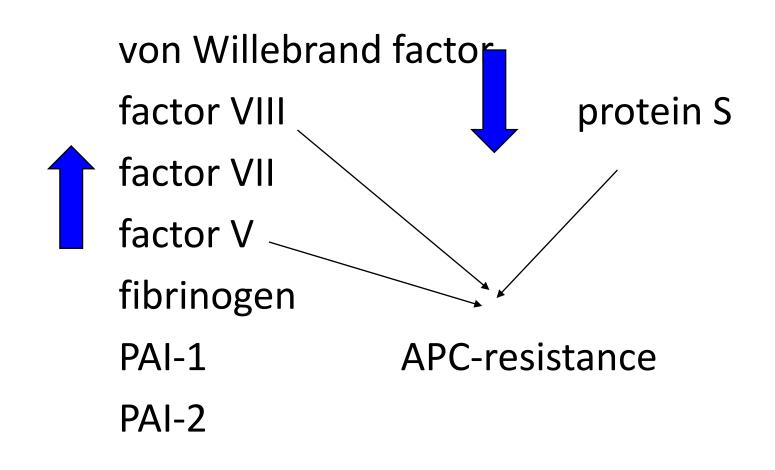
## Prevenzione e Terapia del Tromboembolismo Venoso in Gravidanza

Elvira Grandone Unita' di Emostasi e Trombosi I.R.C.C.S. " Casa Sollievo della Sofferenza" S. Giovanni Rotondo (Foggia)

## **Epidemiology and Risk Factors**

## HEMOSTATIC CHANGES DURING PREGNANCY



## INCIDENCE PER YEAR OF DVT (/ 1,000) J. Int. Med. 232, 155, 1992

- Males < 40 years 0.08</li>
- Males 40 60 years 1.10
- Males > 60 years 4.66

Overall 1.58

- Females < 40 years 0.12
- Females 15 40 years 0.18
- Females 40 60 years 1.00
- Females > 60 years 4.20

# INCIDENCE OF VTE DURING PREGNANCY AND PUERPERIUM (PER 1,000 DELIVERIES)

72.201 deliveries (Glasgow, Scotland)

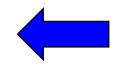
51 cases of DVT and 11 cases of PE (of 50 investigated, 12% AT defect, 8% FV Leiden, 8% FII 20210A)

VTE in pregnancy 0.57

VTE in puerperium 0.29

VTE in pregnancy and puerperium 0.86

T&H 78,1183,1997 - BJOG 107,565,2000



# Venous thromboembolism in pregnant and puerperal women in Denmark 1995–2005

A national cohort study

Rie Adser Virkus<sup>1</sup>; Ellen Christine Leth Løkkegaard<sup>1</sup>; Thomas Bergholt<sup>1</sup>; Ulla Mogensen<sup>2</sup>; Jens Langhoff-Roos<sup>3</sup>; Øjvind Lidegaar

Department of Obstetrics and Gynaecology, Hillerød Hospital, University of Copenhagen, Hillerød, Denmark; <sup>2</sup>Department of Biostatistics, University of Copenhagen, Copenhagen, Denmark; <sup>3</sup>Department of Obstetrics, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; <sup>4</sup>Gynaecological Clinic 4232, Rigshospitalet, University of Copenhagen, Copenhagen, Copenhagen, Denmark

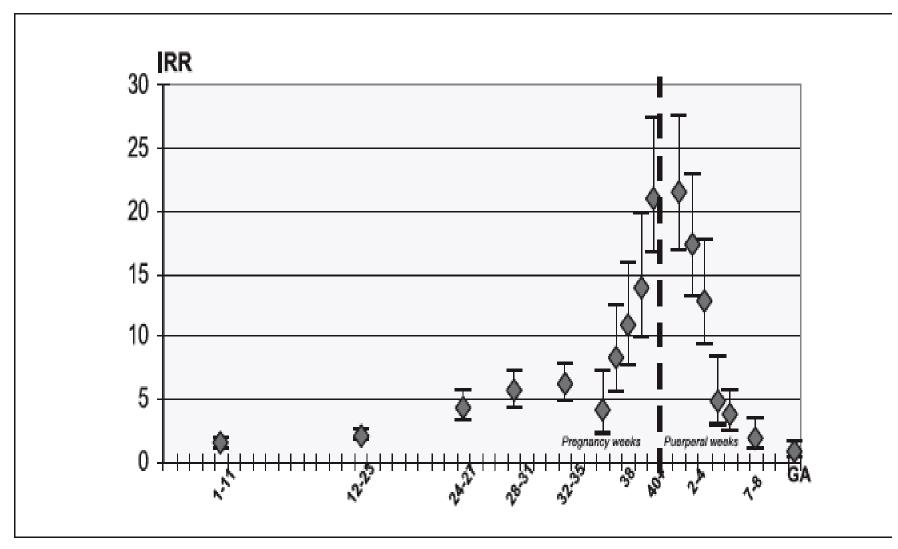


Figure 1: Adjusted\* incidence rate ratios (IRR) of thromboembolism in pregnant and puerperal women versus non pregnant women not using oral contraceptives.

