Mean ± SD / n (%)
Age (years)	28.9 5.0
Gravida	2.9 ± 1.7
History of Miscarriage	79 (32.2%)
BMI (kg/m²)	25.0 ± 3.3
VTE Risk Score	2.3 ± 2.01
Mode of Delivery	
Normal Vaginal Delivery (NVD)	64 (26.1%)
Instrumental Vaginal Delivery (IVD)	10 (4.1%)
Cesarean Section (LSCS)	171 (69.8%)
History of Thrombophilia	
Yes	29 (11.8%)
No	216 (88.2%)
Obesity (BMI >30 kg/m²)	
Yes	32 (13.2%)
No	213 (86.8%)
Newborn Birth Weight	
<2.5 kg	28 (11.4%)
2.5–4 kg	208 (82.3%)
>4 kg	11 (4.5%)

According to the RCOG guidelines and the VTE risk assessment tool, thromboprophylaxis is recommended during early pregnancy for women with a prenatal VTE risk score of ≥4, from 28 weeks of gestation for those with a score of 3, and for a minimum of 10 days postpartum in women with a postpartum score of ≥2, provided there are no contraindications to anticoagulation. Table **2** shows the use of thromboprophylaxis in our study where 176 (71.8%) did not receive any type of anti-coagulation ,43(17.6%) received aspirin. 18(7.3%) received LMWH and only 9 patients (3.3%) received both Aspirin 75mg and LMWH.

Table 2. Thromboprophylaxis during the Antenatal Period.

Thromboprophylaxis Type	Number of Patients (n)	Percentage (%)
None	176	71.8%
Aspirin 75mg only	43	17.6%
LMWH only	18	7.3%
Aspirin 75mg+ LMWH	9	3.3%
Total	**246**	**100%**

In our study population, 50 women (20.4%) were categorized as low risk (VTE risk score = 0), 110 (44.9%) as medium risk (score 1–3), and 84 (34.3%) as high risk (score >3). The average VTE risk score was 2.3. Regarding preexisting risk factors, only one patient (0.4%) was on anticoagulation therapy before pregnancy due to a history of recurrent miscarriage and deep vein thrombosis. None of the participants reported a history of recurrent provoked VTE, active autoimmune disease, or comorbidities such as systemic lupus erythematosus (SLE) or nephrotic syndrome. Thrombophilia (either high or low risk) was identified in 42 patients (11.8%). Patients more than 35 years of age were 40 (16%), BMI > 30 is found in 32 patients (13%) parity of >3 is recorded in 53 patients (13.4%) and varicose veins are found in 5 patients. Antenatal hospitalization occurred in 27 patients (11.2%), most commonly due to per vaginal bleeding. Also, 5 patients (2%), were hospitalized with hyperemesis gravidarum. 4 patients (1.6 per cent) underwent surgery during pregnancy, 3 cervical cerclages, and 1 antenatal polypectomy. The number of patients who had immobilization during pregnancy is only (0.8) or one and it was due to placenta previa and hemorrhage. No participant stated that they had smoked during pregnancy. Assessment of obstetric risk factors indicates that planned cesarean section contributed greatly with 132 cases (53.9%) with cesarean section in labor accounts for 31 cases (12.7%), prolonged labor is observed in 4 patients (1.6%), Pre eclampsia is found in 13 while pre-term labor and PPH is seen in 9(3.7%) Prophylaxis was also used to 69 patients (28.2 percent) in the antenatal period. RCOG VTE risk assessment model clearly divides the risk factors into pre-existing, obstetric and new-onset or transient risk factors. Table **3** shows how many patients belong to these risks.

Table 3. Risk factors of VTE.

