Opinion

Recommendations for the diagnosis and treatment of deep venous thrombosis and pulmonary embolism in pregnancy and the postpartum period

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Venous thromboembolism (VTE) in pregnancy and the postpartum is an uncommon but clinically important condition. It remains one of the most common causes of maternal mortality in the developed world; yet, to date there are no published clinical studies of a validated clinical prediction rules for the diagnosis of deep vein thrombosis (DVT) or PE in pregnancy. A concerning feature in reports of maternal mortality and morbidity is that women who present with symptoms suggestive of PE and DVT are often inadequately investigated. Commonly this is either because of a failure to recognise that women's symptoms may be due to DVT or PE or because appropriate investigations are not carried out because of concerns about the fetal effects of radiation used in imaging studies.

Key words: deep venous thrombosis, diagnosis, pregnancy, pulmonary embolism, treatment, venous thromboembolism.

Introduction

Venous thromboembolism (VTE) in pregnancy and the postpartum is an uncommon but clinically important...
The aim of this document is to provide clinicians with clear and practical recommendations relating to the diagnosis and treatment of pregnancy-associated venous thromboembolism (PA-VTE).

This document was written by a group of clinicians selected to represent opinions from across New Zealand and Australia from the fields of obstetric medicine (CMcL, BW), maternal–fetal medicine and obstetrics (GD, PM), haematology (CMcL, HT, LY, SC, SMcR, TB), and anaesthesiology (NMcD). The authors have wide clinical experience in the management of women with acute VTE and expertise in the development of clinical guidelines and recommendations. The document and recommendations are endorsed by the Councils of the Society of Obstetric Medicine of Australia and New Zealand (SOMANZ) and the Australasian Society of Thrombosis and Haemostasis (ASTH). All authors are members of SOMANZ (CMcL, BW, NMcD, PM, GD) and/or ASTH (CMcL, LY, HT, TB, SMcR, SC). At the time of writing CMcL, PM and BW were elected members of SOMANZ Council and CMcL, HT and SC were elected members of ASTH Council, but the authors did not constitute a majority of either Council.

Methods

Authors were assigned to lead sections of the consensus statement according to their expertise and particular interests, and each conducted a relevant literature review. A reference library of the articles used by each author was developed and made available to all authors. At an initial face-to-face meeting, authors presented a summary of the data relevant to their section, which was discussed by the whole group, and following this, authors wrote the first draft of the background with recommendations for their section. This first draft was circulated to all authors and subsequently revised following a second face-to-face meeting. To assess the level of consensus with the recommendations, all authors were sent a spreadsheet listing all the recommendations and were asked to indicate whether they agreed or disagreed with each statement. Recommendations were then graded with the following levels of consensus: Group Consensus Level 1 – complete consensus: all ten authors in agreement; Group Consensus Level 2 – partial consensus: eight of ten authors in agreement; Group Consensus Level 3 – no consensus – two or more authors disagreed with recommendation. The group consensus level is reported in parenthesis after each recommendation in the final document.

Background

Epidemiological data outlining the prevalence and risk factors for PA-VTE have been extensively reviewed. Signs and symptoms of DVT and PE in pregnancy are unreliable and appropriate management of acute VTE in pregnancy begins with an accurate diagnosis using an objective radiological investigation. These diagnoses in a pregnant or postpartum woman have implications for immediate and long-term health and the potential harm arising from a missed diagnosis is greater than the potential risk of the small amounts of radiation associated with the relevant radiological investigations. Once the diagnosis is established, during pregnancy anticoagulant therapy with heparin is recommended rather than warfarin, which crosses the placenta and is associated with embryopathy and high rate of fetal loss. Warfarin may be used safely in the postpartum period and is safe for breastfeeding. Heparin does not cross the placenta and extrapolating data from non-pregnant patients, low-molecular-weight heparin (LMWH) is now used in pregnancy in preference to unfractionated heparin (UFH) because of improved bioavailability and more reliable anticoagulant effect. However, the evidence to guide dose and duration of therapy in pregnancy is incomplete.

