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Emergency department nurse-based outpatient diagnosis of DVT using an evidence-based protocol

C Dewar,¹ C Selby,² K Jamieson,³ S Rogers⁴

¹Emergency Department, Queen Margaret Hospital, Operational Division NHS Fife, UK; ²General Medicine Department, Queen Margaret Hospital, Operational Division NHS Fife, UK;

³Radiology Department, Queen Margaret Hospital, Operational Division NHS Fife, UK;

⁴Haematology Department, Queen Margaret Hospital, Operational Division NHS Fife, UK

Correspondence to:

Dr C Dewar, Emergency Department, Queen Margaret Hospital, Operational Division NHS Fife, Whitefield Road, Dunfermline, Fife KY12 0SU, UK; colin.dewar@fahf.nhs.uk

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ABSTRACT

Objectives: To investigate the clinical validity of a nurse practitioner emergency department-based service for investigating outpatients with suspected deep vein thrombosis.

Methods: A prospective management study was undertaken to investigate the safety of withholding anticoagulant treatment in patients who were negative for testing after application of an evidence-based protocol. The protocol involved a nurse assessment using the Wells pretest score followed by investigations tailored to the risk category (variable combinations of strain gauge plethysmography, D-dimer and ultrasound). The main outcome assessed was the venothromboembolic complication rate in patients deemed to have deep vein thrombosis excluded by the protocol.

Results: A total of 625 consecutive patients were evaluated between March 2003 and January 2007. Of these, 435 were eligible and 190 were ineligible. Four patients in the negative cohort were confirmed to have venous thromboembolism on follow-up. The incidence of venous thromboembolism in the 6-month follow-up period was therefore 1.04% (95% CI 0.41% to 2.65%).

Conclusion: The evidence-based protocol used in this study can reliably exclude deep vein thrombosis in an outpatient population when applied as part of a nurse-based evaluation.

Deep vein thrombosis (DVT) is a common condition affecting approximately 84 individuals per 100 000 each year.¹ Patients with suspected DVT frequently present to emergency departments, often with clinical signs and symptoms that are non-specific. A wide variety of non-thrombotic disorders can mimic the clinical presentation of DVT.²⁻³ Reliable objective testing for DVT is important because of the well recognised association with fatal pulmonary embolus⁴ and the structural damage to the valves of the deep veins which results in the postphlebotic syndrome. Antithrombotic therapy is effective in reducing both the morbidity and mortality associated with this condition.⁵ Inappropriate treatment carries its own risks;⁶ accurate diagnosis is consequently of considerable importance.

A wide variety of different approaches have been devised to detect lower limb DVT in symptomatic patients. The basic principle of any diagnostic strategy should be accuracy, reproducibility, low invasiveness/toxicity, low cost, rapidity and simplicity of performance.

Compression ultrasound, which is highly sensitive and specific for proximal DVT, is currently regarded as the diagnostic method of choice in patients with suspected DVT. However, it is expensive, requires highly trained personnel and

is not sensitive for isolated calf DVT.⁷ Ultrasound should therefore be repeated 1 week after an initially normal test to exclude proximally extending calf DVT that can cause pulmonary embolus.³⁻⁷ Serial ultrasound at days 1 and 7 has been found to have an incidence of venous thromboembolic events on follow-up after normal testing of 0.7% (95% confidence interval (CI) 0.3% to 1.2%),⁸ compared with a risk of 1.3% (95% CI 0.3% to 4.4%) of venous thromboembolic disease following negative contrast venography.⁹ Serial ultrasound is, however, an expensive diagnostic strategy with a low yield of positive results from the second ultrasound (approximately 2%).⁸

Clinical probability tools have been developed to estimate the probability of venous thrombosis. The principal use of such probability tools is to reduce the need for costly serial investigations, particularly when combined with D-dimer testing. The first tool developed by Wells *et al*¹⁰⁻¹¹ uses a structured assessment of explicit historical and physical examination criteria (table 1) to stratify patients into low, moderate and high risk of DVT. The combination of a low clinical probability and a normal D-dimer test has been shown to safely exclude a diagnosis of DVT.¹² A previous accuracy study using contrast venography as the gold standard showed that impedance plethysmography could be reliably used instead of ultrasound in the low clinical probability group.¹³ Impedance plethysmography measures the change in impedance between two electrodes placed around the calf in response to deflation of an occlusive cuff.¹⁴ Strain gauge plethysmography uses the technique of filling the distal veins of the lower limb by inflation of a tourniquet around the thigh, causing occlusion of the thigh veins, then indirectly measuring the changes in venous outflow and capacitance in response to deflation of an occlusive cuff.¹⁵

