Original Article

Evaluation of risk stratification and adherence to venous thromboembolism prophylaxis among hospitalized obstetric women: Retrospective case file review at East Jeddah Hospital during 2018–2019

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Abstract:

BACKGROUND: Venous thromboembolism (VTE) is associated with substantial mortality as well as morbidity and is largely preventable among hospitalized obstetric women. However, thromboprophylaxis is underutilized in most hospitalized patients.

OBJECTIVES: To evaluate VTE risk and adherence to local thromboprophylaxis protocol among hospitalized pre- and postnatal women.

METHODS: This retrospective study was conducted at East Jeddah Hospital, Jeddah, Saudi Arabia, in 2020. The electronic record database of the hospitalized pregnant Saudi women during the years 2018 and 2019 was reviewed. Based on the local hospital protocol, the risk stratification was reassessed by researchers, and the hospital adherence to the prophylaxis was reviewed separately for antenatal and postnatal women.

RESULTS: One thousand and ninety-five electronic records (539 antenatal and 556 postnatal) were reviewed. The postnatal group showed a significantly higher risk compared with an antenatal group (62.2% vs. 11.7%) ($P = 0.000$). There was a highly significant difference between risk categories assessment by the physicians and the researchers in both groups ($P = 0.000$). Thromboprophylaxis was overutilized in the low risk (5% heparin and 41.4% heparin and mechanical devices for antenatal and 17.08% heparin and 6.1% heparin and a mechanical device for the postnatal group) and underutilized in intermediate groups (50% no prophylaxis in antenatal and 51.5% mechanical devices in the postnatal group). There was less adherence to documentation in postnatal as compared to antenatal group (83.6% vs. 95%, $P = 0.000$) for risk documentation and 85.3% versus 91.5% for physician signature ($P = 0.001$). Thromboprophylaxis was ordered for 21.3% of antenatal (12.2 heparin, 3.5% mechanical, and 5.6% both) and 23.7% of postnatal patients (16.5 heparin, 2% mechanical, and 5.2% both). There were no reported VTE events or bleeding complications.

CONCLUSION: There was a considerable VTE risk among hospitalized obstetric patients which peaked during the postnatal period. Physicians showed good compliance to local VTE protocol

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with no reported VTE events or drug-induced bleeding. However, the implementation of prophylaxis is associated with both under and overutilization. There is a need for increasing the physicians' awareness of optimizing VTE risk assessment and documentation for hospitalized obstetric patients.

Keywords:

Ante-natal care, deep-venous thrombosis, postnatal care, pulmonary embolism, risk assessment tools, risk factors, Saudi women, thromboprophylaxis, venous thromboembolism

Venous thromboembolism (VTE) is one of the major causes of maternal morbidity and mortality worldwide.[1] While the reported incidence of VTE is only 1.2 for every 1000 pregnancies,[2] pregnant women are five times more likely to develop VTE than nonpregnant ones[3] and the risk increases more with hospitalization.[4] However, hospital-acquired VTE is highly preventable, with medical and mechanical measures according to the most hospital local thromboprophylaxis protocols.

In addition to the physiological hypercoagulable changes during pregnancy,[5] other known VTE risk factors (RFs) among obstetric women include thrombophilia, history of previous VTE, hypertension, diabetes, and antiphospholipid syndrome.[6] Moreover, additional pregnancy-related RFs include cesarean sections (CS), hyperemesis gravidarum, preeclampsia, ovarian hyperstimulation, and smoking.[7,8] VTE during pregnancy may lead to mortality and significant morbidity as placenta abruption, preeclampsia, and fetal growth restrictions.[1] Therefore, physicians should bear great attention to screening pregnant women, especially during hospitalization to detect the high-risk patients, to prevent VTE and its possible complication, and to improve the outcome of both mother and fetus.

