

Bilateral lower limb examinations for deep vein thrombosis: a  
single-centre feasibility study comparing request and report  
parameters for bilateral and unilateral referrals

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## Abstract

### Introduction

Deep vein thrombosis (DVT) is a common pathology with significant morbidity and mortality, often occurring in the lower limb. Ultrasound is the modality of choice for diagnosis of DVT, but all guidance in the United Kingdom assumes a single leg referral. Few studies have addressed the question of bilateral referrals and bilateral DVTs, and it is not known how these should be included in ultrasound protocols.

### Methods

A single-centre feasibility study collected data on all single and bilateral leg examinations performed by sonographers, over a six-month period at a small general hospital. Each examination included the referral and report findings. These were compared using basic statistical methods to compare DVT yield by laterality, referrer, DVT site, and patient factors.

## Results

Six hundred and thirty examinations were included, eighteen of which were bilateral examinations. Although the bilateral leg cohort was small, there were significant differences in DVT yield between the groups, with single leg referrals more than eight times more likely to demonstrate a DVT at ultrasound.

## Conclusion

Bilateral DVT examinations are a poor use of limited scan resources. Further data collection will be needed to validate initial results.

## Implications for practice

In a context of limited ultrasound resource, the low DVT yield of bilateral examinations has implications for service design.