\*Adjusted for age, calendar year and education.

Virkus RA et al, Thromb Haemost 2011

# Maternal mortality in Italy: a record-linkage study

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Accepted 7 January 2011. Published Online 10 March 2011.

# Maternal Mortality in Italy (2000-2007)

- The leading causes of direct death were haemorrhage and thromboembolism, followed by hypertensive diseases in pregnancy. All of these causes should be preventable to a large extent and may indicate the need for an improvement in the quality of care.
- It is noteworthy that in Lazio and Piedmont, where stratification by mother's **educational level** was possible, MMR among women with low educational level was twice that among women with high educational level (RR = 1.9;
- 95% CI 1.1–3.6).

## Maternal Mortality in Italy

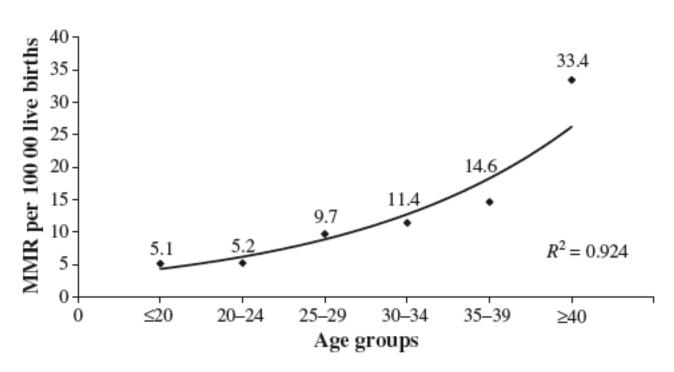


Figure 1. Maternal mortality ratios by age groups.

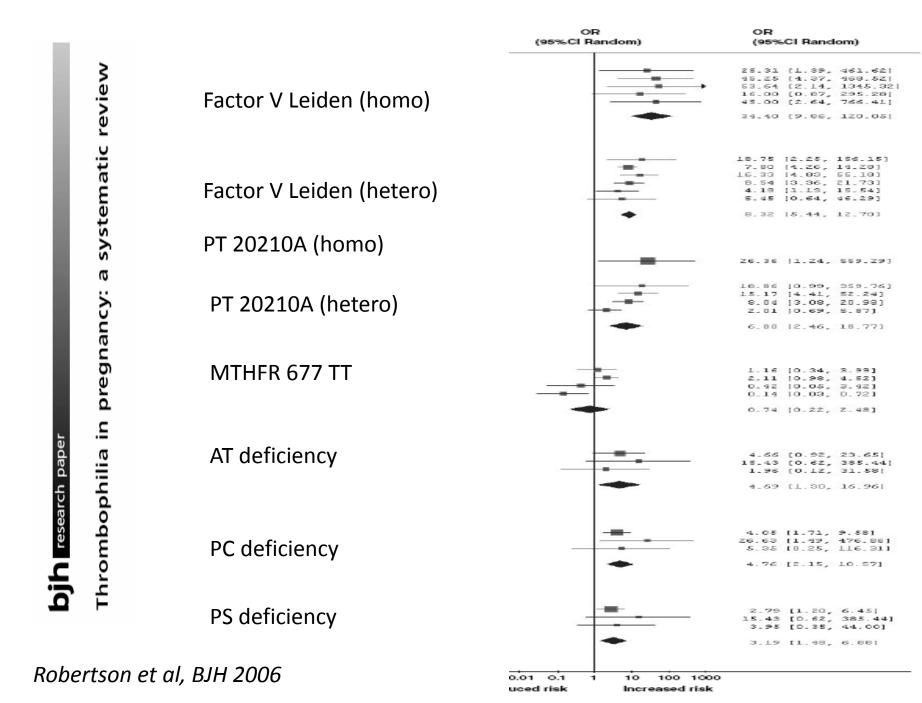
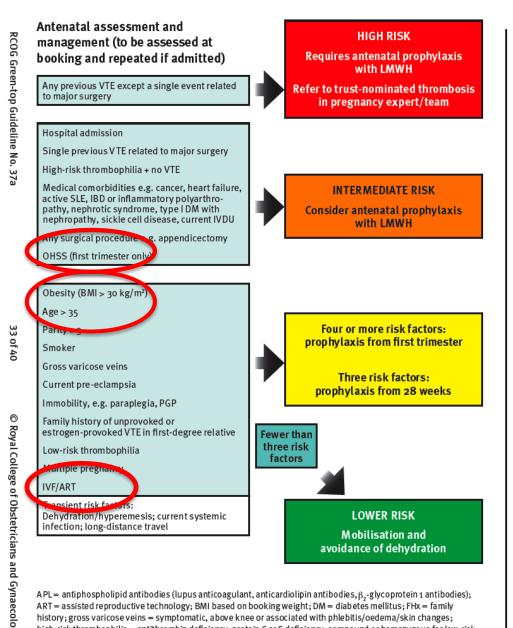