The VTE-related maternal mortality has decreased in one country from 1.26/100,000 births in 2009–2011 to 0.85/100,000 births in 2012–2014[9] after implementing key recommendations of thromboprophylaxis for hospitalized antepartum as well as early postpartum cases with risk for VTE.[10]

Saudi Arabia reported a more or less similar pregnancy-related VTE incidence[11] to other countries with a report of 9% postdelivery incidence in one study.[12] However, few Saudi studies addressed the VTE prophylaxis during hospitalization of obstetric cases. One study in 2018[13] reported underutilization of thromboprophylaxis in eligible obstetric women mainly due to the absence of proper tools. East Jeddah Hospital in Jeddah has a VTE task force that standardized its local policies for VTE risk assessment and thromboprophylaxis.

Therefore, this study was conducted to assess the VTE RFs and to evaluate hospital adherence to the local thromboprophylaxis policies among admitted obstetric women.

Methods

This study was a retrospective case file review at East Jeddah Hospital, Jeddah, Saudi Arabia from December 2019 to February 2020. All hospitalized obstetric women were identified using the hospital electric files database. The inclusion criteria included women admitted on or after January 1, 2018, when the VTE assessment tool was first introduced into the electronic system of the hospital and concluded by December 31, 2019. The included obstetric women were those who were admitted during pregnancy or for labor, of any age, with or without risk for VTE. Records with incomplete personal or clinical data were excluded. The primary objective was to examine whether patients received one of the indicated anticoagulants at the proper dosage and during the relevant hospital days as determined in the local protocol. Rates of compliance were assessed, and the reasons for guideline noncompliance were also determined. The researchers reviewed all inpatient electronic files for their clinical data (age, body mass index (BMI), parity, multiple pregnancies, mobility restriction, smoking, personal history of VTE (single previous VTE related to major surgery, or any previous VTE except a single event related to major surgery), family history of VTE (family history of unprovoked or estrogen-provoked VTE in the first-degree relative), risk assessment and categorization by the attending physicians, the use of thromboprophylaxis (medical, mechanical, or both), and the occurrence of VTE events. Risk assessment was then reassessed by the researchers using the same criteria of the hospital tools [Figure 1a and b].

The study was conducted in accordance with the Helsinki declaration of 1975, as revised in 2000 as well as the ethical standards of the responsible committee on human experimentation. Authors ensured confidentiality of all the obtained data from patients' medical records. The study received ethical approval from the local institutional review board in Jeddah health affairs through review according to KACST GCP regulations (IRB registration number with KACST: KSA: H-02-J-002).