## Keywords

Ultrasound

DVT

Bilateral

Sonography

Yield

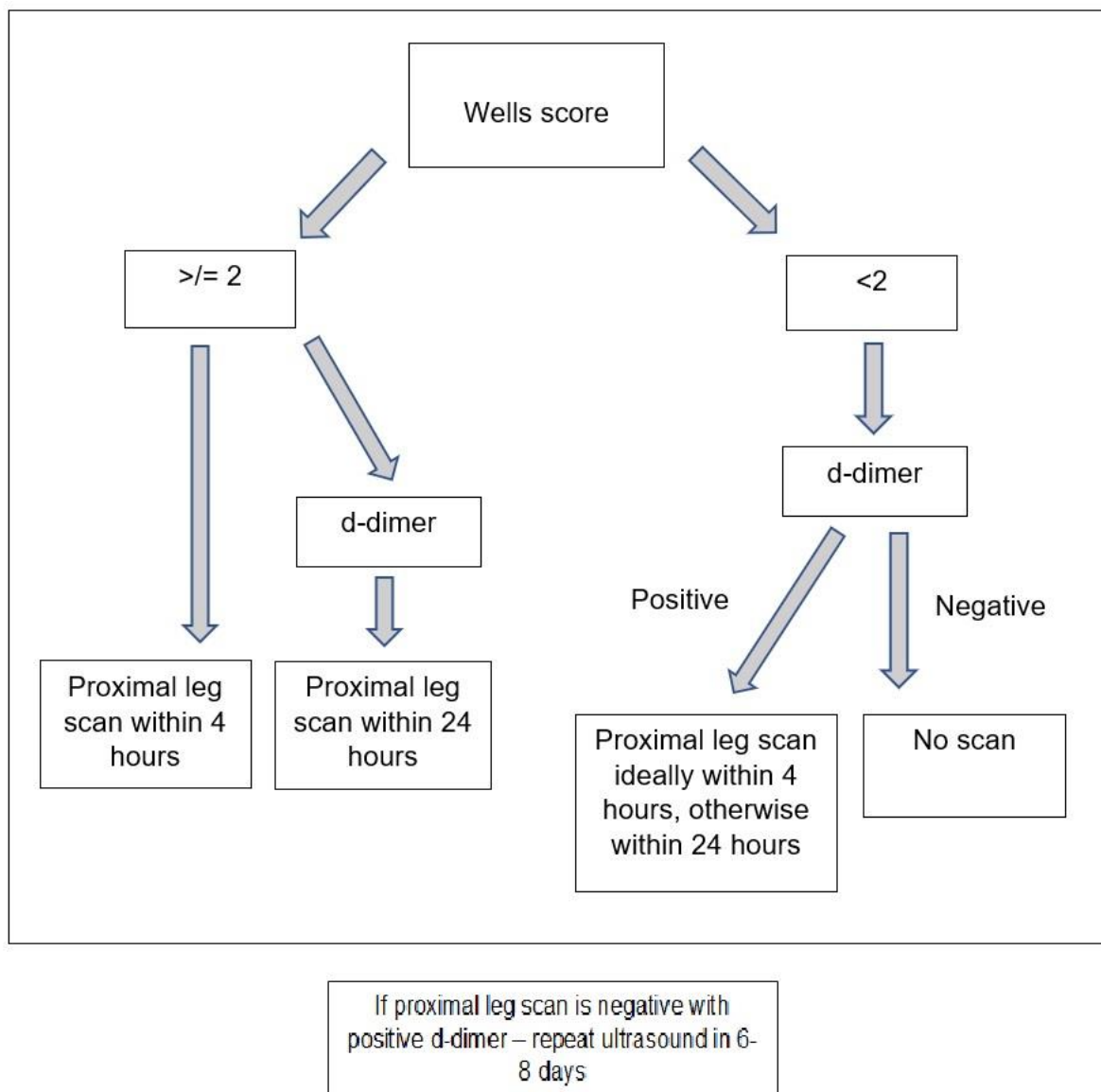


## Introduction

Doppler ultrasound is the modality of choice for detection of deep vein thrombosis (DVT)<sup>1,2,3</sup>. Ultrasound is a non-invasive and well-accepted method for diagnosing DVT of the lower limb, with sensitivity of 79% and specificity of 88% in a recent meta-analysis by Kraaijpoel et al.<sup>4</sup> Yields of positive DVTs across studies vary widely and significant variations in population, referral characteristics, and scan technique between studies make transferability of results difficult. For example, a recent meta-analysis<sup>5</sup> of non-UK studies gave positive DVT yields ranging from 9.7% to 71.6%, an enormous range. Kraaijpoel et al.<sup>4</sup> give a median whole leg compression ultrasound DVT positive rate of 25% across studies, but without benchmarking against venography or rigorous follow up it is again difficult to know if variation is due to scanning accuracy or referral characteristics. Johnson et al produce a whole leg compression ultrasound DVT yield of 23.3%<sup>6</sup>. False negative rates of whole-leg compression ultrasound are quoted as around one percent<sup>4,6</sup>. Further UK-based research is needed to establish DVT yields in the sonographer-led environment.

In the United Kingdom, the National Institute for Health and Care Excellence (NICE) publishes detailed clinical pathways for DVT<sup>3</sup>, with referral partly based on Wells<sup>7</sup> and d-dimer<sup>8</sup> pre-test probability scoring. Both NICE and the Wells score imply referral for a single affected lower limb; the scenario of suspected DVT in both legs is not included and no reason is given for this. The NICE pathway also excludes pregnant patients and children, and these groups have no published guidelines for DVT care, potentially due to lack of evidence. See Figure 1.

Figure 1: Summary of NICE pathway from request to scan, using Wells score and d-dimer (summarised from NICE, 2020<sup>3</sup>)



NICE<sup>3</sup> also refers only to proximal leg vein ultrasound, which necessarily omits more common calf DVTs<sup>9</sup>. A 2013 survey nevertheless showed two thirds of centres surveyed in England scanned the whole leg<sup>10</sup>, and the Society for Vascular

Technology (SVT) leaves the decision to local services<sup>11</sup>. Scanning below the knee is more technically challenging, more time-consuming, and more likely to yield false negatives<sup>4</sup> (Johnson et al.<sup>6</sup> give a false negative rate of 16% for whole leg ultrasound and 1% for proximal leg ultrasound). Detection of calf DVT remains controversial in the literature due to the uncertainty over whether such distal thrombus is likely to cause a pulmonary embolism, and the risks of overtreatment with anticoagulants<sup>12,13</sup>. Whole-leg scanning can however reduce need for an automatic repeat scan as per the NICE pathway (Figure 1).