Table 2b: Estimated absolute risk of pregnancy-associated VTE with different thrombophilic defects in women with one or more symptomatic first-degree relatives

Thrombophilic defect	Pregna	ncy	Antena	Antenatal		tum
	%/pregnancy	95% CI	%/pregnancy	95% CI	%/pregnancy	95% CI
Antithrombin, protein C or protein S deficiency <sup>48</sup>	4.1	1.7–8.3	1.2	0.3-4.2	3.0	1.3-6.7
Antithrombin deficiency type 1 (range) <sup>49–53</sup> *	15–50 (range)	-	0-40	-	11–28	-
V Leiden heterozygous <sup>48</sup>	2.1	0.7-4.9	0.4	0.1-2.4	1.7	0.7-4.3
Prothrombin G20210A heterozygous <sup>48</sup>	2.3	0.8-5.3	0.5	0.1-2.6	1.9	0.7-4.7
V Leiden homozygous or compound heterozygosity V Leiden andprothrombin G20210A (range) <sup>54,55</sup>	1.8–15.8 (range)	-	0–5	-	1–10	-

<sup>\*</sup> From population-based not family study

**Appendix I:** Obstetric thromboprophylaxis risk assessment and management



**RCOG 2015** 

 $APL = antiphospholipid \ antibodies \ (lupus \ anticoagulant, anticardiolipin \ antibodies, \beta_2 - glycoprotein \ 1 \ antibodies);$ ART = assisted reproductive technology; BMI based on booking weight; DM = diabetes mellitus; FHx = family history; gross varicose veins = symptomatic, above knee or associated with phlebitis/oedema/skin changes; high rick thromhanhilia — antithromhin daficiancy, protoin C ar S daficiancy, compayed ar homozygous for law rick

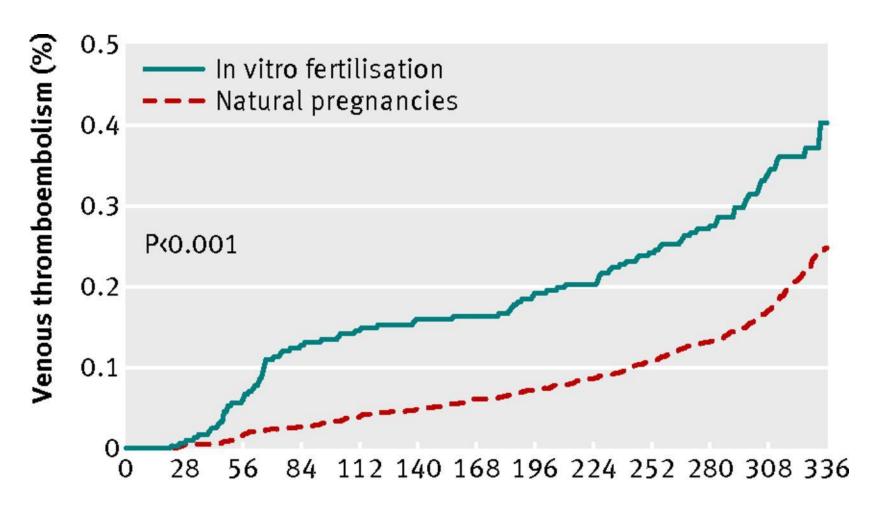
### management (to be assessed on delivery suite) Any previous VTE Anyone requiring antenatal LMWH **HIGH RISK** High-risk thrombophilia At least 6 weeks' postnatal prophylactic LMWH w-risk thrombophilia + FHx Caesarean section in labour Readmission or prolonged admission (≥ 3 days) INTERMEDIATE RISK in the puerperium At least 10 days' Any surgical procedure in the puerperium except postnatal prophylactic LMWH immediate repair of the perineum Medical comorbidities e.g. cancer, heart failure, NB If persisting or > 3 risk factors active SLE, IBD or inflammatory polyarthropathy; nephrotic syndrome, type I DM with consider extending nephropathy, sickle cell disease, current IVDU thromboprophylaxis with LMWH Age > 35 years Obesity (BMI ≥ 30 kg/m²) Two or Parity ≥ 3 more risk Smoke factors Élective caes arean section Low-risk thrombophilia Gross varicose veins Current systemic infection Immobility, e.g. paraplegia, PGP, longdistance travel Fewer than Current pre-eclampsia two risk factors Multiple pregnancy Preterm delivery in this pregnancy (< 37\*0 weeks) Stillbirth in this pregnancy LOWER RISK Mid-cavity rotational or operative delivery Early mobilisation and Prolonged labour (> 24 hours) avoidance of dehydration PPH > 1 litre or blood transfusion

