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Extended Lower Limb Venous Ultrasound for the Diagnosis of Proximal and Distal Vein Thrombosis in Asymptomatic Patients after Total Hip Replacement

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Objective. To assess the performance of extended lower limb venous ultrasound (US) for the diagnosis of asymptomatic deep vein thrombosis (DVT) and to estimate a 3-month DVT incidence on repeated US after total hip replacement.

Design. Diagnostic performance study and prospective cohort study.

Materials and methods. US was compared to phlebography in 70 consecutive patients and interobserver agreement was assessed in the last 48 patients at day 8. US was repeated in these 48 patients at day 13 and day 90.

Results. Phlebography demonstrated a DVT in 18/70 (26%) patients, with five proximal and 13 distal and US in 23/70 (33%) patients, with eight proximal and 15 distal. Sensitivity and specificity of US with 95% CI were 94% (73–100) and 89% (76–96), respectively. Sensitivity in isolated distal vein thrombosis was 92% (67–99). The Kappa coefficient for agreement between observers was 0.84 (0.66–1.00). Follow-up showed a DVT in 15/48 (31%) patients on day 8, in 20/48 patients (42%) on day 13. DVT recurred in two patients during follow-up.

Conclusions. The incidence of asymptomatic DVT is still significant despite prophylaxis but most DVTs remain distal and occur in the first 2 weeks. Extended US could replace phlebography for systematic screening in clinical trials using surrogate endpoints in view of its high accuracy and reliability.

Key Words: Ultrasonography; Phlebography; Asymptomatic; Deep vein thrombosis; Calf; Total hip replacement; Surveillance.

Introduction

The prevalence of asymptomatic deep vein thrombosis (DVT) following major orthopaedic surgery remains high despite adequate prophylaxis. There are two potential advantages in screening patients for asymptomatic DVT: firstly, to help decide on treating those suffering from DVT with anticoagulants and secondly, to compare the efficacy of different prophylaxis regimens.¹ Although the clinical relevance of many of the thrombi found by screening is questionable, phlebography detected thrombosis is nevertheless considered a valid outcome measure. However, phlebography, the reference standard, is invasive, no longer widely accepted by patients or ethics committees, expensive and is associated with a risk related to the administration of contrast media. It also has some limitations due to a significant rate of inadequate

studies and to considerable intra- and interobserver disagreement in interpretation of the results.^{2–6} For these reasons, systematic phlebography is no longer widely used as a screening method.

An alternative to phlebography is the use of venous ultrasonography (US), a non-invasive method, which has proved to be very accurate and is widely accepted for the diagnosis of DVT in symptomatic patients.^{7–10} However, its role as a screening test in high-risk asymptomatic patients is controversial. The moderate sensitivity in most studies.^{11,12} is thought to be related to the small size of the thrombus that is more often confined to the distal (infra-popliteal) veins.¹¹ Published work addressing the accuracy of US examination in asymptomatic patients included considerable variation in the technical approach between series, and few studies attempted evaluation of the distal veins to detect isolated calf vein thrombosis.^{2,13,14} There is as yet no ideal screening method and an accurate, inexpensive non-invasive test is required to assess the entire venous network.

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Objective

The objective of this study was:

1. To assess the diagnostic accuracy of an extended US test as compared to phlebography in high-risk asymptomatic patients.
2. To study the reproducibility of performing and interpreting an extended US.
3. Finally, to estimate by repeated US the incidence of DVT during a 3-month follow-up, following 1 month of prophylaxis with a low molecular weight heparin, whether or not patients had an isolated calf DVT on the initial screening US.

Methods

Study design

To study diagnostic accuracy, we compared US to phlebography prospectively in 74 consecutive asymptomatic patients undergoing a total hip replacement. Non-inclusion criteria consisted of patients with a previous history of DVT or pulmonary embolism based on clinical and preoperative ultrasound assessment, a contraindication to phlebography or to anticoagulant treatment. The research protocol was approved by the local ethics committee. Patients giving informed written consent were included in the study. Both US and phlebography were performed by independent investigators on day 8 ± 1 , with an interval of less than 24 h between the investigations. Findings were interpreted blindly according to pre-established criteria to confirm or exclude the diagnosis of DVT. The sensitivity and the specificity of US and 95% confidence intervals (CI) were calculated using the Wilson's method¹⁵ on the basis of number of patients or lower extremities studied. Phlebography was taken as the reference standard for these calculations.