At a small general hospital with a rural setting, leg DVT scan requests are drawn from primary care over a large geographical area, as well as from secondary care such as the emergency department, wards, and oncology. The DVT service is sonographer-led, with a smaller number of scans performed by radiologists. Bilateral leg requests have been treated on a case-by-case basis: they have historically been either reduced to a single most affected leg, scanned bilaterally to the knee only, put on a radiologist list, or sent back to the referrer for more information. In the absence of UK guidance this approach is based on the perception of local sonographers that bilateral requests are generally unjustified and do not yield DVTs. It is unknown if any DVTs are being missed in the process.

In common with all diagnostics, ultrasound has experienced strong demand growth in the years leading up to the COVID-19 pandemic, with lengthening waiting lists<sup>14</sup>. Pandemic response measures have exacerbated this pre-existing state, and COVID-19 has itself increased the number of DVT referrals<sup>15,16,17</sup>. Additionally, sonographers

have long been a shortage profession<sup>18</sup>, so resources are limited. Bilateral leg examinations take up two scan slots, and since DVT requests are always urgent (Figure 1) this impacts the entire service: delayed DVT scan may prolong unnecessary anticoagulation of the patient, but unnecessary DVT scans may delay care of other patients. If a consistent approach to bilateral referrals can be developed that also reduces unnecessary scans then this would have benefits to the wider ultrasound service<sup>10,19</sup>.

Unfortunately, there is a lack of evidence in the literature from which to make recommendations on an approach to bilateral referrals. Bilateral DVT is not a frequent topic of research in deep vein thrombosis; many of the references found are case reports<sup>20,21</sup> or case series<sup>22</sup>, suggesting rarity. Two studies were found that explicitly address bilateral DVT findings: Le Gal et al.<sup>22</sup> and Pennell, Mantese and Westfall<sup>23</sup>. Both studies look at bilateral DVTs but only Le Gal et al. also address bilateral referrals. Pennell, Mantese and Westfall give a bilateral positive DVT yield of 0.5%. Le Gal et al give a yield of 0.8%, none of which were from bilateral referrals. Bilateral referrals were positive for DVT at half the rate of single leg referrals (10.6% versus 21.8%). They concluded bilateral referrals are unjustified.



Aim: To compare the report and request parameters of bilateral examinations with those for single leg examinations over a six-month period.

Objectives:

- Collect six months of lower-limb DVT data at a single site
  - From the referral: referrer, patient demographics, leg(s) referred, symptoms and risk factors
  - From the report: presence or absence of DVT, site of DVT, and any other findings
- Compare these parameters for single leg and bilateral leg referrals using standard statistical methods
- Describe the direction and magnitude of any statistical differences

## Methods

Data was collected prospectively over a six month period. Within the included period all DVT ultrasound events performed by sonographers for left, right or both legs were identified. If both legs were referred, they were scanned groin to ankle as per single legs. Pregnant patients (and bilateral referrals) fall outside the NICE guidance but are deliberately included as they form part of the overall cohort using the service.

DVT scans were performed using a default lower limb venous pre-set with a 9MHz linear probe and a mix of spectral trace (groin), compression, and augmentation views with colour doppler. The whole leg was scanned, including the common femoral vein, femoral vein, popliteal vein, the posterior tibial and peroneal veins of the calf, and any thrombus within five centimetres of junctions with these veins. Any region of pain indicated by the patient was also scanned.

### Inclusion criteria:

- All DVT events with codes ULLVR and/or ULLVL (ultrasound lower limb veins right, and left) on the hospital radiology information system (RIS) searched over the defined six-month period.

### Exclusions from sample:

- Studies performed by radiologists, as they mostly scan groin to knee only.

- Non-DVT indications as per request form, for example deep venous insufficiency or query Baker's cyst.
- Repeat scans within one month for the same individual were merged into one event as the same thrombotic event, and the highest results Wells and d-dimer recorded. Scans for the same individual more than one month apart were recorded as separate events.
- Upper limb DVT events.
- Patients under 16 years old at time of event.