Antenatal and postnatal prophylactic dose of LMWH

Postnatal assessment and

Weight < 50 kg = 20 mg enoxaparin/2500 units dalteparin/3500 units tinzaparin daily Weight 50-90 kg = 40 mg enoxaparin/5000 units dalteparin/4500 units tinzaparin daily Weight 91-130 kg = 60 mg enoxaparin/7500 units dalteparin/7000 units tinzaparin daily Weight 131-170 kg = 80 mg enoxaparin/10 000 units dalteparin/9000 units tinzaparin daily Weight > 170 kg = 0.6 mg/kg/day enoxaparin/75 u/kg/day dalteparin/75 u/kg/day tinzaparin

### **VTE IN PREGNANCIES AFTER ART**

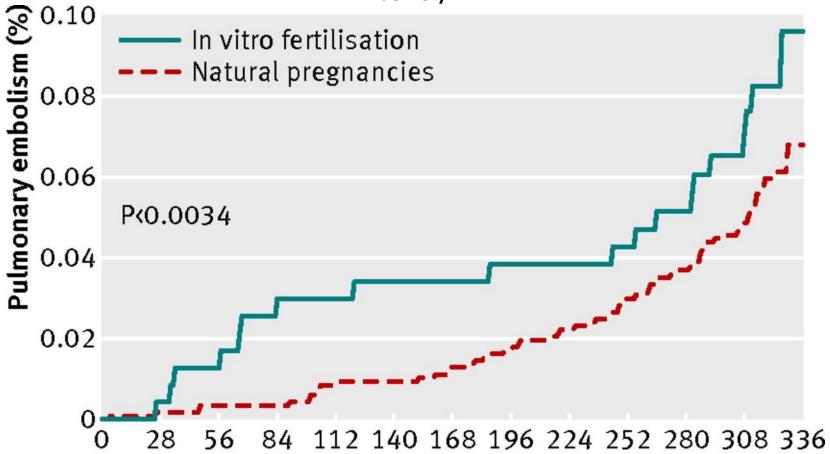


Days from start of pregnancy

Henriksson P et al. BMJ 2013;346:bmj.e8632



Fig 2 Proportional hazard regression of pulmonary embolism in pregnant women after in vitro fertilisation (n=23 498) and in women with natural pregnancies (n=11 960) matched on age and calendar period of delivery.

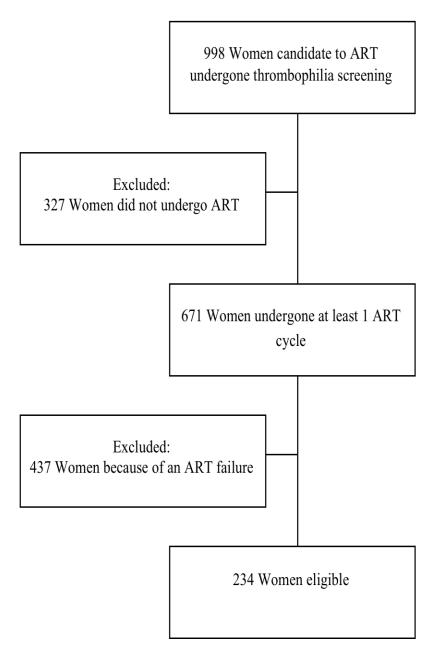


Days from start of pregnancy

Henriksson P et al. BMJ 2013;346:bmj.e8632



Figure 1. Study cohort (April 2002 – July 2011)



Villani M, et al, BMJ Open

Age and live births in the reference cohort and general population from the same geographical area

Maternal age yrs	15	20-29	30-39	40	Live births number
Reference cohort (n= 3359), % 2010-2012	3.7	34.4	55.1	6.8	3451
General population from the same geographical area (n= 106265), % 2008-2010	2.3	32.4	59.5	5.8	107 461

