



Original Research Article

Risk Scoring and Appraisal of Thromboprophylaxis Following Emergency Cesarean Section - A Pilot Study

Shakuntala PN[@], Jhancy, Ashmita D, Rabia M, Shalini N, SK Sharma, Padmini Isacc, Shubha R Rao

Department of Obstetrics and Gynaecology, St. Martha's Hospital, Bengaluru. Karnataka, India.

[@]Correspondence Email: shakuntala_pn@yahoo.com

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ABSTRACT

Introduction: The highest risk period for Venous Thromboembolism(VTE), and pulmonary embolism in particular, is during the postpartum period. Caesarean section is a significant risk factor. Indian data is very sparse.

Aims and Objectives:

1. Retrospective application of the risk scoring proposed by the Indian Venous Thromboembolism Core Group-2006, to identify the need and analyse the routine practice of unfractionated heparin (UFH) prophylaxis in the study group.

2. Study, compare and analyse the safety of unfractionated heparin (UFH) prophylaxis in women receiving heparin following emergency caesarean section and women who did not receive heparin prophylaxis.

Methods: A retrospective analysis (July 2009 to December 2009) of 120 randomly selected women who had undergone emergency section was performed. Study group consisted of (60) women who received prophylactic unfractionated heparin, 6 hours following emergency caesarean section upto 7 days post partum, control group (60) did not receive unfractionated heparin. Results were analysed statistically.

Results: The women characteristics, body mass index, associated medical conditions and post delivery complications were comparable. On applying the Indian Venous Thromboembolism Study Group Scoring -2006, thrombo-prophylaxis was required in 75% vs 80.00% ,(p value 0.1), heparin with graded compression stockings in 02(03.33%) vs none,(p value. NS), in the study and the control groups respectively. 02(03.33%) in study group and 01(01.66%) in control group needed extended prophylaxis upto 4-6 weeks after delivery.

In the study group 3.32% vs 0%,(p value 0.22) required prophylaxis for 6 weeks post delivery. In both the groups 18.34% did not score to require unfractionated heparin except early ambulation and adequate hydration. Post operative wound bleeding, post partum haemorrhage were comparable in both the groups.

Conclusion: Indian venous thromboembolism core group scoring -2006 should be applied to all the women undergoing labour. Thereby, avoiding unnecessary heparin prophylaxis in 18.34 % of women. In a low resource setting unfractionated heparin can be safely used for thromboprophylaxis, with acceptable complications in the post partum period. In women who scored >4- high and ≥ 5 -highest risk groups and who need extended prophylaxis for 4-6 weeks the role of unfractionated heparin appears to be cumbersome and expensive in the long run, as there is a need for evaluation of aPTT. Low Molecular Weight Heparin (LMWH) appears to be convenient. Will this new strategy be cost effective in reducing

the enormous morbidity, mortality and resource expenditure associated with venous thromboembolism needs to be widely researched in the Indian obstetric population?

Key words: Deep venous thrombosis prophylaxis, Unfractionated heparin, Postpartum , Caesarean section.

INTRODUCTION

The relative risk of Venous Thromboembolism (VTE) in pregnancy is increased four- to six-fold ⁽¹⁾ and this is increased further in the postpartum period. ⁽²⁾ The absolute risk is however low, with an overall incidence of VTE during pregnancy and the puerperium of 1–2/1000 deliveries. ^(1,3)

Royal College of Obstetricians and Gynaecology, green top guidelines no 37, also mentioned that many antenatal Venous Thromboembolism (VTE) events occur in the first trimester and therefore prophylaxis, if given, should begin early in pregnancy. ⁽⁴⁾ The highest risk period for VTE, and pulmonary embolism in particular, is during the postpartum period. ^(1, 2) Caesarean section is a significant risk factor. ⁽³⁾ Indian data is very sparse. ⁽⁵⁻⁷⁾

During pregnancy , delivery and puerperium there is hypercoagulability due to circulation of clotting factors essential for placental separation following delivery, venous stasis due compression by the gravid uterus acting as a mechanical impediment to venous return and delivery can cause damage to pelvic vessels, which satisfy Virchow triad of initiating factors. ⁽⁸⁾

Todi SK et al have opined that there is sub-optimal utilization of thromboprophylaxis in our country. Few reasons quoted are the perception that the incidence of VTE in the Indian subcontinent is lower than seen in the western world which may be due to lack of reporting, suboptimal follow up of our patients, treated as a fresh case elsewhere, the fact that a majority of thromboembolic events are clinically silent (80%) and the fear (among

the treating doctors) of bleeding complications associated with thromboprophylaxis. ⁽⁹⁾