Ethical approval was not required for this project. Written permission was given by the hospital research team and the radiology department to process pseudonymised data. Since this project formed the basis of a Masters thesis, permission was also given by the university.

A data collection sheet (Appendix 1) was developed to systematically include all request parameters that could be anonymised: age and sex of patient, leg(s) examined, Wells score (Appendix 2), d-dimer, symptoms, risk factors, and referrer grade. For bilateral requests the worst affected leg was recorded if indicated on the referral. Data collected from the report was presence and location of DVT, and any non-DVT findings. Location of DVT was classified as side (left or right), High (common femoral vein and up), Proximal (femoral vein to popliteal vein), and Distal (calf). Only the most proximal extent of thrombus was recorded for each event.

Collected data were tabulated and descriptive statistics used to define characteristics of the cohort, request parameters, and DVT yields. SPSS Statistics 28 software was used for statistical tests. Chi-square testing to test significance of difference between groups for categorical non-parametric data and as a basis for relative risk measures, and an independent t-test was used to assess difference between means. Significance was defined as p values less than or equal to 0.05, in accordance with convention<sup>24</sup>.

## Results

Over the six-month collection period 714 lower limb ultrasounds were performed. Of these 630 examinations were included as meeting the criteria. Eleven episodes were merged with other events as they were duplicates for the same patient, and two were excluded for non-DVT indications. This left 701 unique DVT events, of which a further 71 examinations were excluded as they were performed by radiologists. Of exams included, 152 or 24.1% were positive for deep vein thrombosis. Results are summarised in Table 1.

Table 1: Summary of results

Referral characteristics	Number (% of total)	Positive DVT n (% of referrals)	DVT location n (% of all DVTs)			Non-DVT finding (%)
			High	Proximal	Distal	
All referrals	630 (100.0)	152 (24.1)	38 (25.0)	67 (44.1)	46 (30.3)	170 (27.0)
Female	351 (55.7)	71 (20.2)	17 (23.9)	28 (39.4)	25 (35.2)	83 (23.6)
Male	279 (44.3)	81 (29.0)	21 (25.9)	39 (48.1)	21 (25.9)	87 (31.2)
Left leg	343 (54.4)	97 (28.3)	25 (25.8)	42 (43.3)	30 (30.9)	92 (26.8)
Right leg	269 (42.7)	54 (20.1)	13 (24.1)	25 (46.3)	16 (29.6)	73 (27.1)
Both legs	18 (2.9)	1 (5.6)	0 (0.0)	0 (0.0)	1 (Left) (100.0)	5 (27.8)