Patients	Age at events	BMI	tHcy	Cycle	Type of event	Thrombophilia OHSS	Antithrombotic prophylaxis
1	31	37.1	n.a.		ε	no	none
2	33		n.a.			Previous SVT after Caesarean section	none
3	28	17.3	n.a.	-	DVT in one leg at 37 weeks of pregnancy	FVL heterozygous	LMWH*
4	33	n.a.	n.a.	-	SVT in the right leg		n.a.
5	37	n.a.	n.a.	-	Bilateral SVT	n.a.	n.a.
6	43		n.a.	-	DVT in the left leg	n.a.	none
7	22		n.a.	-	DVT in the left leg	n.a.	n.a.
8		n.a.	n.a.	-			none
9	36	21.3		-	DVT in the left leg at 21 weeks of pregnancy	FVL + PC deficiency Previous DVT	LMWH* (the event occurred during a suspension period)
10	33	18.7	n.a.	-	DVT in the left leg	FVL heterozygous	n.a.
11	35	n.a.	n.a.		SVT in the right leg	n.a.	n.a.

## Occurrence of Vein Thromboses in women undergone ART (successful cycles)

### Two-tailed Fisher exact test

Patients	A <b>ge</b> a <b>0.06</b> , events	OR:	3.9,95%	CI: 0.87 Cycle	<b>7-15.3.</b> Type of event	Thrombophilia OHSS	Antithrombotic prophylaxis
1					SVT in the left leg	VTE	LMWH*
	p:-0.054	4; OK	: 7.2, 95%	%-CI-0.9	<b>1</b> pregrand PE during twin		
2	38	20.4	6.0	3	pregnancy ended with IUFD (22 weeks)	no	none
3	40	35.9	4.76	3	DVT in the right leg at 18 weeks of pregnancy	PTm heterozygous	none

<sup>\*</sup> Started when pregnancy test was positive

Incidence: 8.5/1000 vs 1.8/1000

## VTE during Pregnancy Treatment

# 7. Treatment of proven acute VTE during pregnancy

For pregnant women with acute VTE, we recommend therapy with adjusted-dose subcutaneous LMWH over adjusted-dose UFH (Grade 1B).

For pregnant women with acute VTE, we recommend LMWH over vitamin K antagonist treatment antenatally (**Grade 1A**).

### 7. Treatment of proven acute VTE during pregnancy

For pregnant women with acute VTE, we suggest that anticoagulants should be continued for at <u>least 6 weeks</u> <u>postpartum</u> (for a minimum total duration of therapy of 3 months) in comparison with shorter durations of treatment (Grade 2C).

For pregnant women receiving adjusted-dose LMWH therapy and where delivery is planned, we recommend discontinuation of LMWH at least 24 h prior to induction of labor or cesarean section (or expected time of neuraxial anesthesia) rather than continuing LMWH up until the time of delivery (Grade 1B).

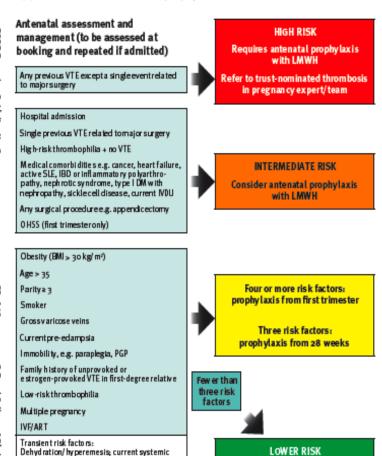
# ANTITHROMBOTIC PRIMARY PROPHYLAXIS DURING PREGNANCY AND PUERPERIUM

## PRIMARY PROPHYLAXIS

- No randomized study is so far available; however heparin prophylaxis in preventing first VTE among women carrying inherited thrombophilia is considered fully effective.
- Considering the low absolute risk of VTE during pregnancy among women carrying factor V Leiden or prothrombin G20210A the indication for primary antithrombotic prophylaxis during pregnancy is debated