The final 48 patients were studied in order to investigate the interobserver agreement of the US test. Two operators, unaware of each other's results performed and interpreted an US examination of the lower limb veins at an interval of less than half an hour during the day 8 studies. They used a standardised protocol and the same criteria to exclude or to confirm the presence of DVT. Results were recorded on a chart according to the location and extent of the thrombus but no video recording was made for later comparison. Similarly, interobserver agreement was also assessed for the phlebogram studies in the same patient sample. Two independent observers examined the X-ray films

and recorded their findings according to a pre-defined system. Agreement was analysed using Cohen's kappa statistic. A kappa coefficient <0.2 represented poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 good and 0.81–1.00 very good agreement between two observers.

The follow-up study included these 48 consecutive patients, in a surveillance program lasting for a period of 3 months and using the US at different time intervals (days 0, 8 ± 1 , 13 ± 1 , and 90 ± 5). A radioisotope ventilation perfusion scan was performed on day 8 ± 1 as well as duplex ultrasonography and phlebography. Patients were asked to return to the centre in the case of any medical event. Only patients with proximal DVT were treated with anticoagulants and initiation of treatment was based on the results of either US examination or phlebography. Patients who had no DVT or who had an isolated calf DVT received prophylaxis with a low molecular weight heparin for 30–40 days as there is no consensus on the need for anticoagulation in asymptomatic patients with isolated calf vein thrombosis. The anticoagulant prophylactic regimens used in this cohort were as follows: Enoxaparin 40 mg injected subcutaneously (SC) once daily in 23 patients (48%), Nadroparin 38 U/kg SC once daily on the first three postoperative days then 57 U/kg SC once daily in 14 patients (29%), and Dalteparin 5000 U SC once daily in 11 patients (23%).

We considered only the results of US or phlebography from the observer(s) who performed and interpreted the test(s) in every patient for the entire study (71 patients) when assessing US accuracy. The results from the second observer(s) were not used except for assessment of interobserver agreement (48 patients).

Diagnostic tests

Venous ultrasonography

An extended lower limb venous US examination including the proximal and distal veins was performed according to a standardised protocol. An Ultramark 9 HDI (high definition imaging) US machine from Philips ATL (Advanced Technology Laboratories) was used. Appropriate probes were selected according to the depth of the vessels examined. We have previously validated this technique.⁷ Doppler US examination was undertaken in the common femoral vein to assess the venous signal as a measure of the patency of the iliac vein and B mode US to image the vessels. The whole venous network was scanned bilaterally: the inferior vena

cava and the iliac veins with the patient supine or in the lateral position when possible, the femoral veins and the popliteal vein with the patient in a semi-upright position, and finally the calf in the sitting position with the patient's feet on a chair. Calf veins were studied using various views: antero-medial, posterior and postero-lateral. Calf veins included the posterior tibial and the peroneal veins up to their confluence, the gastrocnemius (medial and lateral) veins and the soleus (muscular) veins. The anterior tibial veins were not investigated given that they are rarely affected by DVT. The veins were investigated along their entire length in transverse and longitudinal views. Great and short saphenous veins at their junctions with the deep venous system were also studied. The diagnostic criteria used to confirm or exclude DVT relied on the compression test and on the absence or the presence of endoluminal material. The US test was considered negative when the veins were fully compressible with no thrombus visualised. The test was positive when vein incompressibility was combined with the direct image of an endoluminal thrombus, and inadequate when incompressibility was very limited (less than 1 cm) without visualisation of a direct image of the thrombus.