The purpose of the study was to investigate the clinical validity of a nurse practitioner emergency department-based service for investigating outpatients with suspected DVT. The nurse practitioners used an evidence-based protocol incorporating an initial Wells clinical probability followed by a test or combination of tests appropriate to the level of risk (fig 1). The objective was to test the safety of withholding anticoagulant treatment in patients who were negative for testing after application of the protocol. The primary end point was the rate of venous thromboembolism (including death attributed to venous thromboembolism) when anticoagulant therapy was withheld from patients on the basis of negative testing. A 6-month clinical follow-up period was used to test the validity of this approach.

Table 1 Pretest scoring in Wells test

Clinical criteria	Score
(1) Active cancer (treatment ongoing or within previous 6 months or palliative)	1
(2) Paralysis, paresis or recent plaster immobilisation of the lower extremities	1
(3) Recently bedridden for more than 3 days or major surgery within 4 weeks	1
(4) Localised tenderness along the distribution of the deep venous system	1
(5) Entire leg swollen	1
(6) Calf swelling by more than 3 cm compared with the asymptomatic leg (measured 10 cm below the tibial tuberosity)	1
(7) Pitting oedema (greater in the symptomatic leg)	1
(8) Collateral superficial veins (non-varicose) in symptomatic leg	1
(9) Alternative diagnosis as likely as or greater than that of deep vein thrombosis	-2

Low risk: 0 or less; moderate risk: 1 or 2; high risk: 3 or more.

METHODS

Study cohort

From March 2003 to January 2007, consecutive adult patients who presented to the emergency department or were referred to general medicine department with symptoms suggestive of DVT were enrolled in the study. Criteria for exclusion were a previous episode of objectively documented DVT or pulmonary embolism, pregnancy, patients in whom death was imminent, age <18 years or refusal to give informed consent.

Clinical probability and testing for DVT

Consenting patients were assessed by one of the study nurse practitioners using the previously validated Wells clinical model for patients with suspected DVT,¹¹ and ranked accordingly into low, moderate or high pretest probability of having DVT. Nurse practitioners assessed the patients between 09.00 and 17.00 hours Monday to Friday. If there was an attendance with possible DVT outside these hours, daily subcutaneous low molecular weight heparin was administered until an appointment with the DVT service was available. Patients attending out of hours also had blood taken for D-dimer testing before anticoagulation. The nurse practitioners were trained in the

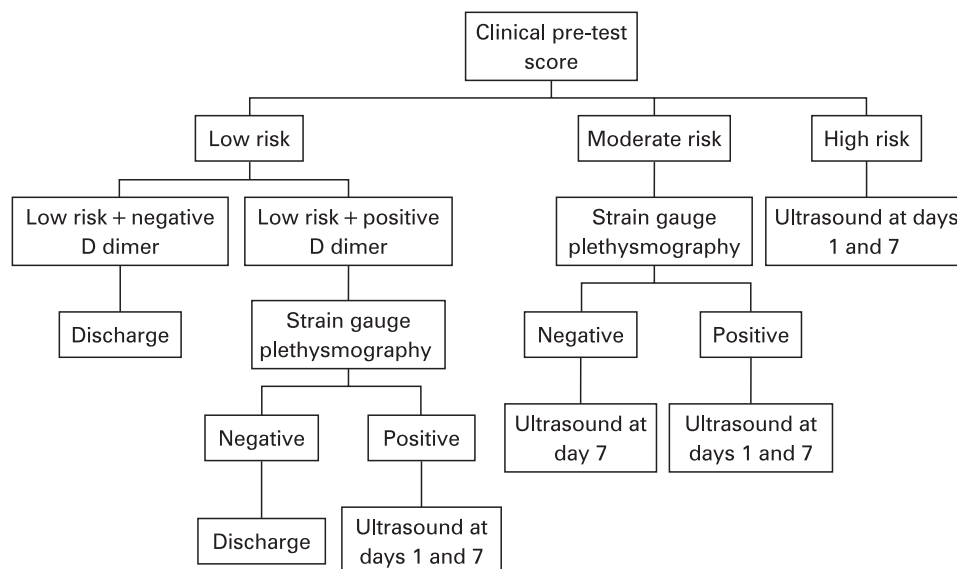
application of the Wells score by two of the investigators (CD and CS). The nurse practitioners and one of the investigators (CD) jointly scored the first 100 patients.

