Financial implications and maternal impact of national recommendations for thromboprophylaxis: a retrospective cross-sectional analysis

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Summary

Background: Thromboembolism was a leading direct cause of maternal death in the UK in the last *Saving Mothers' Lives* report. National guidance proposes that all women should be risk assessed in pregnancy and after delivery.

Methods: An audit was designed to assess the financial implication for our service. One hundred consecutive live and stillbirths were identified using the maternity database; 97 case records were obtained. Risk factors were identified and individual scores were calculated, together with the proportion that would have extended measures (low-molecular-weight heparin [LMWH], antiembolic stockings).

Results: The series appeared to be representative of the UK pregnant population in terms of age, parity, body mass index, smoking and caesarean rate. Antenatally, 2.1% had a Royal College of Obstetricians and Gynaecologists (RCOG) risk score of three or more and would have been advised to have LMWH throughout pregnancy and the puerperium. Postnatally, 40.1% had an RCOG score of two or more and would have required enoxaparin for one to six weeks. The annual cost of stockings, LMWH and sharps bins approximate to GB£44,847 for every one thousand deliveries, GB£2.6 million for each life saved. About 10% of normal-weight postnatal women who achieved a vaginal birth had a risk score prompting thromboprophylaxis for at least seven days.

Conclusions These data suggest that the current guidance might represent overmedicalization of pregnancy and that the criteria for thromboprophylaxis should be refined further.

Keywords: venous thromboembolism, prophylaxis, maternal death

INTRODUCTION

Venous thromboembolism (VTE) was the leading direct cause of maternal death in the UK in the last triennium.¹ There is an even greater number of non-fatal episodes, with an overall incidence of antenatal VTE of 1.9 per 1000 women-years.² These events require investigation with potentially harmful imaging techniques and, if proven, treatment with therapeutic anticoagulation, which increases the risk of serious haemorrhage.

Risk factors identified in those women who die from pulmonary embolus in pregnancy include high maternal age and body mass index (BMI), family or personal history of VTE, dehydration or operative procedures.¹ The chance of fatal pulmonary embolism is greatest in the third trimester and after delivery, but can occur at any stage of maternity care.³ Studies suggest that use of low-molecular-weight heparin (LMWH) can reduce VTE in medical patients by 50%.⁴

Recent guidance documents on provision of thromboprophylaxis have been published by the Royal College of Obstetricians and Gynaecologists (RCOG) (2009) and National Institute for Health and Clinical Excellence (NICE) (2010).^{5,6} RCOG guidance covers all aspects of maternity care. NICE guidance simply relates to inpatient care (antenatally and after

delivery). The aim of this clinical audit was to assess the likely cost of consumables to the maternity service and the impact of these policies on women.

METHOD

One hundred consecutive deliveries were identified using the maternity database taken from 09.00 hours on a Monday morning in December 2009. The series included all deliveries (live and stillborn) beyond the end of the 24th week of pregnancy but did not include early or late miscarriages. Antenatal and postnatal risk factors were identified from the maternity hand-held and hospital care records, and from a computer database. Retrospectively we calculated risk scores for each woman, for each stage of maternity care, using the local implementation sheets derived from NICE and RCOG policy standards. From these scores, we calculated the proportion of women who would have extended measures (LMWH and antiembolic stockings [AES]), antenatally and postnatally. Doses of LMWH as enoxaparin were calculated according to current bodyweight (RCOG, 2009) recommendations for intervention and are included in Table 1 of the implementation tools.

From these data, we calculated the likely annual cost of these preventive measures per 1000 maternities. The cost calculations were based on hospital drug costs for enoxaparin, and women being supplied with two thigh-length pairs of AES, at October 2010 prices. The costs for our unit are: £8.91 for one

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Table 1 Frequency of individual antenatal risk factors for thromboembolism

Risk factor	Number (%)	Comment
Current smoker	18 (18.6 %)	
BMI >30 kg/m ²	16 (16.5%)	Eight data points missing Two >40 kg/m ²
Maternal age >35 years	15 (15.5 %)	
Parity ≥3	6 (6.2%)	
Preeclampsia	3 (3.1%)	
Multiple pregnancy	2 (2.1%)	Both twin pregnancies
Inpatient admission	1 (1.0%)	
Severe varicose veins	1 (1.0%)	
Medical condition	1 (1.0%)	Metastatic cancer

BMI, body mass index

pair of AES bought in bulk; £4.04 for LMWH as enoxaparin 40 mg preloaded syringe; £4.57 for LMWH 60 mg; £6.49 for LMWH 80 mg. A small 0.6L sharps bin for home use 86p. After completion of the audit, we estimated the number needed to prevent one maternal death, assuming that half of episodes are already prevented.⁴ This is likely to be an overestimate.