infection: long-distance travel

### Appendix I: Obstetric thromboprophylaxis risk assessment and management

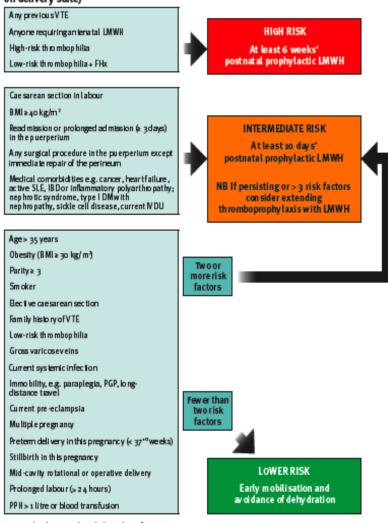


APL = antiphospholipid antibodies (lupusanticoagulant, anticardiolipin antibodies, §,-glycoprotein i artibodies);
ART = assisted reproductive technology; BMI based on bookingweight; DM = diabetes mellitus; FHk = family
history; gross varicoseveirs = symptomitic, a bowe kneer orassociated with phisbitis/coatema/s kinc in igas;
high-risk thrombophilia = a ntithrombindeficiency, protein Cor Sdeficiency, compound or homozogous for low-risk
thrombophilia; BB = inflammatory bowel disease; immobility = 3 gdays; MDI = intravenous drug user; MF= in
vitro fertilisation; UMWH = low-mobicular-weighthe parin; long-distance travel = >4 hours; low-risk thrombophilia =
heter oxegous for factor V Leiden or prothrombin GoozioAmutations; OHSS = ovarian hyperstimulation syndrome;
PGP = politic girdle pain with reduced mobility; PPH = post partum haemorrhage; thrombophilia = inherited or
accurred: VTE = werous thromboembolism.

Mobilisation and

avoidance of dehydration

### Postnatal assessment and management (to be assessed on delivery suite)



### Antenatal and postnatal prophylactic dose of LMWH

Weight< 50 kg = 20 mg eroxaparin/2500 units dalteparin/3500 units tinza parindaily
Weight 50-50 kg = 40 mg eroxaparin/3500 units dalteparin/3500 units tinzaparin daily
Weight 50-30 kg = 60 mg eroxaparin/3500 units dalteparin/3000 units tinzaparin daily
Weight 31-170 kg = 80 mg eroxaparin/10000 units dalteparin/3000 units tinzaparin daily
Weight > 170 kg = 0.6 mg/kg/dayeroxaparin/350 k/kg/daydalteparin/350 k/kg/dayeroxaparin/350 k/kg/daydalteparin/350 k/kg/dayeroxaparin/350 k/kg/daydalteparin/350 k/kg/dayeroxaparin/350 k/kg/daydalteparin/350 k/kg/dayeroxaparin/350 k/kg

## Racial and ethnic differences in the risk of postpartum venous thromboembolism: a population-based, case-control study

M. BLONDON, \*† L. B. HARRINGTON, † M. RIGHINI, \* F. BOEHLEN, \* H. BOUNAMEAUX \* and N. L. SMITH† ‡ §

\*Division of Angiology and Haemostasis, Geneva University Hospitals and Faculty of Medicine, Geneva, Switzerland; †Department of Epidemiology, University of Washington; †Group Health Research Institute, Group Health Cooperative; and §Seattle Epidemiologic Research and Information Center, Department of Veterans Affairs Office of Research and Development, Seattle, WA, USA

Table 2 Characteristics of controls, stratified by race/ethnicity

J Thromb Haemost 2014; 12: 2002-9.

	Non-Hispanic white controls $(n = 7243)$	Black controls $(n = 436)$	Asian controls $(n = 856)$	Hispanic controls $(n = 1458)$	American Indian or Alaska Native controls $(n = 253)$
Maternal characteristics					
Age, yrs, mean (SD)	27.8 (5.8)	26.4 (6.3)	29.5 (5.6)	26.0 (6.0)	25.2 (5.8)
Body mass index, kg m <sup>-2</sup> , mean (SD)	26.1 (6.2)	27.5 (6.6)	24.4 (6.0)	27.5 (6.6)	28.9 (6.7)
Current smoking, $n$ (%)	1153 (17.2)	58 (14.5)	37 (4.6)	54 (3.8)	57 (23.5)
Prepregnancy hypertension, $n$ (%)	75 (1.1)	4 (1.0)	7 (0.9)	4 (0.3)	6 (2.5)
Prepregnancy diabetes, $n$ (%)	28 (0.4)	0 (0)	8 (1.0)	6 (0.4)	4 (1.7)
Education above high school, $n$ (%)	3567 (61.8)	152 (43.3)	501 (68.6)	261 (20.4)	56 (25.6)
Unemployed (including housewife), $n$ (%)	2120 (31.7)	115 (31.8)	268 (36.0)	648 (52.3)	92 (41.3)
Obstetric characteristics					
Parity (before the index pregnancy), median (IQR)	1 (0-2)	1 (0-3)	1 (0-2)	1 (0-2)	2 (0-3)
Gestational diabetes, $n$ (%)	230 (3.4)	20 (5.0)	54 (6.8)	69 (4.9)	14 (5.8)
Gestational hypertension/preeclampsia, $n$ (%)	404 (5.9)	24 (6.0)	28 (3.5)	55 (3.9)	9 (3.8)
Multiple pregnancy, $n$ (%)	116 (1.6)	10 (2.3)	10 (1.2)	15 (1.0)	5 (2.0)
Cesarean section, $n$ (%)	1605 (22.2)	107 (24.5)	225 (26.3)	339 (23.3)	56 (22.1)
Maternal postpartum infection, $n$ (%)	73 (1.0)	6 (1.4)	16 (1.9)	21 (1.4)	4 (1.6)
Postpartum hemorrhage or maternal transfusion, $n$ (%)	229 (3.2)	20 (4.6)	27 (3.2)	64 (4.4)	12 (4.7)
Preterm birth ( $< 37$ wks), $n$ (%)	527 (7.4)	54 (12.5)	78 (9.3)	102 (7.1)	31 (12.4)
Stillbirth, $n$ (%)	36 (0.5)	3 (0.7)	3 (0.3)	7 (0.5)	3 (1.2)
Newborn: small for gestational age, $n$ (%)	339 (4.7)	45 (10.4)	60 (7.1)	71 (4.9)	12 (4.8)
Newborn: large for gestational age, $n$ (%)	767 (10.7)	27 (6.2)	50 (5.9)	121 (8.3)	46 (18.3)