With this background we adopted the risk assessment module published by the VTE core group (5) along with guidelines published by American College of Chest Physicians (ACCP, 2008). ⁽¹⁰⁾ As a departmental protocol following RCOG guidelines ⁽¹¹⁾ all women who underwent emergency cesarean section were administered unfractionated heparin from 6 hours post caesarean section upto 7 days post partum. No risk scoring was applied. The present study was conducted to identify the sub group who did not require any thromboprophylaxis and the safety of unfractionated heparin. At present, all recommendations-Indian VTE Core Group ⁽⁵⁾, ACCP, ⁽¹⁰⁾ RCOG, ⁽¹¹⁾ recommend low molecular weight heparin (LMWH) to be used during pregnancy and puerperium. We rationalized after reviewing the literature that preference of LMWH to unfractionated heparin in the puerperium was due to safety issues especially post partum haemorrhage and wound complications and the need for monitoring activated partial thromboplastin time(aPTT). ⁽¹²⁾ In practice, unfractionated heparin was used in the department for almost 3 years and no such incidences were attributed for by the drug in question. Therefore the safety profile was also analysed.

MATERIAL AND METHODS

This study was conducted at Department of Obstetrics and Gynaecology, St. Martha's Hospital, Bengaluru from July 2010 to December 2010. All puerperial

women who had undergone emergency caesarean section including class 1, 2 and 3 were included. Exclusion criteria were women with coagulation disorders and heart disease with mechanical valves. Out of a total of 340 puerperial women (205 received unfractionated heparin (UFH) +135 no UFH). 60 women in each group, summing upto 30-45% of the sample were randomly selected by drawing a lot of hospital identification numbers closed in an envelope by freshly posted student nurses.

Study group consisted of 60 puerperial women following emergency

caesarean section who received, unfractionated heparin at 6 hours, 5000 IU given subcutaneously 12 hours apart for 7 days (Gland Pharma -5ml vial containing 25,000 IU. Rupees 149 per vial, requiring three vials per patient amounting to rupees 450. Control group consisted of 60 puerperial women following emergency caesarean section who did not receive unfractionated heparin.

The risk assessment module as recommended by the Indian VTE core group (5) and ACCP-2008 guidelines (10) for both the groups were performed.

Table 1 : Risk assessment module

VTE Risk Assessment Score Card for Surgical and Medical Patients
Patient's Details

Name: _____
 Primary Diagnosis: _____
 Consultant: _____
 Address & Phone No. _____

<p>Each Item Represents 1 Risk Factor A</p> <ul style="list-style-type: none"> Minor Surgery <input type="checkbox"/> Age 40-60 yrs <input type="checkbox"/> Pregnancy or Post Partum (<1 month) <input type="checkbox"/> Varicose Veins <input type="checkbox"/> Inflammatory Bowel Disease <input type="checkbox"/> Obesity (>20% of ideal BW) <input type="checkbox"/> Combined Oral Contraceptives/HRT <input type="checkbox"/> <p style="text-align: right;">Total Tick marks <input type="checkbox"/> x 1 Total Score A <input type="checkbox"/></p>	<p>Each Item Represents 3 Risk Factors C</p> <ul style="list-style-type: none"> History of DVT/PE <input type="checkbox"/> Myocardial Infarction <input type="checkbox"/> Congestive Heart Failure <input type="checkbox"/> Severe Sepsis / Infection <input type="checkbox"/> Factor V Leiden / Activated Protein C resistance <input type="checkbox"/> Antithrombin III deficiency <input type="checkbox"/> Protein C & S deficiency <input type="checkbox"/> Dysfibrinogenemia <input type="checkbox"/> Homocysteinemia <input type="checkbox"/> 20210A Prothrombin Mutation <input type="checkbox"/> Lupus Anticoagulant <input type="checkbox"/> Antiphospholipid Antibodies <input type="checkbox"/> Myeloproliferative Disorders <input type="checkbox"/> Disorder of Plasminogen and Plasminic Activation <input type="checkbox"/> Heparin Induced Thrombocytopenia <input type="checkbox"/> Hyperviscosity Syndromes <input type="checkbox"/> <p style="text-align: right;">Total Tick marks <input type="checkbox"/> x 3 Total Score C <input type="checkbox"/></p>	<p>Each Item Represents 5 Risk Factors D</p> <ul style="list-style-type: none"> Elective Major Lower Extremity Arthroplasty <input type="checkbox"/> Hip, Pelvis or Leg Fracture <input type="checkbox"/> Stroke / ISCHEMIC <input type="checkbox"/> Multiple Trauma <input type="checkbox"/> Acute Spinal Cord Injury <input type="checkbox"/> <p style="text-align: right;">Total Tick marks <input type="checkbox"/> x 5 Total Score D <input type="checkbox"/></p>
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Total Score (A+B+C+D) = _____