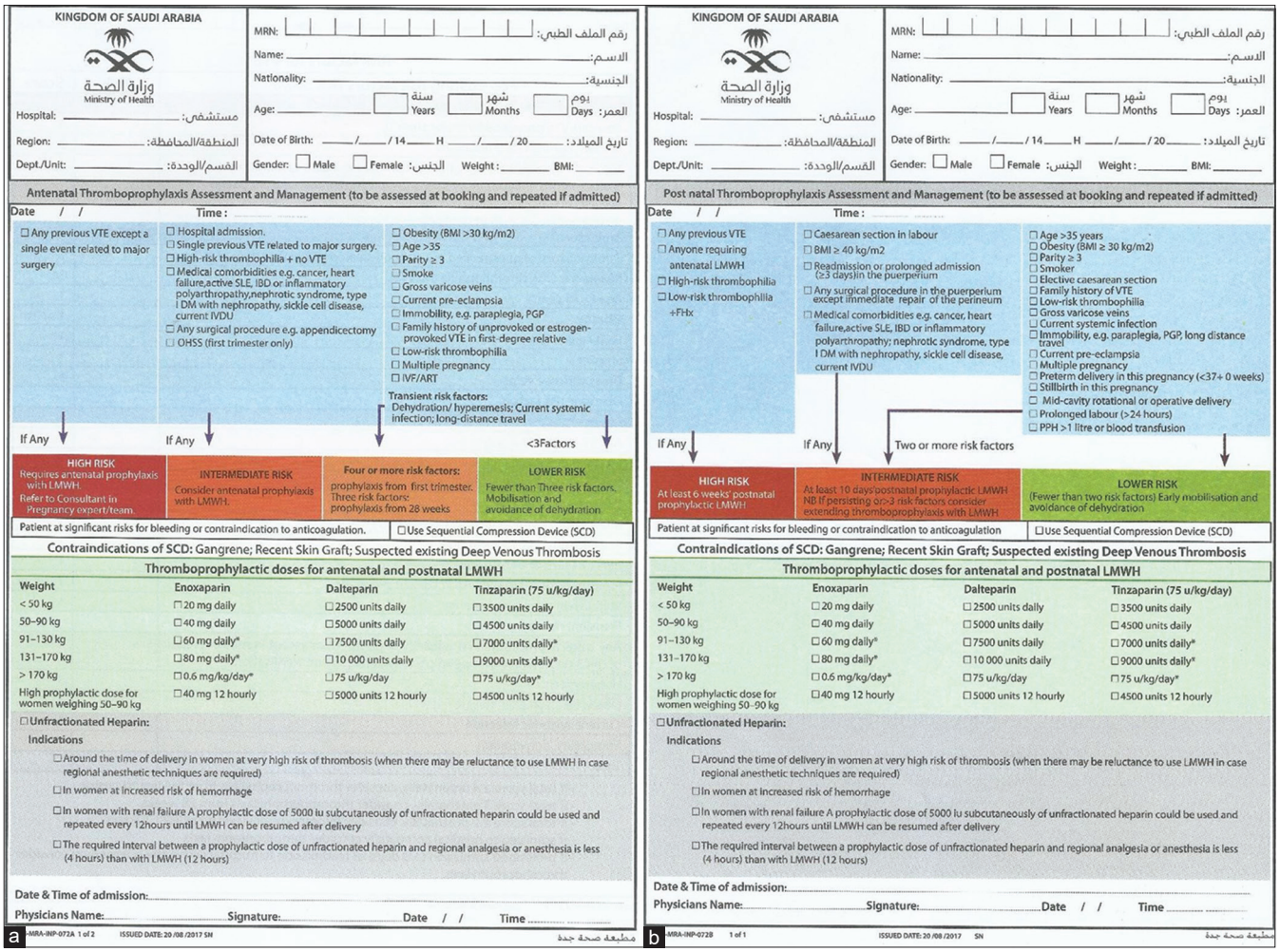

Figure 1: (a) Antenatal risk assessment tools and thromboprophylaxis: (b) Postnatal risk assessment tools and thromboprophylaxis

The hospital tool of the venous thromboembolism risk assessment and thromboprophylaxis for antenatal patients

The protocol of the VTE prophylaxis is based on scientific evidence that describes an effective therapy to prevent VTE. This tool is classified into three groups [Figure 1a]:

- High-risk group includes women with any previous VTE except for a single event related to major surgery
  - This group needs antenatal prophylaxis with low-molecular-weight heparin (LMWH).
- Intermediate risk group includes women with single event related to major surgery, high-risk thrombophilia, medical comorbidities, and any surgical procedure
  - This group needs antenatal prophylaxis with LMWH.
- Low-risk group includes women with obesity >30 kg/m^2, age >35-year, parity >3, multiple pregnancies, smoking, immobility, low-risk thrombophilia, gross varicose vein, family history of unprovoked or estrogen provoked VTE in first-degree relative, current preeclampsia, dehydration, and infection. It is divided as follows:
  - Low risk fewer than three factors need mobilization and avoid dehydration
  - Low risk includes three RFs need prophylaxis from 28 weeks
  - Low risk includes four or more factors need prophylaxis from the first trimester.