Diagnosis of VTE in pregnancy

D-dimer testing in pregnant women with suspected VTE

In non-pregnant patients, the addition of D-dimer testing to clinical assessment is useful in evaluating suspected DVT. In pregnancy, D-dimer levels increase leading to a high rate of false-positive results if standard cut-off values are used irrespective of the laboratory assay used. The use of pregnancy-specific normal ranges of D-dimers may improve the clinical utility of the test if used in combination with clinical probability scores. Such an approach still requires evaluation in prospective clinical trials before it can be recommended for exclusion of clinically suspected VTE in pregnancy.

Recommendation

D-dimer testing is not recommended for the evaluation of suspected DVT or PE in pregnancy or the early postpartum period. (Group Consensus Level 1)

Diagnosis of clinically suspected deep vein thrombosis

Experienced clinicians can identify women at low risk of DVT compared with those at high risk, but clinical diagnosis is of low sensitivity. At this stage, appropriate imaging is required for all pregnant women when there is a clinical suspicion of DVT.

Compression ultrasound

In New Zealand and Australia, compression ultrasound (CUS) is the standard diagnostic test for investigation of pregnant and postpartum women with suspected DVT. In most centres, ultrasound of the whole leg is carried out, looking for proximal and distal DVT. Whilst CUS has a lower sensitivity for distal DVT, it is relatively specific. When thrombosis in these areas is suspected, indirect parameters such as absence of flow, or visible thrombus on B mode imaging of the vessel, can be helpful. If strong
clinical suspicion remains despite a negative CUS, venography or magnetic resonance direct thrombus imaging (MRDI) may be considered. A diagnostic approach to suspected DVT in pregnancy is shown in Figure 1.

**Recommendations**

1. Clinical assessment alone, although helpful in risk-stratification, is not sufficient to confirm or exclude DVT, and appropriate imaging is required. (Group Consensus Level 1)
2. CUS is the diagnostic test of choice in women with clinical suspicion of DVT. (Group Consensus Level 1)
3. Scanning of proximal and distal deep veins is recommended as anticoagulation is recommended for all pregnant women with symptomatic DVT, irrespective of the site of thrombosis. (Group Consensus Level 1)
4. Women with clinical symptoms strongly suggestive of DVT who have no thrombus identified on standard CUS may require further imaging (repeat CUS, venography or MRDI). (Group Consensus Level 1)

**Pulmonary embolism**

In pregnancy, the symptoms of PE (shortness of breath, pleuritic chest pain, haemoptysis and syncope) are not sufficiently specific to allow a confident clinical diagnosis. For this reason, those with symptoms and signs suggestive of PE should undergo imaging. Options include perfusion scanning with or without ventilation scanning and CT-pulmonary angiography (CTPA).

In non-pregnant patients, CTPA has become the test of choice for investigation of suspected PE because of a high rate of non-diagnostic ventilation/perfusion (V/Q) scans and the ability of CTPA to diagnose other chest pathology. However, in pregnant women, the rate of non-diagnostic V/Q scans is lower (3–24%) or equivalent to the rate of non-diagnostic CTPA mainly because of pregnancy-related increases in cardiac output. The performance of isotope scanning in pregnant and postpartum women with suspected PE supports its continued use as the investigation of choice when available. If CTPA is used, technical modifications should be considered, to minimise the number of non-diagnostic scans that result from the physiological changes of pregnancy.

In women investigated for PE using isotope scanning, a normal perfusion scan is generally considered sufficient to exclude thrombosis and a ventilation scan is not required. This approach is reasonable in women with a low clinical probability of a PE, but women with an abnormal perfusion scan require confirmation of ventilation/perfusion mismatch using a ventilation scan. The maternal and fetal risks of exposure to ionising radiation are often a cause for concern for both clinicians and their patients. However, the radiation doses associated with the radiological investigations mentioned earlier are well below the threshold of 50 mGy above which the risk of adverse fetal effects begins to rise (Table 1). Usual doses of the radioisotopes used in V/Q scanning do not deliver high doses to the fetus.