Total Score	Risk Category
1	Low
2	Moderate
3 - 4	High
5 or more	Highest

Table:1- Risk Category Stratification of women according to the ACCP scoring-2008(10), (refer to section 3.2-guidelines during lactation, section 4.2, guidelines supporting use of heparin, section 5.1 guidelines for risk of VTE following caesarean section.) and the use of thromboprophylaxis.

S.No.	RISK CATEGORY STRATIFICATION	RECOMMENDATIONS	GRADE	LEVEL OF EVIDENCE
1	Pregnancy +caesaren section- no risk factors*. A(1)+B(2)=3	Is against the use of specific thromboprophylaxis other than early mobilization.	GRADE 1B	Stronger- Moderate quality
2.	Pregnancy +caesaren section+ one risk factor*. A(1)+B(2)+ one score for risk factor=4	Prophylactic LMWH or UFH or mechanical prophylaxis(GCS or IPC) while in hospital following delivery.	GRADE 2C	Weaker- Low quality (needs RCT)
3.	Pregnancy +caesaren section+multiple risk factors**	Heparin prophylaxis+GCS stockings or IPC	GRADE 2C	Weaker- Low quality (needs RCT)
4.	Pregnancy +caesaren section- significant risk factors persist following delivery(eg.,HIV,CANCER)	Extended prophylaxis upto 4-6 weeks after delivery.	GRADE 2C	Weaker- Low quality (needs RCT)
5.	Thrombosis risk assessment be carried out in all women undergoing caesarean section to determine the need for thromboprophylaxis.		GRADE 2C	Weaker- Low quality (needs RCT)

*A-refers to the first part of the scoring system. Here pregnancy and or puerperium will get a score of 1 and multiplied by factor 1.B- refers to the second part of the scoring system. Cesaeran section is a major procedure and will be multiplied by factor 2.

**C-represents the risk factors multiplied by 3 and D- represents the risk factors multiplied by 4. All the score from each group are then added to derive a complete score.

Therefore, all the patients in puerperium (score 1) and undergoing emergency cesarean section (score 2) would have had a score of 3 when added. The risk category stratification was done according the Table1. The risk of DVT in obstetric patients with pre-eclampsia and other factors is unknown but prophylaxis should be considered. ⁽⁵⁾ And hence the decision for risk category stratification and safety profile of unfractionated heparin in both the study and control groups were analysed.

BMI was calculated using the BMI calender (WHO-2004-13). Weight in kilograms at booking was considered. In some women where BMI could not be calculated a pre pregnancy weight ≥ 70 kilograms was considered a risk factor.

Table 2: The International Classification of adult underweight, overweight and obesity according to BMI.

Classification	BMI(kg/m ²)	
	Principal cut-off points	Additional cut-off points
Underweight	<18.50	<18.50
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 - 16.99	16.00 - 16.99
Mild thinness	17.00 - 18.49	17.00 - 18.49
Normal range	18.50 - 24.99	18.50 - 22.99
		23.00 - 24.99
Overweight	≥ 25.00	≥ 25.00
Pre-obese	25.00 - 29.99	25.00 - 27.49
		27.50 - 29.99
Obese	≥ 30.00	≥ 30.00
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49
		37.50 - 39.99
Obese class III	≥ 40.00	≥ 40.00

The results were compared with the control group and the results were analysed statistically using Chi-Square test/ Fisher Exact test with significance accepted at 95% confidence level ($p < 0.05$).

RESULTS

Table 3: showing characteristics of women.

S.No.	CHARACTERISTICS	STUDY GROUP (60)	CONTROL GROUP (60)	"p value"
1.	AGE			
	≤35 YEARS	59	55	NS
	≥35 YEARS	01	05	NS
2.	PARITY			
	PRIMIPARA	45	33	NS
	MULTI PARA	11	16	NS
	PREVIOUS ABORTION			
	ONE ABORTION.	04	11	NS
3.	*PREVIOUS TWO AND ABOVE ABORTIONS.	03	05	NS

*Anti Phospholipid antibodies were negative. Both the groups were comparable.

Table 4: Distribution of Body Mass Index.