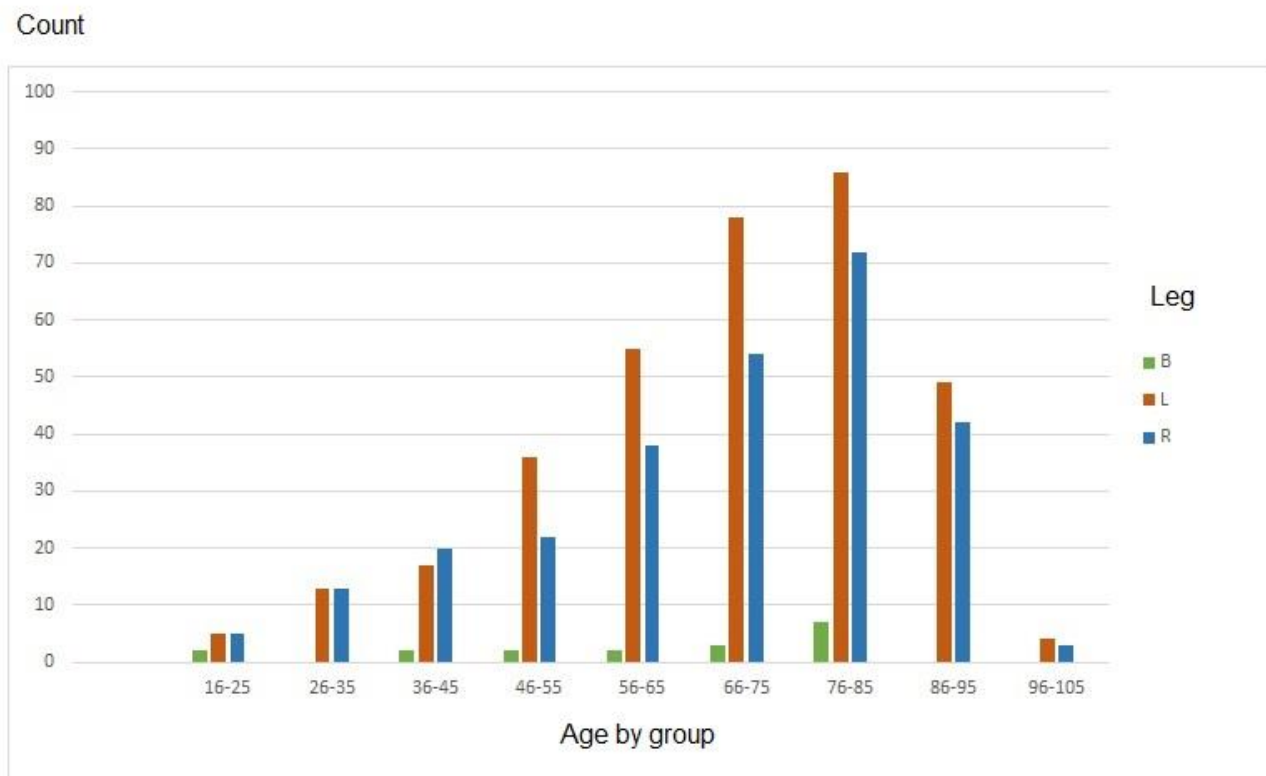
Non-DVT findings relevant to the symptoms were detected in 27% of all examinations, with a small overlap with DVT findings (13 cases or 2.1% of the total cases had both DVT and non-DVT findings). The most common other findings pertinent to patient presentation were:

- suspected cellulitis (oedema with groin lymphadenopathy, 47 cases, 7.5%)
- superficial thrombophlebitis (46 cases, 7.3%)

- Baker's cysts (45 cases, 7.1%).

The cohort had a mean age of 68.2 years, mode 76 years (26 candidates). The youngest patient was 17, and the oldest 100 years. Figure 2 displays age distribution for left, right and both legs.

Figure 2: Population count by age bracket (years) and leg



Presenting clinical information was usually swelling (of one or both legs),

Risk factors were given in over half of all referrals (56.7%) and in total thirty different risk factors were mentioned. The six most common risk factors are given in Table 2.

Table 2: Numbers and percentages of events with the most common risk factors

Risk factors	Bilateral n (% of 18)	Unilateral n (% of 612)
Previous VTE	4 (22.2)	72 (11.8)
Recent operation	1 (5.6)	61 (10.0)
Immobility	3 (16.7)	55 (9.0)
Cancer	2 (11.1)	55 (9.0)
Trauma to affected leg	1 (5.6)	25 (4.1)
Pregnancy	2 (11.1)	22 (3.6)

Over the entire cohort three quarters (75.9%) of referrals contained a Wells score, while half (54.6%) had a d-dimer. Ten percent (10.3%) of all requests contained



neither. Of bilateral requests, all but one had a Wells score of 2 or more, while the last had a Wells score of 0 but a high d-dimer (>20,000). Unsurprisingly the most frequent symptom was swelling (78.3% of all requests).

Five different referrer grades were identified, as shown with DVT outcomes in Table 3.