This project started as an in-house audit. Ethical approval was not sought according to Trust policy.

RESULTS

The data were derived from 100 consecutive deliveries beyond 24 weeks' gestation. Ninety-seven of the notes were available for analysis. All were suitable for assessment but eight data points were missing for BMI. None of these eight women were marked as being obese on the computer database, so we assumed that they were of normal weight for height. The women had a mean age of 27.6 years (range 17–40 years) and a mean BMI of 25.3 kg/m² (range 17.2 to >50). Forty-two (43.3%) of the women were nulliparous, and 18 (18.6%) were smokers. There appeared to have been no complications of enoxaparin therapy in this series of women.

The profile of antenatal risk factors is given in Table 1. None of the women had a personal or family history of thrombosis. Antenatally, 51 women (52.6%) had a VTE risk score of zero, 44 (45.3%) had a score of one or two and two (2.1%) had a score of three. None of the women in this series had a VTE risk score above three antenatally. One woman with an antenatal risk score of two was admitted. Two (2%) of the women in this series should have been recommended LMWH antenatally as outpatients (95% CI 0–4.7%) and one as an inpatient, according to RCOG national guidance. Only one woman would have been recommended thromboprophylaxis for inpatient antenatal care according to NICE guidance alone.

The profile of individual postnatal risk factors is given in Table 2. The frequency distribution of risk scores is given in Table 3. Of the normal-weight women who did not have a caesarean birth, 34 (35.0%; 95% CI 5.1–18.6%) had a score of one or more, and 10 (10.3%; 95% CI 2.5–45.4%) had a score of two or more. The postnatal costs of these interventions are summarized in Table 4.

DISCUSSION

This is a small series from a single level-two maternity unit in the South West of England with 3400 deliveries per year. The series

Table 2 Frequency of individual postnatal risk factors for thromboembolism

Risk factor	Number (%)	Comment
Current smoker	18 (18.6%)	
BMI > 30 kg/m ²	17 (17.5%)	8 data points missing 3 > 40 kg/m ² *
Maternal age > 35 years	16 (16.5%)	
Emergency caesarean*	12 (12.4%)	
Elective caesarean	12 (12.4%)	
Parity ≥3	7 (7.2%)	
Midcavity/rotational instrumental delivery	6 (6.2%)	
Postpartum haemorrhage	4 (4.1%)	>1 litre
Preeclampsia	3 (3.1%)	
Multiple pregnancy	2 (2.1%)	Both twins
Postnatal surgery	1 (1.0%)	Manual removal placenta and repair third-degree tear
Severe varicose veins	1 (1.0%)	
Medical condition	1 (1.0%)	Metastatic cancer

BMI, body mass index

*Scores two points

Table 3 Frequency distribution of postnatal VTE risk scores (n = 97)

VTE risk category (points)	Number (%)	NICE*	RCOG†
Zero	32 (33.0%)		
One	29 (29.9%)	77% scored one or more	
Two	15 (15.5%)		40% scored two or more
Three	14 (14.4 %)		
Four	5 (5.2%)		
Five	1 (1.0%)		
Six	1 (1.0%)		

VTE, venous thromboembolism; NICE, National Institute for Health and Clinical Excellence; RCOG, Royal College of Obstetricians and Gynaecologists; LMWH, low-molecular-weight heparin

*% to be recommended LMWH under NICE

†% to be recommended LMWH under RCOG

Table 4 Costs (GB£) for postnatal thromboprophylaxis for this case series (100 women)

VTE risk score	Cost of AES†	Cost of LMWH	0.6 L sharps bin	Total cost
Zero	–	–	–	–
One‡	–	120.80	–	120.80
Two	276.22	438.34	13.33	736.89
Three§	256.60	410.94	12.38	679.92
Four or more**	106.92	1120.98	5.16	1233.06
Total	639.74	2091.06	30.27	2770.67

VTE, venous thromboembolism; LMWH, low-molecular-weight heparin; AES, antiembolic stockings

†Two pairs issued per woman

‡Assumes average length of stay = 1 day

§One woman in this group would have required 60 mg enoxaparin daily

**One woman in this group would have required 80 mg enoxaparin daily

did not include women who miscarried or had surgery for ectopic pregnancy. Although the audit was undertaken retrospectively, the data required were all collected prospectively as part of routine maternity care. The vast majority of the notes were perfectly informative. The women, who formed a consecutive series of completed maternities from a randomly selected starting

point, appear to be reasonably representative of the UK population in that our caesarean rate of 24.7% was close to the national average of 23%, and the proportion of women with a BMI greater than 30 kg/m² (17%) is also very similar to the UK published data.⁷ Further, 18.5% of the women were cigarette smokers, which is close to the national average of 17% for smoking during pregnancy.⁸ Only one woman in our series had a relevant medical disorder and there were no intravenous drug user patients included in the audit. We therefore think that the proportion of women with higher scores is unlikely to be an overestimate.