Numbers and percentages may not agree due to missing data.

IQR, interquartile range.

### J Thromb Haemost 2014; 12: 2002-9.

Table 5 Stratum-specific and combined associations of race/ethnicity and cesarean section

	Adjusted OR (95% CI)						
	Stratum-specific associat	ions	Combined associations (among all women)				
Race/ethnicity	Among women with vaginal delivery	Among women with cesarean section	Vaginal delivery	Cesarean section			
White	1.0 (ref)	1.0 (ref)	1.0 (ref)	2.69 (2.21–3.29)			
Black	1.03 (0.61–1.74)	2.03 (1.34-3.07)	1.03 (0.61–1.74)	5.47 (3.63-8.25)			
Asian	0.57 (0.34-0.96)	0.78 (0.50-1.21)	0.57 (0.34-0.96)	2.10 (1.36-3.25)			
Hispanic	0.61 (0.40-0.92)	1.03 (0.72–1.46)	0.61 (0.40-0.92)	2.76 (0.77-4.05)			
American Indian or Alaska Native	0.98 (0.50-1.93)	0.66 (0.29-1.50)	0.98 (0.50-1.93)	1.77 (0.77-4.04)			

Adjusted for birth year (matching factor), maternal age, parity, smoking, preeclampsia, gestational diabetes, preterm delivery, small and large for gestational age newborn, postpartum infection, maternal body mass index, and educational status.

OR, odds ratio; CI, confidence interval.



DOI: 10.1111/1471-0528.13706 www.bjog.org

### A comparison pharmacologic caesarean deli

KL Palmerola, ME D'Alton, (

Department of Obstetrics & Gynecology Correspondence: A Friedman, Departmen 168th Street, PH 16-66, New York, NY

Accepted 13 August 2015. Published Onli

Table 1. Summary of major society quideline recommendations for obstetric thromboprophylaxis for patients who have undergone caesarean delivery

### ACOG

Perioperative mechanical thromboprophylaxis recommended for all patients undergoing caesarean delivery Pharmacologic prophylaxis (LMWH or UFH) recommended for High-risk thrombophilias

Any prior VTE event

A family history of VTE and a thrombophilia

Pharmacologic prophylaxis (LMWH) recommended for one major or two or more minor risk factors

Mechanical prophylaxis recommended for those with contraindications to pharmacologic prophylaxis

Major risk factors (one needed for prophylaxis)

Immobility (strict bed rest ≥1 week in the antepartum period)

Postpartum haemorrhage ≥1000 mL with surgery

Previous VTE

Pre-eclampsia with fetal growth restriction

Thrombophilia

Antithrombin deficiency

Factor V Leiden (homozygous or heterozygous)

Prothrombin G20210A (homozygous or heterozygous)

Medical conditions

Systemic Lupus erythematosus

Heart disease

Sickle cell disease

Blood transfusion

Postpartum infection

Minor risk factors (two needed for prophylaxis)

BMI >30 kg/m<sup>2</sup>

Multiple pregnancy

Emergency caesarean

Smoking >10 cigarettes/day

Fetal growth restriction

Thrombophilia

Protein C deficiency

Protein S deficiency

Pre-eclampsia

RCOG

Risk factors (LMWH recommended for any of the following risk

factors)

