Safety of a single duplex scan to exclude deep venous thrombosis

B. Wolf, D. M. Nichols* and J. L. Duncan

Departments of General Surgery and *Radiology, Raigmore Hospital, Inverness, UK

Correspondence to: Mr B. Wolf, Ward 36, Aberdeen Royal Infirmary, Foresterhill, Aberdeen AB25 2ZD, UK

Background: Guidelines advocate that a negative ultrasonographic scan needs to be followed by venography, or a repeat scan after 1 week, to detect potentially missed calf vein thrombosis. This study aimed to evaluate whether anticoagulation can safely be withheld on the basis of a single negative duplex scan in patients presenting with suspected deep venous thrombosis (DVT).

Methods: Duplex scan reports, case notes and questionnaires returned by general practitioners of patients with suspected DVT were analysed retrospectively. The main outcome measure was occurrence of an adverse thromboembolic event, a symptomatic DVT or a pulmonary embolism, within 3 months after a negative duplex scan.

Results: Some 537 patients had 706 leg scans performed, the majority because of leg symptoms or to look for indirect evidence of pulmonary embolism. Among 352 patients, who had 429 negative leg scans, four possible adverse events were identified. The rate of adverse outcome was therefore 1.1 per cent per patient and 0.9 per cent per leg.

Conclusion: Withholding anticoagulation in patients who had a single, complete, negative duplex scan is safe. A repeat scan should be performed if there is ongoing high clinical suspicion and considered in patients in whom the calf veins could not be visualized.

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Introduction

Venous thromboembolism remains a common cause of morbidity and death in surgical patients in spite of widespread use of antithrombotic prophylaxis. Vascular surgeons are confronted with the chronic complication of deep venous thrombosis (DVT), the post-thrombotic leg. The clinical diagnosis of DVT is unreliable and needs to be confirmed by an objective test. Venography is considered to be the gold standard but has been replaced in recent years by ultrasonography as the routine imaging modality in many centres.

Recently published guidelines have recommended that a negative ultrasonographic scan (compression or duplex) should be followed by either venography to detect deep calf vein thrombosis or repeat ultrasonography after 7 days to detect proximal extension of calf vein thrombosis. This would increase the workload of radiology departments or vascular laboratories considerably.

In this hospital, duplex imaging is used in all patients referred with suspected DVT. Venography or serial imaging is not performed routinely after a negative test.

The objective of this study was to evaluate the safety of this practice.

Patients and methods

In a retrospective and descriptive study, all patients who had a duplex scan performed in a 12-month interval because of clinical suspicion of acute lower limb DVT were identified using a computerized database. The patients were referred from the community or within the hospital to the radiology department of a single district general hospital in Scotland with a catchment population of 220,000. Imaging was performed by consultant radiologists only, according to local protocols. Patients with a suspected DVT were added to the next consultant ultrasound list, usually within 2 or 3 h, or scanned as an emergency at the weekend. A 10–5-MHz linear or 7–4-MHz curved array transducer and a colour duplex ultrasound machine (HDI 3000, ATL, Bethel, CT, USA) were used. Attempts were made to visualize the deep veins of the leg using a combination of techniques to identify thrombus, including B-mode compression scanning, augmentation, colour and power imaging. The leg

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was imaged while dependent and, where possible, thrombus was sought in distal (infrapopliteal) deep veins, posterior tibial, peroneal and calf muscle veins, as well as in the proximal leg veins.

The duplex scan reports were reviewed to determine the segments of the venous system examined, the presence and extent of any DVT, and any other findings. Some patients received anticoagulation between presentation and duplex imaging, depending on the delay and the degree of suspicion of DVT.

The case notes of all patients who had a negative duplex scan were evaluated for an adverse event occurring in the 3 months after the initial examination. Where there was insufficient information in the case notes a questionnaire was sent out to the general practitioner (GP). The two endpoints were a symptomatic DVT confirmed by a subsequent test and a pulmonary embolism or death that might have been related to pulmonary embolism. A primary scan was defined as an examination of a leg performed for the first time in a 3-month interval. The binomial distribution for proportions was used to estimate the confidence interval for adverse outcome rates.

### Results

In a 12-month interval 537 patients with suspected DVT were referred for duplex imaging. A total of 706 leg examinations was performed; 669 of these were primary scans. The mean age of all patients was 63.7 (range 9–95) years. There was a slight female preponderance (57.2 per cent).

The majority of patients (74.1 per cent) were referred from the community, usually by a GP. The remainder (25.9 per cent) developed symptoms or signs suspicious of DVT while under treatment in hospital for another condition.

The majority of legs were examined because of symptoms and signs suggesting DVT (72.2 per cent) or to look for indirect evidence of pulmonary embolism (20.1 per cent), or both (5.2 per cent). Examination of the contralateral asymptomatic leg was not a common request (1.6 per cent). Few patients had a planned follow-up scan (0.8 per cent). Only one venogram was performed in the same 12 months, in a patient who had an equivocal duplex scan.

Of 669 primary scans, 165 (24.7 percent) demonstrated the presence of DVT (Table 1). The rate of positive scans in patients referred from the community was almost identical to the rate in patients who were already hospitalized. The proximal extent of thrombus was most commonly in the femoral vein. In 29.1 per cent of the positive scans, thrombus was isolated in the deep calf veins. The calf veins were visualized in 58.6 per cent of the negative scans, in 23.4 per cent they could not be seen and in the remainder the.....