Table 3: Referrals and DVT yields for different referrer grades

Referrer Grade	Total referrals n (%)	DVT n (%)	Unilateral n (% of 612)	Bilateral n (%) of 18)
Junior Doctor	230 (36.5)	46 (20.0)	216 (35.3)	14 (77.8)
Nurse	51 (8.1)	18 (35.3)	50 (8.2)	1 (5.6)
Assistant Care Practitioner	17 (2.7)	4 (23.5)	17 (2.8)	0 (0.0)
General Practitioner	298 (47.3)	75 (25.2)	296 (48.4)	2 (11.1)
Consultant	34 (5.4)	9 (26.5)	33 (5.4)	1 (5.6)

Table 4: Raw data for bilateral examinations included

Case	Age	Sex	Presenting symptoms	Wells	d-dimer	Referrer	Risk factors	DVT	Other
1	46	F	Bilateral swelling, pain	N	1028	JD	Travel	N	N
2	25	F	Pain	$\geq 2$	N	JD	Pregnancy	N	N
3	22	F	Pain	$\geq 2$	995	JD	Pregnancy	N	N
4	38	F	Bilateral swelling	N	N	JD	Cancer, covid	N	N
5	64	M	Bilateral swelling	N	RAISED	JD	Cancer	N	N
6	82	F	Bilateral swelling	2	532	GP	Covid	N	N
7	59	F	Bilateral swelling	N	4232	JD	None	N	Ruptured Baker's Cyst
8	81	F	Bilateral pain	$\geq 2$	5642	JD	Immobility	N	N
9	42	M	Bilateral swelling, pain	$\geq 2$	868	N	Past DVT	N	R deep venous insufficiency, L old thrombus
10	78	F	Bilateral swelling	N	1137	JD	Past DVT	N	N
11	84	M	Bilateral pain	N	N	JD	Recent operation, past DVT, covid	N	N
12	80	F	Ulcer left leg	$< 1$	21000	JD	Ulcer	N	N
13	53	F	None given	N	N	JD	None	N	Cellulitis
14	78	F	Bilateral swelling	2	1700	GP	Trauma left side	N	L superficial thrombophlebitis, both cellulitis
15	75	F	Bilateral swelling	$\geq 2$	N	JD	Past venous thromboembolism	N	Cellulitis

Case	Age	Sex	Presenting symptoms	Wells	d-dimer	Referrer	Risk factors	DVT	Other
16	72	F	Ulcers, varicose veins	$\geq 2$	N	C	Immobility	N	N
17	68	F	Bilateral swelling	N	N	JD	PMH DVT	N	N
18	85	F	Bilateral swelling and pain	$\geq 2$	N	JD	Immobility	Y, distal left	N

Key: Wells  $\geq 2$  is how Wells scores are given on electronic requesting system, if there is also a Wells score in the clinical information this is the preferred value; referrers JD=Junior Doctor, N=Nurse, C=Consultant, GP=General Practitioner;

## Discussion

This project arose from local sonographers' perception of increase in DVT workload and uncertainty over how to treat bilateral DVT requests. A literature search demonstrated lack of evidence and central UK guidance on bilateral referrals. Bilateral requests are a small proportion of DVT referrals, but each takes twice as much ultrasound time and resource as a single leg; if bilateral examinations do not result in DVTs then this has implications for service design. For this pilot study a small sample of bilateral lower limb DVT events was collected over a six-month period. Six hundred and twelve examinations were for single legs, and 18 examinations were bilateral.

### Deep vein thrombosis outcomes

The overall percentage of DVTs detected (the yield) is similar to levels of DVT found for whole leg ultrasound in the literature, allowing for undefined variations in cohort and technique: overall yield was 24%, compared with 25% for Kraaijpoel et al.<sup>4</sup>, and 23% for Johnson et al.<sup>6</sup>, both large volume systematic reviews. This suggests the ultrasound service is detecting DVTs at the expected rate.

The small group of bilateral leg events made up 2.9% of all studies and produced a single distal DVT in one of the legs. Since 18 bilateral scans were performed this gives 36 legs scanned for one DVT, a yield of 2.8% and significantly less than that for unilateral scans ( $p=0.03$ ). Single referred legs were therefore 8.8 times more likely to

have a DVT. The bilateral yield of 2.8% is lower than the 10.8% reported by Le Gal et al<sup>22</sup>, but the sample size is small, and the literature scarce. Larger samples could validate and refine these results.