Following informed consent, the patients were managed in accordance with the algorithm outlined in fig 1. Low-risk patients underwent a D-dimer test and, if this was negative, DVT was deemed to be excluded. If the test was positive they were then investigated with strain gauge plethysmography performed by the nurse practitioners and, if this was negative, DVT was again excluded. If the strain gauge plethysmography was positive, a subsequent ultrasound was performed. Moderate-risk patients were assessed with strain gauge plethysmography and, if this was negative, they were followed up with an ultrasound on day 7. Positive plethysmography resulted in an ultrasound at the time of presentation. Training was provided on the use of the venometer by Amtec Medical (Antrim, Northern Ireland, UK) before commencing the study. High-risk patients were investigated with ultrasound on the day of assessment and 7 days later. Patients were anticoagulated with subcutaneous heparin between tests in view of the risk of calf vein thrombosis and subsequent propagation into the proximal venous system. If DVT was deemed to be excluded by the protocol, anticoagulation was withheld. All patients who were deemed to have a negative test and DVT excluded were reviewed before discharge by one of the emergency medicine consultants.

If the patients required ultrasound as per the protocol, they were examined by a consultant radiologist, an SPR in diagnostic radiology or an experienced sonographer. These individuals had no knowledge of the previous results from pretest scoring or strain gauge plethysmography. Compression of the common femoral, superficial femoral and popliteal veins was performed. Colour Doppler was then applied down to the level of the popliteal trifurcation and assessed for the presence or lack of normal augmentation and respiratory variation. Lack of compression was deemed to be positive for DVT. Colour flow allowed identification of non-occlusive thrombus.

D-dimer testing with the HemosIL immunoassay (Instrumentation Laboratory, Lexington, USA) was performed according to the manufacturer's instructions. This is an automated latex-enhanced immunoassay and is run on an ACL 8000. It is a quantitative assay with an upper limit of the normal range set at 250 ng/ml. Laboratory technologists

Figure 1 Evidence-based protocol for investigating deep vein thrombosis.



performing and interpreting the D-dimer assays were unaware of the clinical presentation of the patients or the results of other objective tests.

Patient follow-up

All patients recruited into the study received written instructions to contact a member of the study team or attend the emergency department if they had any symptoms of chest pain, shortness of breath or pain or swelling of the legs. Patients were routinely assessed by telephone every 2 months for a total of 6 months. Issues addressed were general health, specific symptoms of venous thromboembolism and hospitalisation.

All patients who returned during the follow-up period with clinically suspected venous thrombosis underwent diagnostic testing. For suspected DVT, compression ultrasound was performed. There were no cases of suspected pulmonary embolism in the follow-up period.

Statistical analysis

The 95% confidence intervals (CI) were calculated on the basis of the presence or absence of diagnosed DVT in the patient over the duration of the study. The 95% CI for venothromboembolic complications in the follow-up period were calculated using the Wilson score method. All other 95% CI were calculated using the modified Wald method.

RESULTS

Study cohort

A total of 625 consecutive patients were evaluated between March 2003 and January 2007. Of these, 435 were eligible and 190 were ineligible. The reasons for ineligibility are shown in table 2. All three of the patients who were unable to have strain gauge plethysmography were as a result of lower limb plaster immobilisation. The mean age of the study group was 58 years (range 18–92). Fourteen of the 435 patients who participated in the study were admitted (5 for intravenous antibiotics to treat cellulitis, 4 as a result of an extensive DVT on ultrasound, 3 for social reasons, 1 for an extensive haematoma and 1 for a coincidental pneumonia); 97% of patients were treated entirely as outpatients.

Results of initial Wells pretest scoring

A total of 166 (38%) were found to be at low risk with a DVT prevalence of 5% (9/166). In the moderate-risk group there were a total of 161 patients (37%) with a DVT prevalence of 11% (17/161). The high-risk group had a total of 108 patients (25%) with a prevalence of DVT of 28% (30/108). The overall prevalence of DVT in the study group was 13% (56/435).