Maternal radiation exposure, in particular to the breasts, is up to 40 times higher with CTPA (16–50 mGy) than with V/Q scanning. The major concern with this is a potential to increase the lifetime risk of breast cancer, especially given the increased radiosensitivity of proliferating breast tissue in pregnancy or during lactation. Some studies have suggested an increase in the lifetime risk of breast cancer by 14.6%, but recent data suggests that the absolute risk increase is likely to be in the order of 0.2%. In all studies, the risk is based on mathematical calculations of known effects of radiation at certain doses and not on clinical follow-up. Bismuth shielding reduces breast radiation exposure by >50% and is recommended with CTPA. Women investigated for PE who are breastfeeding do not

<table>
<thead>
<tr>
<th>Radiological procedure</th>
<th>Fetal dose (mSv)</th>
<th>Maternal dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest X-ray</td>
<td>0.001–0.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ventilation scan 99mTc</td>
<td>0.01–0.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Perfusion scan 99mTc</td>
<td>0.1–0.6</td>
<td>0.6–1.0</td>
</tr>
<tr>
<td>Single slice CTPA</td>
<td>0.03–0.06</td>
<td>1.6–4.0</td>
</tr>
<tr>
<td>Multislice CTPA</td>
<td>0.003–0.1</td>
<td>2–6</td>
</tr>
<tr>
<td>Pulmonary angiography</td>
<td>&gt;0.5</td>
<td>5–30</td>
</tr>
</tbody>
</table>

CTPA, CT-pulmonary angiography.

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**Figure 1** Diagnostic pathway for suspected deep venous thrombosis in pregnancy.
need to discard milk following CTPA or MRI, but following V/Q scan, breast milk should be discarded for a period of 12 h. Following V/Q scan, breast milk should be discarded for a period of 12 h. A diagnostic approach to suspected PE in pregnancy is outlined in Figure 2.

**Recommendations**

1. All pregnant or postpartum women with clinical suspicion of PE should have appropriate imaging. (Group Consensus Level 1)

2. Radioisotope (V/Q) scanning is the preferred investigations in pregnant or postpartum women with suspected PE who have a normal chest X-ray. (Group Consensus Level 1)

3. CTPA should be used in women with an abnormal CXR or where V/Q scanning is inconclusive or not available. (Group Consensus Level 1)

4. The fetal and maternal radiation dose with either V/Q scanning or CTPA is within acceptable limits, and neither test should be withheld in a pregnant woman who has clinical symptoms that raise the suspicion of PE. (Group Consensus Level 1)

**Treatment of acute VTE during pregnancy**

**Vitamin K antagonists**

Vitamin K antagonists such as warfarin cross the placenta and have the potential to cause both teratogenicity and fetal bleeding. Warfarin embryopathy occurs in 5–6% of infants exposed to warfarin between six and nine weeks of gestation. Late complications of warfarin, most likely due to fetal haemorrhage, include fetal loss (15–40%) and central nervous system defects (5–10%).

**Recommendation**

1. Women with VTE in pregnancy should not be treated with vitamin K antagonists such as warfarin. (Group Consensus Level 1)

**Unfractionated heparin or LMWH as initial treatments**

There are no adequately powered randomised controlled trials comparing UFH with LMWH for the treatment of

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**Figure 2** Diagnostic pathway for suspected pulmonary embolism in pregnancy. *Low likelihood of positive scan in absence of leg symptoms.
VTE during pregnancy. Studies in non-pregnant patients have demonstrated a reduced rate of thrombotic complications, major haemorrhage and death in patients receiving LMWH compared with those receiving UFH.33

Efficacy of LMWH

Evidence for the role of LMWH in the treatment of PA-VTE comes from a systematic review34 in which only two of 174 women treated with LMWH for PA-VTE developed recurrent events (1.15%; 95% CI 0.14–4.09%). A subsequent prospective observational study reported no recurrent events in 112 women treated with LMWH for PA-VTE.35

Safety of LMWH

A retrospective review of 100 women who received UFH in therapeutic or prophylactic doses during pregnancy reported that 2% of these women experienced major bleeding,29 the same rate reported in a study of women receiving a therapeutic dose of LMWH.34 A further study reported antenatal bleeding in 6% of women receiving LMWH, with no major bleeds. The incidence of postpartum bleeding (>500 mL blood loss) was 5%, similar to that in normal pregnancy.35