S.No.	BODY MASS INDEX(13)	STUDY GROUP(60)	CONTROL GROUP(60)	"p value"
1.	<18.50-(under weight)	02(03.33%)	00(00.00%)	NS
2.	18.50 - 24.99(Healthy)	12(20.00%)	13(21.67%)	NS
3.	25.00 - 29.99(overweight or pre obese)	24(40.00%)	21(35.00%)	NS
4.	30.00 - 34.99(obese class I), 35.00 - 39.99 (obese class II)	18(30.00%)	21(35.00%)	NS
5.	40-70(very obese) ≥40.00	01(01.67%)	00(00.00%)	-
6.	≥ 70 kilograms(5)	02(03.33%)	03(05.00%)	-
7.	< 70 kilograms (5)	01(01.67%)	02(03.33%)	-
	Total	60(100%)	60(100%)	

Body mass index ≥ 25 and when not available the present pregnancy booking weight ≥ 70 kilograms were considered as a separate risk factor.70% of women in both the groups had a BMI of ≥ 25 .

Table 5: Associated medical conditions contributing to thrombosis.

S.No.	MEDICAL CONDITIONS	STUDY GROUP(28/60)	CONTROL GROUP(30/60)	"p value"
1.	Gestational hypertension			
	Mild	06	06	NS
	Severe	08	06	NS
2.	Gestational diabetes on insulin	02	03	NS
3.	Anaemia	07	09	NS
4.	Hypothyroidism	00	02	-
5.	HIV	02	01	NS
6.	Asthma- on inhalers*	03	01	NS
7.	Seizure disorder*	00	01	-
8.	Ovarian cyst**	00	01	-
	Total	28(46.66%)	30(50.00%)	NS

*non ambulatory. **mechanical pressure causing stasis of venous return.

Huge ovarian tumor (mucinous cystadenoma measuring 10x 10x 10 centimeters and excised during the caesarean section) causing mechanical obstruction to venous flow was also given a separate score.

Table-6: Risk stratification of women in both the groups.

Risk score	Study group	Control group	P value	Interpretation
Score-3	11(18.34%)	11(18.34%)	NS	Is against the use of specific thromboprophylaxis other than early mobilization and maintaining hydration.
Score 4 (high) One risk factor	45(75.00%)	48(80.00%)	NS	Prophylactic LMWH or UFH or mechanical prophylaxis(GCS or IPC) while in hospital following delivery.
Score 5 and above(highest) Two or more risk factors	02(03.33%)	00(00.00%)	NS	Heparin prophylaxis+ graded compression stockings(GCS) or intermittent pneumatic compression device(IPC)
Score 5 and above with significant risk factors persist following delivery(HIV)	02(03.33%)	01(01.66%)	NS	Extended prophylaxis upto 4-6 weeks after delivery.
Total	60(100%)	60(100%)		

Table 7: Post cesarean section complications.

S.No.	COMPLICATIONS	STUDY GROUP (4/60)	CONTROL GROUP (3/60)	"p value"
1.	Post partum haemorrhage	01(01.66%)	02(03.33%)	NS
2.	Wound haematoma requiring drainage	00(00.00)	00(00.00%)	-
3.	Wound induration(MgSo4 dressing)	02(03.33%)	01(01.66%)	NS
4.	Ecchymosis \$	01(01.66%)	00(00.00%)	-
5.	Cerebrovascular thrombosis	01(01.66%)	00(00.00%)	-
	Total	04(08.31%)	03(05.00%)	NS

DISCUSSION

An overall incidence of Venous Thromboembolism during pregnancy and the puerperium is of 1–2/1000 deliveries. (1, 3)

The highest risk period for VTE, and pulmonary embolism in particular, is during the postpartum period. (1, 2-10, 11) Caesarean section is a significant risk factor, (3-13) Vora S(6) have reported that the prevalence of deep venous thrombosis in pregnancy and post partum in India is more or less the same as reported in the literature. The VTE core group also opined that, VTE is an important healthcare problem the world over, resulting in significant morbidity, mortality and resource expenditure. Indian perspective on this topic is lacking due to the nonavailability of published Indian data. (5)

Quite rightly rationalised it is difficult to justify the routine use of thromboprophylaxis in clinical practice, but certainly there is a role for thromboprophylaxis in orthopedic surgery,

high risk pregnancies, and acutely ill medical patients. Studies have proven the cost effectiveness of this treatment keeping in mind the increased cost incurred during hospitalization for treatment of a symptomatic patient. (15) The use of Low Molecular Weight Heparin to treat selected patients with VTE outside the hospital has the potential to dramatically reduce the cost of health care. (12)