The hospital tool of the venous thromboembolism risk assessment and thromboprophylaxis for postnatal patients

This tool is classified into three groups [Figure 1b]:

- High-risk group includes any previous VTE, anyone requiring antenatal LMWH, and high- and low-risk thrombophilia
  - This group needs at least 6 weeks postnatal prophylactic LMWH.
- Intermediate risk group includes
- Cesarean section in labor, BMI >40 kg/m^2, readmission or prolonged admission >3 days, medical comorbidities, and any surgical procedure except immediate repair of the perineum
- Two or more of low RFs or

  - This group needs at least 10 days postnatal prophylactic LMWH (if persist or >3 RFs consider extending thromboprophylaxis with LMWH).
- Low risk fewer than two includes obesity 30 kg/m^2, age >35-year, parity >3, multiple pregnancies, smoking, immobility, elective cesarean section, low risk thrombophilia, gross varicose vein, family history of VTE, preterm or prolonged labour, current preeclampsia, dehydration, and infection.
  - It needs early mobilization and avoidance of dehydration.

Statistical analysis

Statistical analysis was performed using the SIBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. A descriptive analysis of the categorical variables was reported as number (%). The Chi-squared tests were used to compare between different obstetric risk groups for both antenatal and postnatal women. Microsoft Excel worksheet was used to construct Figures 2 and 3. All statistical tests were two-sided, and a $P < 0.05$ was considered statistically significant.

Results

Overall, 1095 electronic files met the inclusion criteria, they were classified into antenatal (539 (49.2%)) and postnatal (556 (50.8%)) groups, 77.4% of them aged <35 years. Reasons for admission for antenatal women were mainly medical comorbidities (94.4%) rather than pregnancy-related conditions (5.6%). For postnatal cases, CS (25.5%) and spontaneous vaginal delivery (50.9%) were the main causes of admission [Table 1]. The risk assessment at admission for the antenatal group was mainly in the ward (93.9%), whereas it was more in the delivery room (43.7%) for the postnatal group, with a significant difference between both groups ($P = 0.000$).

RFs of groups, including BMI, multiple pregnancies, parity, smoking, personal or family VTE history, and mobility restriction are seen in Table 1. Prenatal women showed a significantly higher frequency of BMI ≥30 ($P = 0.000$) than postnatal women who showed significantly higher parity ($P = 0.006$), multiple pregnancies ($P = 0.000$), and VTE family history ($P = 0.025$). There was no significant difference between both groups concerning other RFs including smoking ($P = 0.051$), VTE past history ($P = 0.233$), or mobility restriction ($P = 0.882$). The total risk among the postnatal group was 62.2% which was significantly higher than the antenatal (11.7%) group and included mainly the low (38.3% vs. 5.4%) and the intermediate-risk groups (23% vs. 4.1%) with very few patients in the high-risk group (1.1% vs. 0.7%) ($P = 0.000$).

In Figures 2 and 3, there was a highly significant difference between risk categories assessment by the physicians as compared to those assessed by the researchers in both groups ($P = 0.000$). In the antenatal group [Figure 2], physicians overestimated all categories with under-estimation of the no-risk group. In the postnatal group [Figure 3], physicians under-documented the no-risk category with overestimation of the high and underestimation of the intermediate-risk categories.

In Table 2, prophylaxis was overutilized in the low-risk groups (17.2% heparin, 41.4% both heparin and mechanical devices in the antenatal group & 17.08% heparin, 6.1% both heparin and mechanical devices in the postnatal group), and underutilized in the intermediate groups (50% no prophylaxis in the antenatal group & 51.5% mechanical devices in the postnatal group).

In Table 3, there was less adherence to documentation in postnatal compared to the antenatal group (83.6% vs. 95% $P = 0.000$ for risk documentation and 85.3% vs. 91.5% for physician signature [$P = 0.001$]). The main defect was in the documentation of the contraindication of VTE prophylaxis in both groups (25.2% vs. 22.7%, $P = 0.567$). Thromboprophylaxis was ordered for 21.3% of antenatal (12.2 heparin, 3.5% mechanical devices,