These data do not represent an audit of compliance but what should happen according to combined recommendations published by the RCOG in 2009 and NICE in 2010. The primary reason for this assessment was to understand the financial impact on our service. We publish the data now to share that information with other units who are implementing the guidance but the information also provides an opportunity to review the impact on pregnant women, and to set that against existing understanding of the risk they face. Overall, the scheme of care represents an annual cost of consumables for both antenatal and postnatal care of GB£94,203 to our unit. If RCOG guidance were implemented alone, without NICE recommendations, the annual cost would only be slightly lower at GB£90,096.

Using our data as a model for a unit of 1000 deliveries per year, we would estimate the costs of AES, enoxaparin and sharps bins for postnatal women at GB£27,707 p.a. Antenatally the annual cost of LMWH as enoxaparin and eight sharps bins for 2% of the women in a unit of this size is GB£17,140. The total cost for 1000 maternities amounts to GB£44,847 annually. These data should help maternity units plan for implementation of the guidance.

In the last UK *Saving Mothers' Lives* (SML) triennial report, there was an average of 704,000 maternities each year.¹ Based on our figures, we estimate that the total cost for implementing the guidelines for thromboprophylaxis for the UK is of the order of GB£34 millions p.a. There were 41 deaths from VTE in the 2003–2005 triennium, an average of just over 13 maternal deaths annually.¹ If one assumed all of these later deaths could be prevented, the cost of saving one life with the current scheme of care is about GB£2.6 million. This is likely to be a significant underestimate, however, as 21% of women who died in the last SML report had no risk factors, and studies on medical patients suggest that a significant proportion of thromboembolic events are not prevented with LMWH.⁴ It should also be noted that this calculation does not include the cost of midwifery and medical care involved in risk scoring, counselling, prescribing and administering thromboprophylaxis. Equally, it does not take account saving from avoiding investigation and treatment of women with suspected and proven thromboembolism.

Looking at the antenatal data, just two of our 97 women had a VTE risk score of three or more. The current recommendation is for these women to be considered for daily LMWH thromboprophylaxis throughout pregnancy and the puerperium. Although the impact on the individual woman is significant, overall the number of woman affected is likely to be relatively small. In contrast, postnatally, 77% of the women were scored one or more and would be recommended enoxaparin while in hospital (according to NICE guidance), and 40% were scored two or more which would prompt a recommendation of enoxaparin for one to six weeks (according to RCOG guidance).

Perhaps the most noteworthy figure is that of 10% of normal-weight postnatal women who achieved a vaginal birth had a risk score prompting a recommendation for thromboprophylaxis

for a minimum of seven days. In the 2003–2005 SML report, the report that resulted in extension of guidance to cover more women, there were 15 deaths in the postnatal period related to VTE. Of the 15 women, eight had undergone caesarean birth and five of those who had delivered vaginally were obese. Just two women, less than one each year, had been of normal weight and had undergone a vaginal birth. Taking into account that 2.1 million maternities were covered by the 2003–2005 triennium, we estimate that in this specific group of women, more than 100,000 individuals would require preventive interventions in order to avoid one maternal death. Although maternal death is not the only adverse effect of VTE, it appears to have been the primary reason the new guidance was introduced since 2000, extending measures significantly beyond those women with thrombophilia and caesarean birth.

VTE represents a highly important health issue for pregnant women, and any means of prevention merits very serious consideration. The most recent SML report (2006–2008) showed a large drop in the number or deaths from thromboembolism from 41 to 18 women, the lowest since the 1985–1987 triennium.⁹ This suggests that that guidance issued to reduce the risk of death from VTE is having a very positive effect. Despite this important advance in maternity care, we believe that a question that needs to be considered by the health community and user groups is whether some parts of the current guidance represent an unnecessary medicalization of maternity care, particularly postnatally. Is some refinement warranted?

DECLARATIONS

None of the authors has any competing interests or other declarations. In particular none holds stock in any pharmaceutical or medical device companies.

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