Phlebography

Phlebography was performed by injecting 60–80 ml of non-ionic low osmolality contrast agent (Omnipaque^R) into a dorsal foot vein in both lower limbs. The patient lay supine with tourniquets placed around the lower part of the calf and the thigh, in order to direct the contrast to the deep venous system. The diagnostic criteria for DVT were the finding of a constant intraluminal-filling defect. The location of thrombosis was defined as proximal or distal as for US investigation. Phlebography was considered negative when at least four main venous segments within the calf, as well as all the proximal veins up to the external iliac veins, were opacified without any equivocal image. Phlebography was otherwise interpreted as inadequate.

Popliteal level

In order to distinguish proximal from distal vein thrombosis, the level of the popliteal vein which varies between series, was defined on US and phlebography as the vein segment above the confluence of the posterior tibial and the peroneal veins; this limit is easily recognised on US and is very close to the point where the anterior tibial vein reaches the popliteal vein. All vein segments including the main veins and the muscular veins below this confluence as well as the gastrocnemius veins were defined as distal veins.

Data analysis

Sensitivity and specificity of US as compared to phlebography were computed according to the results from the observer who performed the tests in the whole population sample.

For data analysis, the confidence interval analysis software (CIA software version 2.0.0, University of Southampton, UK) was used.¹⁵

Results

Diagnostic accuracy

For the diagnostic performance study, 74 patients were eligible but four patients were not included because of an inadequate phlebography in one patient and because of the presence of a preoperative DVT detected in three patients (one bilateral femoral iliac DVT, two distal DVTs). Data analysis was therefore undertaken in 70 patients (140 legs). There were 38 females (54%) and 32 males (46%) and mean age was 61 (SD 16) years. Results by patients and by legs are shown in [Table 1](#).

US detected all proximal DVTs (5/5) that were shown on phlebography and all except one calf (distal) DVT: 12/13 (92%) on the basis of analysis by patient, and 18/19 (95%) on an analysis by limbs. The sensitivity of US in isolated calf vein thrombosis was estimated at 92% (67–99) and 95% (75–99), respectively. The calf DVT missed on US was a very small (1 cm) soleus vein thrombus.

Conversely, six patients (nine limbs) had DVTs diagnosed by US that were not shown by phlebography. In three cases, DVTs were located in the proximal veins and were very small in length: once in the superficial femoral vein (less than 2 cm) and twice in the profunda femoral vein (more and less than 2 cm). In six other legs, the thrombus was located in the soleal veins segments and measured less than 2 cm in three legs, between 2 and 5 cm in two, and more than 5 cm in one.

If the phlebogram results were also analysed taking the US examination as the reference standard, the sensitivity and specificity of phlebography would have been respectively: 74% (54–88) and 98% (89–100) on the basis of analysis by patients, and 72% (55–84) and 99% (95–100) on the basis of analysis by limbs.

Interobserver agreement

The interobserver agreement for the US investigation

Table 1. Diagnostic accuracy of venous ultrasound

	Phlebography +	Phlebography -
<i>Patients (n = 70)</i>		
US +	17 (Prox. 5, Dist. 12)	6 (Prox. 3, Dist. 3)
US -	1 (Dist. 1)	46
Prevalence (0.95 CI):	0.26 (0.17-0.37)	
Accuracy (0.95 CI):	0.90 (0.80-0.96)	
Sensitivity (0.95 CI):	0.94 (0.73-1.00)	
Specificity (0.95 CI):	0.89 (0.76-0.96)	
PPV (0.95 CI):	0.74 (0.54-0.88)	
NPV (0.95 CI):	0.98 (0.89-1.00)	
<i>Legs (n = 140)</i>		
US +	23 (Prox. 5, Dist. 18)	9 (Prox. 3, Dist. 6)
US -	1 (Dist. 1)	107
Prevalence (0.95 CI):	0.17 (0.12-0.24)	
Accuracy (0.95 CI):	0.93 (0.87-0.96)	
Sensitivity (0.95 CI):	0.96 (0.80-1.00)	
Specificity (0.95 CI):	0.92 (0.86-0.96)	

US, ultrasound; Prox., proximal; Dist., distal; PPV, positive predictive value; NPV, negative predictive value.