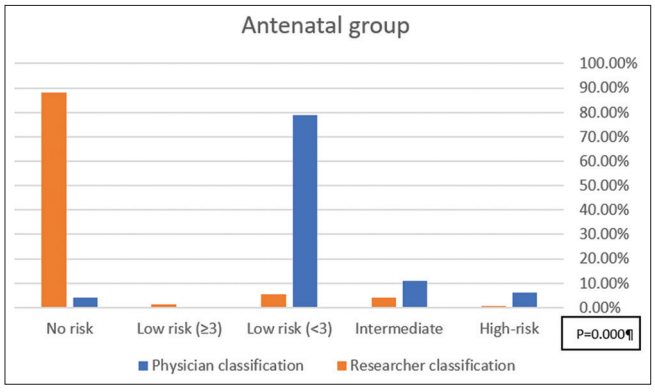

Figure 2: Comparing the venous thromboembolism risk categories of the antenatal women assessed by physicians and researchers

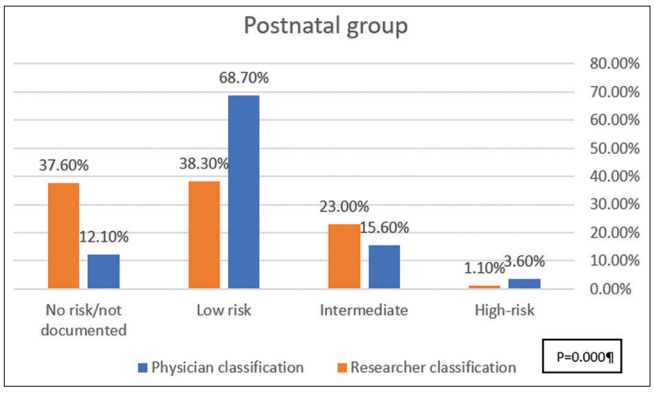

Figure 3: Comparing the venous thromboembolism risk categories of the postnatal women between physicians and researchers

Table 1: The characteristics of the hospitalized obstetric women and their venous thromboembolism risk factors

	Antenatal group (*n*=539), *n* (%)	Postnatal group (*n*=556), *n* (%)	*P*
Age (year)			0.085
<35	405 (75)	442 (79)	
35 or more	134 (25)	114 (21)	
Reasons for admission	Medical comorbidities - (94.4) Pregnancy related conditions - (5.6)	Cesarean section - 142 (25.5) Spontaneous vaginal delivery - 283 (50.9) Others - 131 (23.6)	
Admission			
Delivery room	33 (6.1)	243 (43.7)	0.000
Ward	506 (93.9)	313 (56.3)	
BMI (kg/m^2)			
Underbuilt <18.5	66 (12)	19 (3.4)	0.000
Lean 18.5-24.9	107 (19.9)	201 (36.2)	
Overweight 25-29.9	158 (29.3)	174 (31.3)	
Obese 30-34.9	96 (18)	82 (14.7)	
Overt obesity 35 or more	112 (21)	80 (14.4)	
Parity			
Nulliparous	128 (23.7)	116 (20.9)	0.006
Multiparous	411 (76.3)	440 (79.1)	
Multiple pregnancy	19 (3.5)	103 (18.5)	0.000
Smoking	8 (1.5)	2 (0.4)	0.051
VTE personal history	0	3 (0.5)	0.233
VTE family history	4 (0.7)	2 (0.4)	0.025
Mobility restriction:	10 (1.9)	11 (2)	0.882
VTE risk	126 (11.7)	347 (62.4)	0.000
High risk	4 (0.7)	6 (1.1)	
Intermediate risk	22 (4.1)	128 (23.0)	
Low risk (<3)	29 (5.4)	213 (38.3)	
Low risk (≥4)	8 (1.5)		

BMI=Body mass index, VTE=Venous thromboembolism

Table 2: Venous thromboembolism thromboprophylaxis for both antenatal and postnatal women