Left legs were more commonly requested (54.4%) and more commonly positive for DVT (Left: 28.3% vs Right: 20.1% positive), with a relative risk of 1.4 times a right leg DVT ( $p=0.019$ ). There was no significant difference in the distribution of DVTs by site (High, Proximal, Distal) between left and right legs ( $p=0.667$ ), and data is insufficient to comment on distribution for bilateral scans.

Non-DVT findings that may explain the presenting symptoms were found in over a quarter of all examinations. There was no significant difference in proportion of non-DVT findings among left, right, or both leg examinations ( $p=0.899$ ). With DVT and non-DVT findings combined the ultrasound scan found a reason for the given symptoms in single legs about half the time, and 30% of the time in bilateral scans.

### Notable cases

A few cases have been singled out as notable findings. The sole bilateral referral with a DVT was 85 years old, female, immobile, referred by a Junior Doctor for both legs with swelling and pain worse in the left leg, and a Wells score greater than 2. The detected DVT was in the distal left leg, therefore if this event had been reduced to the single most affected leg the thrombus would have been found, but if both legs had been scanned to the knee only, it would have remained undetected.

Two cases of genuine bilateral DVT were detected. The first was a 65-year-old female referred for left leg scan, no Wells or d-dimer given, symptoms of swelling and pain, with thrombus found in the external iliac vein on the left and the common femoral vein on the right. The second was a 76-year-old male referred by his GP for right leg scan with Wells score of 6, with thrombus in the common femoral veins bilaterally.

Both cases of bilateral DVT had been referred for a single leg scan. Bilateral DVTs are therefore 1.3% of the DVTs detected. This is again in line with the literature with incidence of around 1%<sup>22,23</sup> however these were picked up incidentally rather than as routine practice. In both cases there was high thrombus on the referred leg, and the contralateral groin was then also examined, as indicated by the sonographer on the report. This is not a part of any recommendation by NICE or the SVT, and was not performed for the entire sample, so the two true bilateral DVTs must stand as an interesting finding from which no conclusions can be drawn.

#### Population: age, sex, risk factors

Mean ages for male (69.0) and female (67.5) groups were not significantly different (independent samples t-test,  $p=0.246$ ). Bilateral referrals had a mean age of 62.9 years, which was not significantly different to the mean for single legs ( $p=0.195$ ). Twenty-three female patients were pregnant or within ten days postpartum and had pregnancy given as a risk factor; the mean age of this group was 29.5 years.

Overall, females were more likely to be referred (55.7% of total) but significantly less likely to have a positive finding for DVT, risk ratio 0.697 ( $p=0.01$ ). For bilateral examinations there were 15 females (83.3%) and 3 males, so females were significantly ( $>4$  times) more likely than males to be referred for bilateral examinations ( $p=0.017$ ). The reasons for this are still uncertain, but a larger data set could allow more detail to be drawn out linking sex and risk factors.

Thirty different risk factors appeared on requests and of the six most prevalent risk factors, none show significant differences in frequency between unilateral and bilateral events. Pregnancy was the sixth most commonly mentioned risk factor with the largest apparent difference in frequency between unilateral and bilateral groups, yet this difference was not significant ( $p=0.278$ ). There is therefore no evidence in this sample that pregnant patients are more likely to be referred for both legs. However, pregnancy as a risk factor resulted in a positive DVT rate half that of the overall cohort (12.5%), broadly in line with the literature<sup>25</sup> (7-8%) and about half the overall result (24.1%). Pregnant patients are themselves an example of the limitations of guidance, and DVT yields may always be lower than in the general population, since pre-test probability methods are less reliable due to difficulties interpreting d-dimer in this group<sup>26</sup>.

Most requests gave symptoms, usually swelling and pain. There was no significant difference between the unilateral and bilateral groups for either of these symptoms ( $p=0.151$ ).

#### Referrers and requests

Among the different referrer groups there was no difference in yield of DVT ( $p=0.066$ ). However, Junior Doctors were significantly more likely to request both legs than the other groups ( $p=0.01$ ). The reason for this is unknown, although it may reflect the medical hierarchy, workload, or experience.

Presence of a Wells score on requests made no difference to the DVT yield ( $p=0.424$ ).