Previous VTE

Antenatal anticoagulation

Caesarean in labour

Asymptomatic thrombophilia

Prolonged admission

Major medical co-morbidities (e.g. heart or lung disease,

systemic Lupus erythematosus, cancer, inflammatory conditions, nephrotic syndrome, sickle cell disease, intravenous drug user

Age >35

BMI >30 kg/m<sup>2</sup>

Parity >3

Smoker

Any surgical procedure

Gross varicose veins

ral obstetrics

### axis after ines

1 Surgeons, 622 West

Under RCOG guidelines, 85.0% of patients would receive post-caesarean pharmacologic prophylaxis (95% CI 80.5–88.6%). In comparison, 1.0% of patients would receive pharmacologic prophylaxis under ACOG guidelines (95% CI 0.3–3.0%) and 34.8% of patients would receive

prophylaxis under Chest guidelines (95% CI 29.6-40.4%).

**Heparin use according to different GL** 

## Risk factors according to different GL

The most common risk factors for prophylaxis using RCOG criteria were caesarean during labour, maternal age ≥35, and obesity. Other risk factors included pre-eclampsia, infection, and high parity. Leading indications for prophylaxis based on Chest guidelines included emergency caesarean, pre-eclampsia, obesity, multiple gestation, and postpartum haemorrhage. Prophylaxis based on ACOG recommendations resulted in three women receiving prophylaxis, all on the basis of having a prior event.

Palmerola KL et al, BJOG 2015

Queensland, Australia

Swedish guidelines

### Conclusion

Our findings highlight a major concern regarding strategies to reduce obstetric thromboembolism: what is the optimal management for postpartum patients at increased risk for an event? Current recommendations diverge significantly, with the ACOG recommending pharmacologic prophylaxis for a small minority of patients, and the RCOG recommending treatment for a large majority of patients. Research on obstetric VTE is challenging because of relatively low incidence, but VTE is one of the leading causes of maternal morbidity and severe morbidity, and there is an urgent clinical need to clarify optimal prophylaxis regimens.

and prolonged repair

Risk factor	Venous thromboembolism	Score
Personal history of ∀TE	History of ∨TE related to pregnancy (occurred during the antepartum), or cerebral vein thrombosis or massive PE or ∨TE in childhood (<16 y.o.)	6
	Spontaneous or estrogen-induced PE or proximal DVT	3
	Transient risk factor-induced PE or proximal DVT	2
	Spontaneous or estrogen-induced distal calf DVT	2
	Transient risk factor induced distal calf DVT	1
If there is a personal history of ∀TE	Recurrent VTE history	3
	Residual venous thrombi with clinical signs of post-thrombotic syndrome	3
	Recent ∀TE history < 2 years	2
Thrombophilia	Homozygous mutations, combined thrombophilia risk factors	3
	Protein C deficiency, protein S deficiency, heterozygous F5 G1691A mutation, heterozygous F2 G20210A mutation	1
	If no hypercoagulability detected, family history of severe or recurrent VTE	1
Other risk factors	Bedrest, immobilisation	2
	Twin pregnancy	1
	Age > 35 years	1
	Body mass index > 30 kg/m²	1

Total score =

No. antenatal prophylaxis if score < 3. Early heparin prophylaxis in patients with a score  $\ge 6$ . LMWH was prescribed only in the third trimester to patients with a score between 3 and 5.

VTE, venous thromboembolism; CVT, Cerebral venous thrombosis; PE, pulmonary embolism; DVT, deep vein thrombosis.

	Score < 3:	Score 3–5:	Score ≥ 6:
Lyon–VTE score based strategy for LMWH prophylaxis	No LMWH ante- partum; LMWH postpartum	LMWH during 3rd trimester; LMWH postpartum	Early LMWH during antepartum; LMWH postpartum
Number of patients, n = 445	158	153	134
Number of pregnancies, n = 542			
Personal history of VTE	36 (22.7%)	141 (92%)	134 (100%)
Thrombophilia	125 (79.1%)	102 (66.7%)	55 (41%)
Prophylaxis with LMWH by score	139 (=158 -19)	172 (=153 +19)	424
VIE occurred during antepartum	1	0	1
VTE occurred during postpartum	0	3	1
Bleeding complications	2	0	0

# Strategy to reduce risk of VTE in pregnancy

- Identifying & modifying risk factors in women planning to embark on pregnancy —
- To reduce BMI below 30kg/m2
- Stop smoking
- History of VTE
- Optimizing chronic medical illnesses
- Improve awareness: e.g. Making patient information leaflets/brochures available

"Risk scoring of antenatal and postnatal women for VTE is probably the most effective way of identifying who is at significant risk and needed intervention or treatment with thromboprophylaxis"

An Expert is someone who made all possible mistakes in a very narrow field

**Niels Bohr**