Table 2 Reasons for ineligibility

Reasons for exclusion	No of patients
Refused consent	84
Previous DVT or pulmonary embolus	67
Unable to consent	13
Signs or symptoms consistent with a pulmonary embolus	9
Pregnancy	5
Leaving the country during the follow-up period	5
Not appropriate for strain gauge plethysmography	3
On anticoagulation at time of enrolment	2
<18 years of age	2

DVT, deep vein thrombosis.

Venous thromboembolism in the follow-up period

Four patients in the negative cohort were confirmed to have venous thromboembolism on follow-up. The incidence of venous thromboembolism in the 6-month follow-up period was therefore 1.04% (95% CI 0.41% to 2.65%). The first patient presented with a 3-week history of a swollen erythematous leg which had been gradually increasing in size. He was subsequently scored as low risk, but D-dimer testing and strain gauge plethysmography were both positive. Serial ultrasound was therefore performed but both investigations were negative for DVT. Three weeks after entry into the study the patient re-attended with persistent symptoms and ultrasound performed at that time revealed a proximal DVT. The other three patients who presented with symptoms and signs suggestive of superficial thrombophlebitis were all scored as low risk. In all three cases D-dimer was >1000 but strain gauge plethysmography was negative and the patients re-presented within 1 week with worsening symptoms and a positive ultrasound. No patients were lost to 6-month follow-up.

Deaths in the follow-up period

Three patients died during the follow-up period. The first was a 61-year-old patient in the negative cohort who had a past history of insulin dependent diabetes, ischaemic heart disease, hypertension and hyperlipidaemia. He presented with a 2-week history of calf swelling and was scored as moderate risk; subsequent strain gauge plethysmography and ultrasound on day 7 were normal. The ultrasound performed on day 7 proved to be a technically difficult scan and, in view of this, it was decided to proceed to contrast venography which was entirely normal. Two weeks after study entry the patient was found dead at home. An autopsy was not performed and the death certificate listed the cause of death as myocardial infarction. The second was a 69-year-old patient who presented with a 1-week history of a swollen leg. She was scored as high risk and subsequent serial ultrasound was normal. Five months after study entry she died of metastatic breast cancer which had been diagnosed before her initial presentation. The third patient was aged 71 and presented with a 2-day history of calf pain. He was scored as moderate risk; initial strain gauge plethysmography was negative and an ultrasound performed on day 7 showed a Baker's cyst. Six weeks after study entry he died of metastatic pancreatic cancer which had been present before enrolment in the study.

Results of investigation protocol

The number of patients who underwent each step of the protocol is shown in fig 2. A negative D-dimer test excluded DVT in 87/166 patients (52%, 95% CI 44.8% to 59.9%) who were scored as low risk. A further 65/166 (39%, 95% CI 32.1% to 46.8%) were excluded after a positive D-dimer test and a negative strain gauge plethysmography. This resulted in a total of 152/166 patients (92%, 95% CI 86.2% to 95%) in the low risk group who had DVT correctly excluded with D-dimer alone or D-dimer and strain gauge plethysmography. Of the 383 patients in all risk groups in whom DVT was subsequently excluded, 152 (40%, 95% CI 34.9% to 44.7%) were excluded without the need for ultrasound. Thus, a diagnosis of DVT was correctly excluded on the day of initial assessment in 40% of patients.

In the moderate-risk group there were five false negatives (3%, 95% CI 1.1% to 7.3%) after strain gauge plethysmography compared with two (1%, 95% CI 0.05% to 4.7%) after D-dimer testing. The combination of a positive D-dimer test and negative strain gauge plethysmography had a false negative