Factors	Cases	Proportion %
History of previous VTE (except for surgery related VTE history)	0	0
Surgery-related VTE history	0	0
Known high-risk thrombophilia	0	0
Medical complications, such as cancer, cardiopulmonary disease, SLE, inflammatory polyarthrosis, inflammatory bowel disease, nephrotic syndrome, type 1 diabetic nephropathy, sickle cell disease	0	0
Family history of VTE with unknown cause or estrogen in first-degree relatives	0	0
Known low-risk thrombophilia	29	11.8
Age (> 35 yr old)	40	16
Obesity (BMI > 30)	32	13.1
Parity ≥ 3	5	2
Varicose veins	13	5.3
Smoking	0	0
Preeclampsia	7	2.9
Assisted reproductive technology	132	53.9
Multiple pregnancies	31	12.7

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Continue

Caesarean section	4	1.6
Cesarean section in labour	9	3.7
Extended labour (> 24 h)	9	3.7
Postpartum haemorrhage (bleeding > 1000 mL or blood transfusion)	0	0
Pregnancy or puerperal surgery (except for perineal repair immediately after delivery)	5	2
Hyperemesis gravidarum	0	0
Ovarian hyperstimulation syndrome	27	11
Hospitalization or bed rest, immobilization ≥ 3 d	1	0.4

Patients classified as obese, smokers, high-risk and those hospitalized all showed significant associations with use of prophylaxis in Chi-square analysis. Further exploratory analysis was conducted using multivariate logistic regression. Obesity (OR = 6.56; 95% CI 2.96–14.56; p < 0.001), Risk Score (OR = 8.41; 95% CI 4.48–15.78; p < 0.001), and cesarean delivery (OR = 2.58; 95% CI 1.29–5.18; p = 0.01) were observed as the strongest independent predictors of prophylaxis use (Table **4**). Both age (OR = 1.10; p < 0.001) and BMI (OR = 1.21; p < 0.001) also remained significant predictors after adjustment. Thrombophilia (OR = 55.93; 95% CI 12.79–244.55; p < 0.001) also remained significant, but the wide CIs limit interpretability of model output.

Table 4. Predictors of use of Thrombo Prophylaxis in Pregnancy.

Variable	OR	Cl-low	Cl-high	p-value
Obesity	6.56	2.96	14.56	<0.001
Cesarean	2.58	1.29	5.18	0.01
Thrombophilia	55.93	12.79	244.55	<0.001
HighRisk	8.41	4.48	15.78	<0.001
Age	1.10	1.04	1.17	<0.001
BMI	1.21	1.11	1.32	<0.001

Multivariate binary logistic regression showing predictors of prophylaxis use amongst pregnant women.

DISCUSSION

This paper evaluated VTE risk in 246 pregnant women measured on the RCOG score and appraised the use of antenatal thromboprophylaxis. A significant percentage were moderate to high risk of VIT meaning systematic risk stratification is crucial as well as prompt prophylaxis. The average age (28.9 +- 5 years) and the large proportion of people with multiple births (60.1, 15.8 grand multipara) indicates normal obstetric demographics. All these put together with the history of miscarriage (32.2) add up to an increased risk of thrombosis [15]. There were 13.2 percent participants who were obese (BMI >30 kg/m^2), and the mean BMI was 25.0 +- 3.3. The current literature of large-scale studies can affirm that even small changes to BMI during early pregnancy are strongly associated with an increase in the long-term VTE risk up to 2.35 to 3.5-fold of BMI, directly proportional to the BMI during pregnancy 30-35 kg/m^2 [16]. This highlights the significance of working on obesity as a measure of risk in antenatal care. Thrombophilia was detected in 11.8 per cent -which is in agreement with global trends in obstetric populations [17]. This is in accordance with the changing recommendations, implying personalized thromboprophylaxis in both the low and high-risk instances of thrombophilia, balancing the risk of VTE with hemorrhage [18]. Cesarean delivery, which is a well-documented risk factor of VTE in our cohort observed in 69.8 percent. Recent changes in perioperative care suggest mechanical prophylaxis in all cases of cesarean section, and pharmacologic prophylaxis (LMWH 7 days in routine, 6 weeks in patients at risk) Minor surgical (1.6) and antenatal hospitalization (11.2) have transitory risk of VTE. The present European guidelines recommend the use of thromboprophylaxis in these cases until maximum regaining of ambulation [19].