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<th>Table 1 Findings of venous duplex imaging (669 primary scans)</th>
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<td>Popliteal vein</td>
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<td>Calf veins</td>
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<td>No deep venous thrombosis</td>
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<td>Calf veins visualized</td>
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<td>Calf veins not visualized</td>
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Values in parentheses are percentages

![Fig. 1 Outcome of patients with negative duplex imaging for suspected deep venous thrombosis. GP, general practitioner](image-url)
suspicion of DVT or a cardiac condition. In the group of 352 patients (429 leg examinations) who were not anticoagulated following a single negative duplex scan, four adverse events were identified within 3 months (Table 2). All four patients were treated in hospital for another condition and belonged to a moderate- or high-risk group for DVT. Three patients had progressive or recurrent leg signs and a DVT was revealed by a repeat duplex scan (two patients) or at autopsy (one). All three patients died from the primary condition. The fourth patient presented with chest symptoms 6 weeks after a negative scan and was anticoagulated as for a pulmonary embolism on the basis of moderate clinical and intermediate radiological (ventilation-perfusion scan) probability. In two of these patients the calf veins could not be visualized at the initial examination and this was stated positively by the radiologist in the report. Twenty-six patients with a negative scan died within the follow-up interval. Although the majority did not have a post-mortem examination their deaths could not be related to venous thromboembolism. The rate of adverse outcome was therefore 1.1 (95 per cent confidence interval 0.0-2.2) per cent per patient and 0.9 (0.0-1.8) per cent per leg examination.

Discussion

Venous thromboembolism is a common condition affecting patients in hospital but also seemingly healthy people in the community. Clinical assessment can predict the probability of DVT but is not accurate on its own and needs to be combined with an objective test. In the present study only 24-7 per cent of legs referred with suspicion of DVT had a positive examination, which is similar to other studies using ultrasonography as the diagnostic test. Venography has been regarded as the gold standard test for DVT but is invasive, and is associated with both minor and serious risks owing to endothelial toxicity and adverse contrast reactions. Venography has a 2 per cent risk of causing a DVT and is uncomfortable for the patient; it involves the use of ionizing radiation, is expensive, time consuming, and has a significant rate of inadequate examination, as well as misinterpretation.

Ultrasonography is non-invasive and is now used widely as the routine test for suspected DVT. The term ‘ultrasound scan’ has been used in the literature to cover several distinct techniques. Augmentation imaging relies on insonation of the femoral veins during calf compression to listen for a transmitted signal. Real-time scanning (B mode) uses compression of the vein to establish the presence of thrombus (an incompressible vein is assumed to contain thrombus). Duplex ultrasonography is a combination of pulsed-wave Doppler and real-time imaging that allows assessment of flow as well as direct visualization of echogenic material within the vein lumen. Colour and power Doppler techniques are useful adjuncts to the duplex ultrasonographic examination. Although ultrasonography is operator dependent, high sensitivity and specificity (exceeding 95 and 98 per cent respectively) have been reported for the diagnosis of DVT involving the proximal leg veins.

There is concern that ultrasonography may miss deep calf vein thrombi. The clinical significance of calf vein thrombosis is controversial. The risk of pulmonary embolism from isolated calf vein thrombosis seems negligible; however, a recurrence rate of 29 per cent and propagation rate into more proximal veins of up to 28 per cent have been reported. The accuracy of ultrasonography for the diagnosis of calf vein thrombosis has been highly variable in the few studies available. Sensitivity and specificity have ranged between 11 and 100 per cent and 90 and 100 per cent respectively. The rate of isolated calf vein thrombosis in the present study (29.1 per cent) compares with a rate of 12 per cent in a study using...
venography as the diagnostic test. This would suggest that a significant number of calf vein thromboses were not missed.

The argument for repeat ultrasonography or venography in patients with a negative scan is based on the potential risk of missing calf vein thrombosis that might propagate into more proximal veins. The incidence of thromboembolic complications after a single negative ultrasonographic scan in the present study was low (1.1 per cent per patient or 0.9 per cent per leg), even using the widest possible definition. One DVT was diagnosed within a week of the index scan because progressive leg signs mandated a repeat scan. Clearly a protocol using serial scans over 7 days would not have altered the outcome of this patient. The other two cases of DVT presented 4–6 weeks later and it is debatable whether these were missed or new. The patient with a possible non-fatal pulmonary embolism had an infected knee prosthesis and required multiple procedures as well as immobilization in the 6 weeks between the negative scan of the same leg and chest symptoms. A causal relation of the two events could not be excluded for the purpose of this study but is doubtful clinically. The rate of adverse outcomes was comparable to that in other reported studies using serial ultrasonographic imaging.

All thromboembolic complications after a negative ultrasonographic scan occurred in moderate- or high-risk, hospitalized patients. In two of the four patients the calf veins could not be visualized and this was stated positively by the radiologist. No adverse event was identified in 296 patients (368 leg examinations) referred from the community. Duplex imaging is currently the investigation of choice for patients with suspected DVT. Duplex imaging is non-invasive, highly sensitive and capable of demonstrating an alternative cause in a significant proportion of patients. From the present data, withholding anticoagulation in patients who had a single, complete, negative duplex scan appeared safe. A repeat scan should be done if there is ongoing high clinical suspicion of DVT. A further scan should also be considered in patients who had an incomplete scan (i.e. visualization of calf veins compromised) and no alternative diagnosis.

Post-thrombotic syndrome is another potential complication of missed DVT. Given the time necessary for this to develop, it is difficult to study, but there is no convincing evidence that isolated calf vein thrombosis leads to chronic venous insufficiency.

The large number of patients referred for imaging of deep veins and the relatively low prevalence of DVT in this population has initiated the search for alternative strategies. Using the D-dimer test in conjunction with assessment of clinical pretest offers the possibility of further refining the selection of patients for imaging.

Acknowledgements

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References