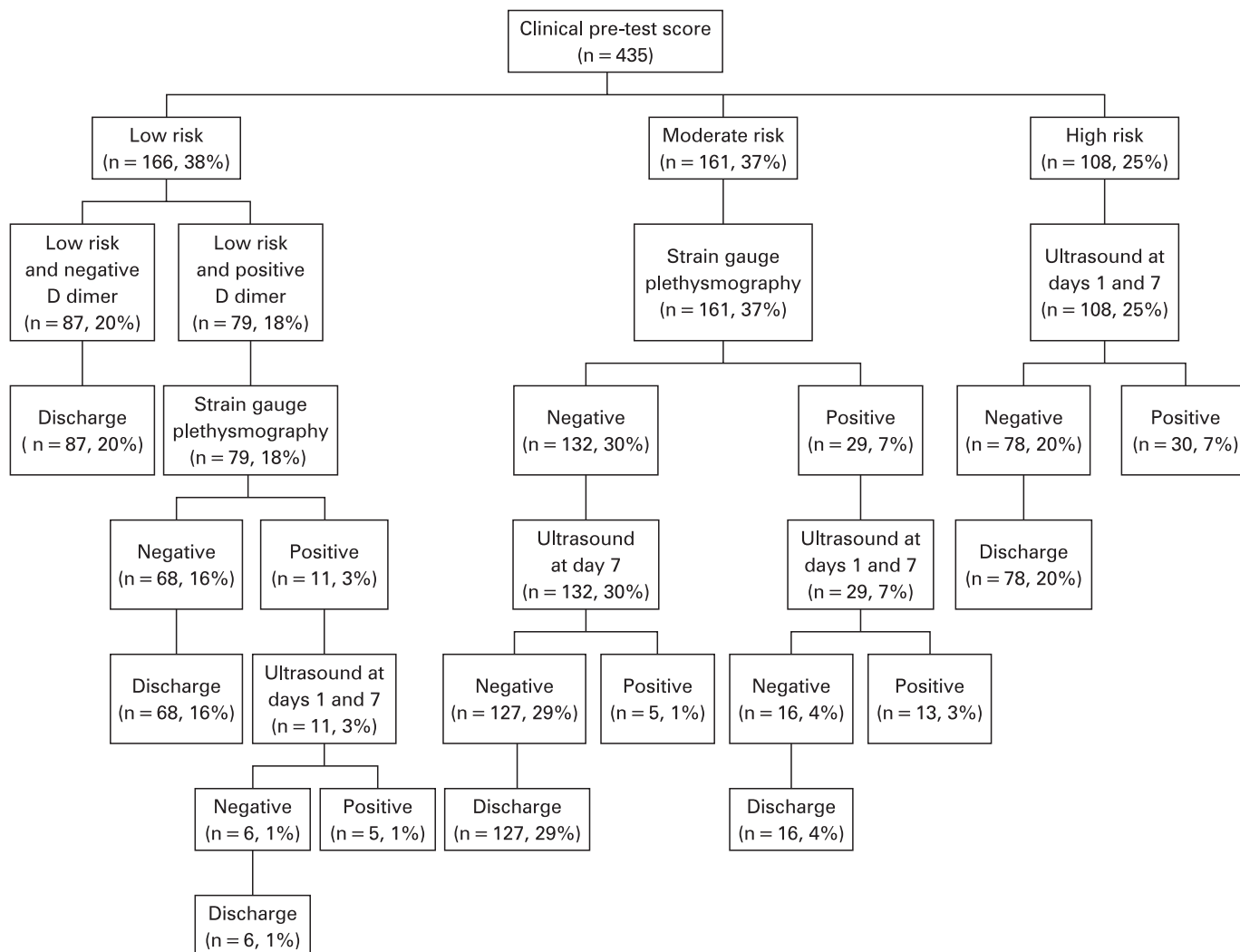


Figure 2 Flow diagram of investigation protocol with results.

rate of 4/93 (4%, 95% CI 1.3% to 10.9%). The combination of a negative D-dimer test and negative strain gauge plethysmography correctly ruled out DVT in 44/161 patients in the moderate-risk group (27%, 95% CI 21% to 34.7%) with no false negatives. One patient had a positive plethysmography followed by a negative first ultrasound with DVT subsequently confirmed following the ultrasound test on day 7. Four patients in the high-risk group had no evidence of DVT on the ultrasound performed on day 1 but a positive ultrasound on day 7.

A total of 388 ultrasound tests were performed as part of the protocol. This compares with a predicted number of 573 ultrasound tests if low-risk patients with a positive D dimer had one ultrasound test and other risk groups were investigated with serial ultrasound. The protocol therefore reduces the requirement for ultrasound by 32% (95% CI 28.6% to 36.2%) compared with current evidence-based investigation of DVT.