The risk scoring done by RCOG showed that 34.3, 44.9 and 20.4 percent of the women were high-risk, moderate-risk, and low-risk respectively (mean score 2.3+-2.01). But there was only 28.2% use of anti-thrombotic that was given to the pregnant women in the form of antithrombotic prophylaxis (aspirin, LMWH, or both); the remaining 71.8% were not given antithrombotic prophylaxis. Like underuse has been attested in various investigations conducted in the middle income zones pointing to the areas of consistent guideline-practice divergence [20]. Recent cohort studies indicate a gradual increasing VTE risk of the antenatal women since the year 2009-2019 (9.2% per year) where obesity was the most modifiable risk factor (adjusted RR 1.91), then cesarean delivery and other comorbid conditions [21]. Our information in which we can see similar regional trends also supports the implementation of structured risk evaluation into regular antenatal cars.

The current study also showed that obesity, higher VTE risk score, and cesarean delivery were the most significant predictors of prophylaxis use. These results are validated by the available literature, highlighting that higher BMI and type of delivery increase the likelihood of thromboembolic events during pregnancy [22]. The relationship of age, smoking and BMI with prophylaxis use also demonstrates appropriate identification by clinicians of women at higher physiological risk [23]. Although thrombophilia showed a strong statistical association, the wide confidence intervals in our model suggest the need for cautious interpretation and larger sample validation. The results underline the importance of using structured risk scoring systems, such as the RCOG model and others (such as the Caprini Score), to ensure that prophylaxis is given to those most likely to benefit [24].

LIMITATIONS

This is a single-center study and, therefore, might not be an adequate reflection of the large population. Additional limitations

are a possible under diagnosis of thrombophilia, and the unavailability of data on postpartum outcomes of thrombosis as well as incidence of DVT in post-partum period due to lack of follow up of patients [25].

CONCLUSION

The proportion of patients in the study population who were classified as moderate to high risk for VTE was considerable; however, less than one-third of those identified as at risk actually received thromboprophylaxis. This gap highlights the urgent need to implement structured and evidence-based risk assessment strategies, such as the RCOG VTE risk assessment model, within routine antenatal and postpartum care. Strengthening preventive measures like targeting obesity, cesarean prophylaxis, and improving adherence to internationally recognized guidelines has the potential to significantly reduce maternal morbidity and mortality associated with VTE. Further researches are of utmost need to identify the barriers for effective prophylaxis, under estimation of high risk patients by health professionals and lack of local available protocols.

ABBREVIATIONS

ACOG: American College of Obstetricians and Gynecologists.

DVT: Deep Vein Thrombosis.

D&E: Dilatation & Evacuation.

IOL: Induced Labor.

LMWH: Low Molecular Weight Heparin.

MOD: Mode of Delivery.

PE: Pulmonary Embolism.

RCOG: Royal College of Obstetricians and Gynecologists.

GTH: The Society of Thrombosis and Hemostasis.

VTE: Venous Thromboembolism.

AUTHORS' CONTRIBUTION

Aliya Nasim: Conceptualization, Study design, Writing draft.

Sagheera Anjum Manaver: Conceptualization, Writing draft.

Naima Shah: Methodology, Data analysis and interpretation, Critical review and revision the manuscript.

Humaira Tahir: Study design, Writing draft.

Mehvish Kanval: Methodology, Data analysis and interpretation, Writing draft.

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Declared none.

ETHICAL DECLARATIONS

Data Availability Statement

Data will be available from the corresponding author upon a reasonable request.

Ethical Approval

This study was approved by the Ethical Review Committee of Liaquat College of Medicine & Dentistry/Dar ul Sehat, Hospital, Karachi, Pakistan. (Ref. No. IRB/M-000074/23, Dated: November 13, 2023).

Consent to Participate

All the study participants were enlisted with their written informed consent.

Consent for Publication

All authors give consent for the publication of this work.

Conflict of Interest

Declared none.

Competing Interest/Funding

Declared none.

Use of AI-Assisted Technologies

The authors declare that no generative artificial intelligence (AI) or AI-assisted technologies were utilized in the writing of this manuscript, in the creation of images/graphics/tables/captions, or in any other aspect of its preparation.

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