(Table 2) was very good either for an analysis by patients (kappa = 0.84 (0.66-1.00)) or for analysis by limbs (kappa = 0.81 (0.64-0.97)). The two investigators did not agree for two proximal and three distal vein interpretations. Between reader agreement for phlebography was good for the patients analysis (kappa = 0.78 (0.55-1.00)) and for the limbs analysis (kappa = 0.73 (0.5-0.96)). There was disagreement in interpretation of phlebography for one proximal vein and four calf veins.

Table 2. Reproducibility of ultrasound and phlebography

<i>Reproducibility of ultrasound</i>		
	Observer 1 US +	Observer 1 US -
<i>Patients</i>		
Observer 2 US +	11	0
Observer 2 US -	3	34
Cohen's kappa (0.95 CI):	0.84 (0.66-1.00)	
<i>Legs</i>		
Observer 2 US +	13	0
Observer 2 US -	5	78
Cohen's kappa (0.95 CI):	0.81 (0.64-0.97)	
<i>Reproducibility of phlebography</i>		
	Observer 1 P +	Observer 1 P -
<i>Patients</i>		
Observer 2 P +	7	2
Observer 2 P -	1	37
Cohen's kappa (0.95 CI):	0.78 (0.55-1.00)	
<i>Legs</i>		
Observer 2 P +	8	2
Observer 2 P -	3	81
Cohen's kappa (0.95 CI):	0.73 (0.5-0.96)	

Interobserver agreement evaluated in the last 48 patients for Ultrasound (US). Interobserver interpretation of x-ray films assessed for the last 47 patients undergoing phlebography (P). In one patient, phlebography was inadequate.

Surveillance

The US follow-up study (Table 3) showed on day 8 a proximal DVT in seven patients with an asymptomatic PE in one, a distal DVT in eight and no DVT in 33. Therefore, 15/48 (31%) patients had a DVT detected by US on day 8. On day 13, four additional calf DVT and one additional proximal DVT were detected by ultrasound in patients initially free from DVT. One more proximal DVT developed in a patient presenting initially a calf DVT. Thus five additional DVTs were detected on day 13 as compared to day 8, accounting for a total of 20/48 patients (42%) with DVT. According to the results of phlebography and US, on days 8 and 13, most DVTs were located on the operated side; in eight patients, DVT was bilateral and was either isolated in the distal veins in four patients or isolated in the proximal veins in one patient, or both in the proximal and in the distal veins in three patients. On day 90, all except four patients had their US performed but there was no clinical event in these four patients. Two patients had a recurrent DVT on US on the same side with one proximal and the other one distal. During the 3 months follow-up period from day 8, of patients with a distal DVT receiving prophylaxis, one distal DVT became bilateral then extended into the popliteal on day 13 (13%), three remained distally located and four recanalised. In the DVT free patients group, there were one proximal and four distal DVTs on follow-up (15%), despite adequate prophylaxis. In this subgroup, DVT was bilateral in three patients.

Discussion

The diagnostic accuracy of US was compared to phlebography using a rigorous methodology: a prospective study, consecutive patients, pre-defined diagnostic criteria for the study and the reference methods, investigation and blind interpretation by independent operators. The results show a diagnostic accuracy for US higher than that published in other series. The limited number of patients results in large CIs but the method seems to be very accurate for the detection of asymptomatic DVT, whether proximal or distal. The results are quite different from those found in the meta-analysis of Wells.¹¹ Wells found a sensitivity of only 62% for the detection of asymptomatic proximal DVT in the qualified level 1 studies. However, the series in this meta-analysis were heterogeneous. The study technique varied from one series to another using B mode, duplex or colour Doppler. Some series used 2-point investigation only, few included calf