Other potential complications of heparin include heparin-induced thrombocytopenia (HIT) and, with long-term use, decreased bone density and osteoporosis. HIT is very uncommon in women receiving either type of heparin during pregnancy.36 Symptomatic vertebral fractures are reported in 2–3% of pregnant women receiving longer-term UFH as well as reductions in bone density of up to 30%.37,38 There is no evidence of reduced bone mineral density attributable to prophylactic dose LMWH.39

Recommendations
1. Women with DVT and/or PE during pregnancy should be treated with therapeutic dose LMWH rather than UFH. (Group Consensus Level 1)
2. In women judged to be at high risk of haemorrhage, UFH may be preferred because of its shorter half-life and the ability to fully reverse its anticoagulant activity if necessary. (Group Consensus Level 1)

Frequency of LMWH dosing

In non-pregnant patients with acute VTE, the risks of recurrent thrombosis and bleeding are similar in patients treated with either once-daily or twice-daily LMWH.40 Although there are several studies in non-pregnant populations that have supported outpatient treatment of patients with symptomatic PE,41,42 there are no such studies in pregnancy.

Pharmacokinetic data showing increased renal clearance of LMWH during pregnancy has led to recommendations for twice-daily dosing during pregnancy.36 However, there is preliminary data suggesting that the use of a once-daily dose regimen may also be effective in pregnancy. Studies using once-daily tinzaparin (175 IU/kg) in women with acute VTE reported no recurrent events,43,44 and a prospective multicentre observation survey from the UK reported that 60% of practitioners use once-daily dosing of enoxaparin and dalteparin for treatment of acute VTE in pregnancy.35

Recommendations
1. Treatment of acute VTE in pregnancy should be with LMWH given once-daily or twice-daily at therapeutic doses. There is currently insufficient evidence to favour one dose regimen over the other. (Group Consensus Level 1)
2. Women with PE or more extensive DVT (i.e. iliofemoral thrombosis) during pregnancy should receive initial treatment with twice-daily LMWH for at least 8–12 weeks, after which time a reduction to a once-daily regimen may be considered. (Group Consensus Level 2)
3. Inpatient observation and treatment of women with PE, for the first few days following diagnosis is recommended. (Group Consensus Level 1)

Duration of full intensity anticoagulation

In non-pregnant patients with proximal DVT and/or PE, a minimum of six months of anticoagulation is currently recommended and up to three months for isolated distal DVT. Following acute VTE in pregnancy, anticoagulation should be continued for the remainder of pregnancy and at least six weeks postpartum.4,45 Reduced intensity of anticoagulation after a period of full-dose treatment has been shown to be safe in other patient populations,46 and is an appealing concept in pregnancy; however, the safety of this approach has not been established.

Recommendation
1. Anticoagulant therapy in pregnant women with acute proximal DVT and/or PE should be continued until at least six weeks postpartum or longer, if necessary, to complete a minimum total treatment period of six months. (Group Consensus Level 1)
2. A shorter total duration of therapy (6–8 weeks) may be appropriate in women with isolated distal DVT, with consideration given to prophylactic dose LMWH for the remainder of the pregnancy. (Group Consensus Level 1)

Monitoring anti-Xa levels in women on LMWH

Monitoring of LMWH therapy is usually unnecessary in non-pregnant patients.47 Weight-related changes in volume of distribution and increased renal clearance during pregnancy have been suggested as reasons for monitoring women on therapeutic LMWH. However, there is no data demonstrating clinical benefit from dose adjustment of LMWH according to anti-Xa levels during pregnancy. If monitoring is to be used, for twice-daily regimens the current recommended therapeutic range in pregnancy is 0.5–1.0 IU/mL (four h post dose).48,49 In patients treated with LMWH once-daily, the target range at four h is less clear, but 1.0–2.0 IU/mL is accepted as reasonable.50 The ACCP guidelines provide a detailed discussion of the possible role of anti-Xa monitoring in pregnancy.4
Recommendations
1. There is insufficient evidence to recommend monitoring of anti-Xa levels to guide dosing in women on therapeutic dose LMWH. (Group Consensus Level 1)
2. Anti-Xa levels are not required in women on prophylactic dose LMWH. (Group Consensus Level 1)

Post-thrombotic syndrome in pregnancy
Post-thrombotic syndrome (PTS) is characterised by symptoms of leg heaviness, itching, cramps and pain, with physical signs of leg oedema, hyperpigmentation, new venous ectasia and, rarely, in its most severe manifestation, by the presence of a venous stasis ulcer. Around 15–50% of patients who have suffered with DVT will develop PTS; however, regular use of an elastic compression stocking reduces the incidence of PTS by around 50%. A large recent study shows that 30% of women develop PTS following DVT in pregnancy, the rate of which is similar to the rate in non-pregnant women of the same age. These data suggest pregnancy per se does not increase the risk of PTS after a DVT.