To the best of our knowledge there are no published Indian data regarding the use of Unfractionated heparin in thromboprophylaxis during the puerperium following an emergency caesarean section. Further risk category stratification and implementation of pharmacologic therapy is unheard of. Hence, we designed a retrospective analysis, which could address the need to prevent the use of unfractionated heparin in all the women undergoing emergency caesarean section, the sub set of women who would need heparin along with graduated compression stockings, subset

that need extended prophylaxis and therefore, the need to change over to LMWH which appears to be as effective as and safer than unfractionated heparin. (5,14)

Table 3 shows characteristics of women. Age ≥ 35 years was considered an independent risk factor; it was comparable in both the groups. Parity and details of previous abortions had no much difference. Two women in the study group and one woman in the control group were tested for antiphospholipid syndrome and found to be negative. In the present study we had 70% each in the study and control groups where women had a BMI ≥ 25 , table-4. BMI ≥ 25 was considered an independent risk factor for VTE. Similar opinion was put forth by VTE core group. (5) Obesity in pregnancy is associated with an increased risk of a number of serious adverse outcomes, among them thromboembolism, and higher caesarean section rate have been reported. (3,16)

The contribution by associated conditions like pre-eclampsia, gestational diabetes, anaemia, hypothyroidism, human immunodeficiency syndrome (HIV), asthmatics on nebulisation and seizure disorder who do not ambulate, effect of large ovarian tumors during pregnancy and postpartum predisposing to venous stasis have not been specifically studied in relation to risk scoring stratification but has been assigned in the risk scoring module by the VTE core group. (5) In the present study we include the parameter in table 5 as risk factors. Conditions like HIV in pregnancy need to be explored as the disease persists post delivery. (5)

18.34% each in the study and control groups did not require any thromboprophylaxis according to the recommendation, (5,10) and could have been avoided. Majority of the women in both the groups 75% in study and 80% in control group needed thromboprophylaxis

reiterating the fact the importance of associated risk factors contributing to thromboembolism and thereby its prevention is the supreme goal as depicted by the present study, table 6. Similar experiences are mentioned by other authors. (3, 5, 10, 11, 15)

However, both the groups did not report occurrence of VTE. 4(06.66%) in study group and 3(5.00%) in control group had minor wound complications and postpartum haemorrhage which however did not require blood transfusion, table 7. Hence, the safety profile is acceptable even in the absence of a PTT monitoring of unfractionated heparin. Decision by the treating physician is final. Working out the logistics revealed it would cost only rupees 450 per patient as against rupees 1500 for prophylactic dose of LMWH, which is three times costlier!. But, authors recommend the use of LMWH during pregnancy (does not cross placenta) and in the post partum period, as LMWH is as effective as and safer than UFH and does not need monitoring. (12)

Only two women 02(03.33%) in study group and none in the control group needed heparin prophylaxis and graded compression stockings or intermittent pneumatic compression device. One woman in study group had cerebrovascular thrombosis on the tenth puerperal day, table 7. She had received a prophylactic dose of unfractionated heparin, although on applying the risk scoring, she needed heparin prophylaxis and graded compression stockings. It is still uncertain if this woman has persisting risk factors and if we had treated her with LMWH with graded compression stockings, this catastrophe could have been avoided. The exact contribution by associated HIV infection needs to be explored. Many authors are of the same opinion. (5,10)

CONCLUSION

The incidence and prevalence of thromboembolism in the Indian context needs to be researched. By applying the Indian VTE Group risk scoring -2006 to all the obstetric patients following emergency caesarean section, we were able to decide the need for unfractionated heparin (UFH) prophylaxis. About 75-80% of women following emergency caesarean section with one risk factor will need heparin thromboprophylaxis. We recommend the use of UFH, from 6 hours following caesarean section; 12 hours apart for upto 7 days post partum, at dose of 5000 IU subcutaneously. The safety profile of this drug is acceptable even without monitoring of aPTT, in low resource settings. However the choice of heparin and the monitoring is left to discretion of the practicing physicians. In 18.34% of women any prophylaxis can be avoided (grade 1). When the risk scoring is above 5, it is better to embark on extended thrombo prophylaxis with an outpatient setting, where LMWH proves to be cost effective, there by alleviating the morbidity, mortality and the economic burden posed by the catastrophic outcomes of thromboembolism. The present study is only a pilot study, more randomized controlled trials are needed and maintenance of thromboembolism registry would be ideal!

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