Table 3. Incidence of deep vein thrombosis (DVT) on follow-up

	Day 8 ± 1	Day 13 ± 1	Day 90 ± 5
No DVT	33	28	28
DVT distal	8	11	11
DVT proximal	7	9	9
Total DVT	15/48 (31%)	20/48 (42%)	20/48 (42%)

examination, different diagnostic criteria were applied. The largest number of patients is in the series of Davidson¹⁶ investigated using colour Doppler. This method was shown to be insensitive by Lensing's study.¹⁷ Colour Doppler is even more limiting distally where low flow velocities need to be augmented by distal muscular compression. Regardless of the examination method, the sensitivity of US for detecting isolated calf vein thrombosis is low to moderate.^{18–22} In the systematic review of Kearon¹⁰ which included series up to 1997, the sensitivity of US for detecting proximal and distal vein thrombosis was 62% (53–71) and 53% (32–74), respectively. In different series^{21, 23–27} in orthopaedic surgery not included in this systematic review, extended lower limb venous US shows a sensitivity varying from 74 to 86%. Recent results in the literature^{2,13,14,28} are consistent with those obtained in our study with a distinctly higher sensitivity for US compared to phlebography for both proximal and distal DVT.^{2,13,14}

We consider that reliable US examination for DVT depends on: high quality equipment and adequate US probes, systematic examination of all proximal and distal veins in transverse and longitudinal views. Diagnostic criteria should be based exclusively on combination of both vein incompressibility and direct images of thrombus and not on flow characteristics. Contrarily to phlebography, US imaging provides views of the extra-vascular structures and the muscle veins, and shows directly the occlusive thrombus,

ensuring that veins are correctly identified and completely assessed and thrombosis more specifically identified. The failure to fill vein segments on phlebography is not specifically associated with DVT and can be related to a compression phenomenon such as a haematoma or to technical problems of opacification. Thus, DVTs are more easily visualised with US. We acknowledge that very small thrombi may only be shown on phlebography; however, this situation is exceptional in our series. In agreement with other series,^{7,13} we have found that the specificity of US, and consequently its positive predictive value is related to the lack of sensitivity of phlebography. In this series, three proximal and three distal DVTs were shown on US but not on phlebography. Considerable precautions were taken in order to avoid false positive results with US: diagnostic criteria for DVT included the requirement to obtain an image of the thrombus as well as to demonstrate incompressibility of the vein with the patient being relaxed. In order to prevent extravascular structures being mistaken for the image of a thrombus, complete scanning of the vein was performed until the upper or the lower limit of the thrombus was visualised.

In common with other authors^{14,29} we found that extended US is reliable when experienced operators examined the same patients independently. The diagnosis was based on the operators' interpretation since we did not use video recordings for subsequent analysis. In comparison we used independent interpretation of X-rays films to assess the outcome of phlebography.

This non-invasive method is also useful for surveillance in high risk patients as it can be performed and repeated in the pre- and postoperative period. In our study, preoperative screening enabled detection of an asymptomatic DVT in three patients and in one of them it was proximal and bilateral.

In general, the postoperative incidence of phlebography detected DVT under adequate prophylaxis is about 15–20% after total hip replacement (THR). A higher incidence has been reported in large series where either phlebography³⁰ or US examination³¹ was used and these are similar to the DVT rates we found in the data presented above. Repeated US showed that the highest rate of detected DVT was found in the first 2 weeks. The outcome is favourable as recanalisation usually occurs and a thrombosis seldom remains or recurs. A proximal DVT isolated or extended from the distal part of the leg, occurs rarely in patients under prophylaxis. The limited number of our surveillance study patients in the two groups (calf DVT group and DVT free group on initial screening) is not of help in deciding on the need for an anticoagulant therapy. Our

study was not empowered to address this question. In two series, a systematic US screening for asymptomatic DVT, in patients under adequate prophylaxis, addresses the question of its utility^{32,33} and cost.³⁴ Indeed, the clinical significance of asymptomatic DVT remains controversial because of the differences in the rate of phlebography detected DVT (15–20%) and the thromboembolic events (3%).^{35–37} In a recent series the value of treating asymptomatic patients with proximal DVT after total hip arthroplasty has been challenged.³⁸

In clinical practice, screening patients systematically for asymptomatic DVT seems not to be recommended. However, US examination could be undertaken for patients at very high risk of venous thromboembolism. In clinical trials using surrogate endpoints, systematic US could be performed pre- and postoperatively. In patients in whom no DVT is detected, clinical and US surveillance could be used. For complete documentation of a DVT phlebography might have to be employed should video recording be unavailable.

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