Complications of anticoagulation

In both the moderate- and high-risk groups, patients were anticoagulated with subcutaneous heparin between tests in view of the risk of calf vein thrombosis and subsequent propagation into the proximal venous system. There were also 11 patients who required anticoagulation between the ultrasound tests on days 1 and 7 in the low-risk group after a positive

D-dimer test and positive strain gauge plethysmography. This resulted in a total of 280 patients who required anticoagulation for a minimum of 6 days. Three patients experienced bleeding into the soft tissues of the leg as a result of the anticoagulation between investigations; they were all moderate risk and made a complete recovery (complication risk for anticoagulation between tests 1%, 95% CI 0.2% to 3.3%). Patients were also anticoagulated if testing could not be performed on the day of attendance (maximum duration 3 days if attending on a Friday after 17.00 h.) None of the patients who required anticoagulation before testing subsequently developed complications.

DISCUSSION

The protocol used in this study resulted in a low incidence (1.04%, 95% CI 0.41% to 2.65%) of confirmed symptomatic venous thromboembolism after 6 months of follow-up in patients with negative testing after presentation. The diagnostic protocol was found to have a comparable performance to the current gold standard of ultrasound on days 1 and 7 (0.7%) with 95% CIs comparable in range (0.3% to 1.2% vs 0.41% to 2.65%).⁸ Our findings suggest that nurse-based evaluation of patients presenting with symptoms or signs suggestive of DVT can reliably exclude a diagnosis of DVT when supported by the combination of testing used in the studied protocol. In addition,

97% of patients (421/435) were managed entirely as outpatients and 40% (152/383) had a diagnosis of DVT correctly excluded on the day of initial assessment.

The overall prevalence of DVT was 13%; this is consistent with other studies investigating the diagnosis of DVT in an outpatient population.^{16 17} In all, 30% of patients screened were excluded from the study. This is compatible with previous management studies where the proportion of screened patients excluded has ranged between 10% and 41%.^{18–21}

It has been recommended that patients with an initial negative non-invasive test should have the test repeated in 7 days to detect extending calf vein thrombi.^{22–24} However, the serial testing strategy is costly because most patients who return for repeat testing do not have DVT.²⁵ In our protocol, serial ultrasound was reserved only for the high-risk group. In the low-risk group the principal aim was reliably to exclude DVT and reduce the requirement for ultrasound. As has been previously noted, the combination of a low-risk score and negative D-dimer test can safely exclude a DVT; in our study this accounted for 87/166 (52%) of this group of patients. A negative strain gauge plethysmography excluded a further 65/166 patients (39%) who would have required ultrasound investigation if D-dimer testing alone was used to exclude DVT in the low-risk group. The study protocol meant that only 14/166 patients (8%) in the low-risk group required investigation with ultrasound (8%). In addition, the protocol reduced the requirement for serial ultrasound in the moderate-risk group by replacing the first ultrasound investigation with strain gauge plethysmography performed by the nurse practitioner (132/161, 82% reduction). The combination of tests performed in the low- and moderate-risk groups resulted in a 32% reduction in the requirement for ultrasound compared with current evidence-based practice.

It has previously been suggested that a negative quantitative latex D-dimer assay can reliably exclude DVT in the moderate-risk group.¹⁶ However, we found a false negative rate of 1% for D-dimer testing in the moderate-risk group compared with no false negatives if a combined strategy of strain gauge plethysmography and ultrasound was employed. The recommendation by Bates *et al*¹⁶ was based on a false negative rate of 1.1% (1/90 patients) in the moderate-risk group. It is our opinion that a 1% false negative rate in a risk group with an 11% prevalence of DVT is too high when there are available diagnostic strategies with no false negatives on follow-up.

The combination of a positive D-dimer test and negative strain gauge plethysmography did not perform as well in the moderate-risk group as in the low-risk group (false negative rate 4% vs 2%). However, the combination of a negative D-dimer test and negative strain gauge plethysmography in the moderate-risk group had no false negative results. If this strategy was added to the existing protocol, it would increase the number of patients who did not require a single or serial ultrasound to exclude DVT from 40% to 51% (DVT excluded patients). It is our intention to examine the possibility that this is both a safe and effective strategy for the moderate-risk group with a larger sample size.