Recommendation
1. All women with a confirmed DVT should wear a below-knee class 2 (30–40 mmHg) compression stocking for up to two years. (Group Consensus Level 1)

Special situations in management
Use of vena caval filters in pregnancy
In the only randomised controlled trial of inferior vena caval (IVC) filter use in combination with anticoagulant therapy, filter insertion was associated with a decrease in the short-term incidence of PE, but had no effect on mortality and increased the long-term risk of recurrent DVT. Filter insertion should only be considered in women who are either unable to receive therapeutic anticoagulation because of an unacceptable risk of bleeding, or who have had objectively confirmed extension or recurrence of VTE despite therapeutic anticoagulation.

Recommendation
1. Insertion of a temporary IVC filter should only be considered in pregnant patients with recent acute venous thrombosis in whom therapeutic anticoagulation is contraindicated because of a high risk of bleeding, or who have objectively confirmed recurrent VTE despite therapeutic anticoagulation. (Group Consensus Level 1)

Thrombolysis
The potential role of thrombolysis for acute VTE during pregnancy has been extrapolated from studies in non-pregnant patient populations. There is consensus for the use of thrombolysis in non-pregnant patients with massive PE associated with hypotension/circulatory collapse at presentation, or with limb- or life-threatening ischaemic complications from massive iliofemoral vein thrombosis. A review of use of thrombolytic therapy for pregnant patients with PE identified thirteen cases. No maternal deaths occurred, although major bleeding (30.8%; 95% CI 9.1–61.4) and fetal deaths (15.4%; 95% CI 1.9–45.5) were significant complications. Thrombolysis should be considered in pregnant women with major embolism threatening life or limb only if they understand and accept these potential risks.

Recommendation
1. Thrombolysis should only be considered in pregnancy for women with life or limb-threatening complications of acute VTE. (Group Consensus Level 1)

Management of women with acute VTE close to term
In women who develop VTE close to term, there may be concern at the risk of bleeding at the time of delivery if on therapeutic dose anticoagulation. The risk of stopping anticoagulation must be balanced with the risk of recurrent thromboembolism. The highest risk for recurrence following VTE is the first two weeks after presentation. The timing and mode of delivery for women with VTE diagnosed late in the third trimester should be based on obstetric considerations but planned delivery by induction of labour (IOL) or elective CS is recommended for women at high risk of thrombosis in whom time off therapeutic dose anticoagulation must be minimised and transition to intravenous UFH in preparation for delivery may be required. An approach to management of such women is summarised in Table 2. Insertion of a temporary IVC filter has been used in women who present very close to term but carries significant hazards, as mentioned earlier, and is rarely justified.

Table 2 Suggested protocol for peripartum management of anticoagulation in women who require therapeutic level anticoagulation

<table>
<thead>
<tr>
<th>Antepartum</th>
<th>Postpartum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day-2</td>
<td>Last dose of LMWH</td>
</tr>
<tr>
<td>Day-1</td>
<td>Start iv UFH 5000 U bolus then 1250 IU/h adjusting APTT to 2–3 x baseline</td>
</tr>
<tr>
<td>Day 0</td>
<td>Day of induction of labour or Casearean section</td>
</tr>
<tr>
<td>6–12-h post-NVD</td>
<td>Restart iv UFH 500 IU/h for 6 h</td>
</tr>
<tr>
<td>12–24-h post-CS (if no bleeding concerns)</td>
<td>Increase to 1000 IU/h for 6 h Check APTT and adjust iv UFH as per APTT (2–3 x baseline)</td>
</tr>
<tr>
<td>Day 2</td>
<td>Loading dose of warfarin 10 mg day 1, 5 mg day 2, 5 mg day 3 then as per INR Continue iv UFH† until INR ≥2</td>
</tr>
</tbody>
</table>