All of the bilateral requests and most (90%) of the unilateral requests were justified due to high pre-test probability. All but one of the bilateral requests had a Wells score of 2 or greater, and the remaining request gave a d-dimer over 20,000. If these had been single leg scans they would all have been justified, but the Wells score is not adapted to the two-leg scenario so pre-test probability for both legs is more difficult to determine. Eleven of the 18 bilateral requests indicated a worst leg. A larger number of examinations would be needed to determine the utility of indicating the worst leg, or if these bilateral requests could sometimes be reduced to single leg scans.

#### Limitations/sample size

Apart from the small sample size of bilateral requests other limitations of the present data include the six-month window for collection falling over UK summer, although it is uncertain if seasonality would affect results<sup>26,27</sup>. Any such effect could be negated by collecting further events over complete calendar years.

Twenty-nine bilateral examinations occurred over the six months of this study, but eleven were excluded due to being performed by radiologists. Agreement had been



sought prior to data collection for sonographers to scan bilateral requests as whole legs, but worklists, waiting lists, and institutional inertia could have affected these being diverted to radiologist lists. From a population of 600 a sample size of 25 bilateral exams, more than have been collected here, would be necessary to give sufficient statistical power<sup>24</sup>. However, there is a readily accessible historical data set of bilateral examinations, which although limited to groin-to-knee scans could be used to build a larger sample for further statistical comparison.

### Overview

In the current limited data set a DVT would be expected in every fourth single leg scanned, but more than thirty legs would be scanned for one DVT in the bilateral group. Prior to data collection there was no consistency in treatment of bilateral requests: notably the sole case of a bilateral presentation with DVT detected here would have been detected if the request had been reduced to the most affected leg, but may have been missed if both legs were scanned groin-to-knee only. More whole leg bilateral event data would need to be examined to establish if distribution of high, proximal and distal DVTs is similar in both groups, and further evidence is required to develop a consistent approach to these bilateral referrals for DVT scan.

Findings from the initial six months of whole leg data demonstrate a significant difference in DVT yields between single and bilateral referrals, with single legs eight times more likely to contain a DVT. This is an important finding that will be re-examined with a larger data set.

## Conclusion

Although they loom large in the imaginations of sonographers, bilateral DVT examinations remain a small part of the overall DVT service. The sample size obtained over six months was consequently small, but this has been used to establish feasibility of further data collection. Even with the present small sample, bilateral DVT studies have been found to be significantly less likely to yield a DVT. More data is required to fully draw out characteristics of the population that may increase likelihood of bilateral referral, as well as referrer factors. A decision has been made to limit further results to groin-to-knee scans, which would allow for retrospective data collection from an existing data set. Future work will attempt to validate the current findings.

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# Appendix 1 – Data Collection Sheet

Study participant number			
Age			
Sex	M – F – Other		
Requested limb(s) If both, also circle worst side if identified	Left – Right – Both		
Referrer grade			
Wells Score			
d-dimer			
Symptoms			
Risk factors (as recorded on request)			
DVT	+ve	-ve	
Left leg result/location (Most proximal)	High – Proximal – Distal		
Right leg result/location (Most proximal)	High – Proximal – Distal		
Other findings			

Appendix 2 – Wells Score (from Wells et al, 2003)

<b>Clinical feature</b>	<b>Points</b>
Active cancer (treatment ongoing, within 6 months, or palliative)	1
Paralysis, paresis or recent plaster immobilisation of the lower extremities	1
Recently bedridden for 3 days or more, or major surgery within 12 weeks requiring general or regional anaesthesia	1
Localised tenderness along the distribution of the deep venous system	1
Entire leg swollen	1
Calf swelling at least 3cm larger than asymptomatic side	1
Pitting oedema confined to the symptomatic leg	1
Collateral superficial veins (non-varicose)	1
Previously documented DVT	1
An alternative diagnosis is at least as likely as DVT	-2
<b>Clinical probability simplified score</b>	<b>Points</b>
DVT likely	2 points or more
DVT unlikely	1 point or less