Antenatal group	High-risk *n* (%)	Intermediate risk *n* (%)	Low risk 3 *n* (%)	Low risk 4 *n* (%)	No risk *n* (%)
Not ordered	1 (25.0%)	11 (50.0%)	10 (34.5%)	1 (12.5%)	401 (84.2%)
Mechanical	0 (0.0%)	0 (0.0%)	2 (6.9%)	0 (0.0%)	17 (3.6%)
Heparin	0 (0.0%)	10 (45.5%)	5 (17.2%)	0 (0.0%)	51 (10.7%)
Both	3 (75.0%)	1 (4.5%)	12 (41.4%)	7 (87.5%)	7 (1.5%)
Postnatal group	**High-risk *n* (%)**	**Intermediate risk *n* (%)**	**Low risk *n* (%)**		**No risk *n* (%)**
Not ordered	3 (50.0%)	66 (51.5%)	154 (72.3%)		201 (96.2%)
Mechanical	0 (0.0%)	0 (0.0%)	8 (3.8%)		3 (1.4%)
Heparin	1 (16.7%)	49 (38.3%)	38 (17.08%)		4 (1.9%)
Both	2 (33.3%)	13 (10.2%)	13 (6.1%)		1 (0.5%)

and 5.6% both) and 23.7% of postnatal patients (16.5 heparin, 2% mechanical, and 5.2% both). Only 4.6% of the antenatal women had to continue prophylaxis after discharge compared to 10.4% of the postnatal women with a significant difference (P = 0.000). Although the study, there were no reported VTE events or bleeding complications from thromboprophylaxis.

Discussion

In this study, evaluation of 2-year implementation of VTE risk assessment and thromboprophylaxis protocols in obstetric patients in one governmental hospital showed effectiveness, compliance, and safety. Most physicians were compliant to risk classification and documentation in the risk assessment form and ordered thromboprophylaxis with no reported in-hospital VTE events or drug-induced bleeding. Except for the high-risk category, the implementation of the local protocol was associated with both under and overutilization of thromboprophylaxis. The risk stratification was not precise with overestimation of high risk and mixing between low and no risk categories. Another preventable flaw was found in the documentation at admission as well as after discharge.

Table 3: Documentation of venous thromboembolism risk categories and thromboprophylaxis among hospitalized obstetric women

	Antenatal group (*n*=539), *n* (%)	Postnatal group (*n*=556), *n* (%)	*P*
VTE risk assessment documented			
Not documented	27 (5)	91 (16.4)	0.000
Documented somewhere	512 (95)	665 (83.6)	
Documented in the risk assessment form	509 (94.4)	443 (79.7)	
Risk assessment signed by treating physician			
No	46 (8.5)	82 (14.7)	0.001
Yes	493 (91.5)	474 (85.3)	
VTE prophylaxis ordered	115 (21.3)	132 (23.7)	0.104
Mechanical	19 (3.5)	11 (2)	
Heparin	66 (12.2)	92 (16.5)	
Both	30 (5.6)	29 (5.2)	
Contraindications to VTE prophylaxis	2 (0.4)	3 (0.5)	0.567
VTE prophylaxis documentation on discharge plan	25 (4.6)	58 (10.4)	0.001
VTE prophylaxis discharge plan and duration			0.000
Ambulation and good hydration	1 (0.2)	28 (5)	
Antenatal prophylaxis with LMWH	16 (3.0)	5 (1)	
Postnatal 5 days-6 weeks	7 (1.3)	24 (4.3)	

VTE=Venous thromboembolism, LMWH=Low-molecular-weight heparin

The postnatal group showed more RFs with higher parity and multiple pregnancies and a higher total risk of 62.4% which is far exceeding the risk in the prenatal group (11.7%). In agreement with our results, others showed the VTE risk during pregnancy to peak in the postpartum period[13] with prevalent obesity, multiple pregnancies,[13] previous VTE, and smoking.[6,7] This postnatal group, in particular, suffered under-documentation perhaps because many of the women were first assessed in the delivery room. Moreover, physicians were confused between no risk and low-risk categories, underestimated the intermediate, and overestimated the high-risk categories [Figure 3] with consequent overutilization of heparin and a possible increase in the risk of bleeding. Similarly, in the antenatal group, the physicians were confused between no risk and the 2 low-risk categories, did not adhere to the categorization of the second group of low-risk category despite their difference in their management and overestimated the intermediate and the high-risk categories [Figure 2].