LMWH, low-molecular-weight heparin; UFH, unfractionated heparin.
†It may be possible to restart therapeutic dose LMWH postpartum; however, this can be difficult to reverse if secondary haemorrhage occurs and the decision should be individualised.
Pregnancy is unpredictable, and in some cases, preterm labour or other maternal or fetal complications necessitate urgent delivery in women who are fully anticoagulated. The APTT will not provide an accurate indication of the degree of anticoagulation and risk of bleeding in women taking LMWH. Protamine administration may partially reverse the anticoagulant effect of LMWH; however, fresh frozen plasma and other coagulation factors should not be given as they will have no effect.

Postpartum it is reasonable to restart prophylactic dose LMWH around 6–12 h after delivery if there are no bleeding concerns, but it is generally recommended to wait at least 24 h before restarting therapeutic anticoagulation (Table 2). Delayed postpartum bleeding is a frequent complication in women who require therapeutic levels of anticoagulation in the postpartum period and careful clinical review is essential. Warfarin may be commenced by usual dosing regimen starting 36–48 h after delivery, provided bleeding is not problematic.

### Anaesthesia and anticoagulation in pregnancy

The planning of labour and delivery in women on prophylactic or therapeutic anticoagulation requires close consultation with the anaesthetist. Whilst the incidence of spinal or epidural haematoma is rare, most case reports describe abnormal coagulation states at either the insertion or removal of a neuraxial catheter. For this reason, coagulation should be normalised for the performance of neuraxial blockade. Recommendations relating to the timing of insertion and removal of neuraxial blockade in women receiving either LMWH or UFH are summarised in Table 3. In some women who present unexpectedly these requirements may not be met and the options include patient controlled intravenous analgesia for labour pain relief or general anaesthesia if caesarean delivery is required. It is not recommended to commence therapeutic anticoagulation with a neuraxial catheter in situ secondary to the requirement for normal coagulation when the catheter is removed. For this reason, it is recommended that neuraxial catheters be removed prior to therapeutic anticoagulation commencing, and that there is at least a 24-h window post removal before re-commencing therapeutic LMWH. All women should be educated about the potential signs of a neuraxial haematoma and be monitored closely for the development of such signs.

### Conclusions

Use of appropriate medical imaging is essential when DVT or PE are suspected on clinical grounds in pregnant and postpartum women, as the utility of clinical probability tests and D-dimer testing has not been established in this group. LMWH provides safe and effective treatment of such events with no adverse fetal effects. Whilst there is as yet less than ideal evidence, this paper has presented a logical and reasonable consensus-based approach to the investigation and management of suspected and confirmed thromboembolism in pregnancy. Clinical trials are required to address these matters definitively.

### Acknowledgements

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### References


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**Table 3 Management of LMWH, UFH and neuraxial blockade**

<table>
<thead>
<tr>
<th>LMWH – prophylactic dose</th>
<th>Ensure a minimum of 12 h after LMWH dose before the performance of a neuraxial block or removal of a neuraxial catheter. Wait at least 2 h following neuraxial blockade or neuraxial catheter removal before giving subsequent LMWH dose.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LMWH – therapeutic dose</td>
<td>Preferable to avoid therapeutic dosing with catheter in situ. Wait at least 24 h after the last dose LMWH before performing neuraxial blockade or removing a neuraxial catheter.</td>
</tr>
<tr>
<td>UFH – prophylactic dose</td>
<td>Wait at least 6 h after last dose of UFH (doses ≤10 000 U) before performing neuraxial blockade or removing a neuraxial catheter. Wait at least 2 h after performing neuraxial blockade or removing a neuraxial catheter before giving subsequent UFH dose.</td>
</tr>
<tr>
<td>UFH – therapeutic dose</td>
<td>Stop intravenous UFH 4–6 h prior to performing neuraxial blockade or removing a neuraxial catheter. Document normal aPTT (3–4 h after stopping infusion). Wait at least one h after performing neuraxial blockade or removing a neuraxial catheter before recommencing UFH.</td>
</tr>
</tbody>
</table>

LMWH, low-molecular-weight heparin; UFH, unfractionated heparin.
Diagnosis and treatment of pregnancy-associated VTE