Wells *et al* recently modified their clinical probability tool into just two groups: DVT likely and DVT unlikely.²⁶ They specifically divided the moderate probability group into two groups and assigned those with the lower score of 1 to the lower probability group (DVT unlikely) and those with a score of 2 to a higher probability group (DVT likely). The original Wells score did not account for a history of DVT; however, the modified classification assigns 1 point for a prior history of DVT. The

results of this study cannot therefore be applied to patients categorised by the modified clinical probability tool.

CONCLUSION

The evidence-based protocol used in this study can reliably exclude DVT in an outpatient population when applied as part of a nurse-based evaluation. The protocol also reduces the requirement for ultrasound investigation in this common condition.

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Competing interests: None.

Ethics approval: Ethics approval for the study was granted by the local research ethics committee (reference number 1041).

Contributors: CD had the original idea for the study, developed and designed the project, performed data analysis and wrote the first draft of the paper; CS helped in the development of the original idea and design of the study and reviewed the paper; KJ and SR assisted with study preparation and reviewed the paper; CD is the guarantor of the paper.

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Images in emergency medicine

Pneumocephalus after epidural injections

Two cases of pneumocephalus are described, one after epidural anaesthesia and one after a steroid injection in the lumbar spine.

The first case was a 28-year-old woman who presented with a severe headache, numbness in the upper extremities, photophobia and vomiting 3 days post partum from a vaginal delivery and an epidural anaesthesia. The second case was a 37-year-old man who had recently been treated in a local pain clinic with lumbar steroid injections and who presented 24 h later complaining of a severe headache, nausea, vomiting and photophobia. Both patients were afebrile, vital signs were unremarkable, they had no focal neurological deficits and were otherwise healthy individuals. Both cases were unique in that intraventricular air predominated in the head CT scan (figs 1 and 2). They were treated with oxygen and their condition resolved after 2–3 days in hospital.

A diagnosis of pneumocephalus was made in both patients. Pneumocephalus is more common after head or facial trauma that involves a leak of cerebrospinal fluid, occurring in up to one-third of such patients. Pneumocephalus after epidural steroid injections or epidural anaesthesia is very rare and only case reports have been reported in the literature.^{1 2} Although the absolute incidence of this condition is unknown, only 1–2 cases a year are reported in the literature. The mechanism involves inadvertent puncture of the dural layer during epidural injections for treatment of radiculopathy or induction of epidural anaesthesia with the introduction of air in the dural space. The headache of pneumocephalus is usually immediate in onset, aggravated by any motion, and is not relieved by lying down. As little as 2 ml of air can cause symptoms. The air is usually reabsorbed after 2 days and the headache usually resolves within 5 days of the dural puncture. The development of pneumocephalus following blood patches and epidural anaesthesia involving the placement of catheters has also been reported. Many of these procedures are performed in an outpatient setting and therefore it is important to include pneumocephalus in the differential diagnosis of sudden severe headache in a patient in the emergency department. No randomised trials have studied the treatment of pneumocephalus, but administration of 40–100% oxygen has been suggested. Patients should be admitted for observation if symptoms are severe.

R B Nolan, D A Masneri, D Pesce

Darnall Army Medical Center, Fort Hood, Texas, USA

Correspondence to: Dr R B Nolan, 209 Liscio Loop, Georgetown, TX 78628, USA; irisherdo@yahoo.com



Figure 1 CT scan of the head in case 1.

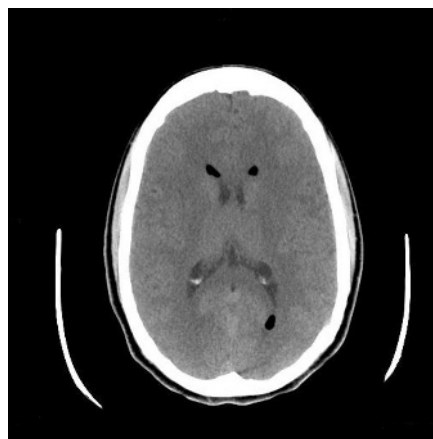


Figure 2 CT scan of the head in case 2.

Competing interests: None.

Patient consent: Content was obtained to publish the details of these two cases. *Emerg Med J* 2008;**25**:416. doi:10.1136/emj.2006.044412

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