This mismatch between the proper risk categorization and that performed by physicians would not explain the over and under-utilization of the thromboprophylaxis in this study but could add to the defects of the implementation of the local protocol. Despite the wide variation in the risk and in the presence of few contraindications, thromboprophylaxis was ordered similarly for both antenatal and postnatal patients [Table 3]. Moreover, applying the physicians' assessment of the RFs, it was found that prophylaxis was overutilized in the low-risk categories and underutilized in the intermediate-risk categories [Table 2]. Unfortunately, the protocol lacked flexibility and did not allow the admitting physician to use or document their clinical judgment or patients' values and preferences and this may explain the variability in the assessment and prophylaxis. Another explanation for this variability may be the different reasons of admission, the transfer of patients from the ward to the delivery room, the assessment of patients in the delivery room for the first time, and absence of simple assessment tools.

Similar results were found in one prospective cohort study that assessed VTE prophylaxis compliance in 1035 women (309 antenatal and 731 postnatal) over 2 years. They had a higher risk compared to our patients (3% high risk and 35.4% intermediate risk). Thromboprophylaxis was given to all high-risk women and almost half of the intermediate-risk women. They reported only one VTE event from the intermediate group despite receiving the prophylaxis. Another multicenter study evaluated 540 pregnant women from 16 hospitals for VTE and reported 31.7% pharmacological thromboprophylaxis but almost half of them received smaller doses than indicated with some deviation away from the protocol.[14]

Our results also are in parallel with other studies which assessed in-hospital VTE prophylaxis. One retrospective study reviewed the Health Facts database and found the low rates of compliance with guidelines for thromboprophylaxis among hospitalized patients at risk of VTE.[15] Among the hospitalized patients, the ENDORSE global study reported the variable rates of compliance to prophylaxis use according to the cause of acute care admission and presence of comorbidities and were reported to be underutilized in some countries such as India.[16] The results of Prospective Registry on Venous thromboembolic Events study were very interesting as

they found that after thromboprophylaxis, only 7% of inpatients developed VTE event.[17]

The low compliance with VTE protocol with underutilization of thromboprophylaxis seen in our studies as well as in others could not be fully explained by the fear of bleeding complications of anticoagulation.[18] As there was underutilization of mechanical thromboprophylaxis as well. In the present study, some patients in the intermediate-risk category in both groups (13 antenatal and 25 postnatal) did not receive even the mechanical device for thromboprophylaxis despite clear recommendations in the local protocol [Figure 1].

This study had some potential limitations to be considered while interpreting the results. Due to the retrospective review design of the study, we were unable to capture all relevant data or review the follow-up data as the prophylaxis duration and the compliance with the recommendations of the local protocol, especially among the postnatal group. The data were collected from the patient charts, and there was a possibility to include inaccurate or missing data including the physicians' clinical judgment of the VTE risk. Moreover, the reflection of the physicians on the clinical utility, applicability, and complexity of the protocol could not be assessed. Besides, although we have collected the data of contraindication for anti-coagulation from the records at the time of admission, actual bleeding risks during admission were not possible to be obtained. Finally, the study enlisted only a single hospital, which might not fully represent the demography in a country.

Conclusion

Our results showed a considerable VTE risk among hospitalized obstetric patients which peaked during the postnatal period. The applicability of local hospital protocol of risk assessment and thromboprophylaxis by physicians was associated with good compliance, outcomes with no reported VTE event or drug-induced bleeding. However, the implementation of prophylaxis is associated to some extent with both under and overutilization. Therefore, VTE prophylaxis among obstetric women continues to be complex and inappropriately utilized in clinical practice. This confirms the need for increasing the physicians' awareness toward optimizing the VTE risk assessment and documentation, especially for at-risk hospitalized obstetric patients. Health-care authorities also should find easily applicable appropriate VTE thromboprophylaxis protocols to standardize the necessary care for better preventive strategies to prevent the consequent fetal and maternal morbidity and mortality.

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Conflicts of interest

There are no conflicts of interest.

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