

An “All-Comers” Venous Duplex Scan Policy for Patients with Lower Limb Varicose Veins Attending a One-stop Vascular Clinic: Is It Justified?

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Objective. To determine whether clinical assessment could predict the correct management of patients with varicose veins (VVs), select those who would need duplex scanning, and identify deep venous reflux (DVR).

Methods. Prospective study of 342 consecutive limbs with VVs. These were divided into 3 groups: 170 (50%) limbs with primary VVs without skin changes (group I), 37 (11%) with recurrent VVs without skin changes (group II), and 135 (39%) with primary or recurrent VVs with skin changes (group III). Clinicians were asked to document whether they would normally request a duplex scan because of clinical uncertainty. Agreement between decision-making based on clinical and on duplex findings was documented.

Results. Agreement between clinical and duplex findings for groups I, II, and III was 82%, 59%, and 67%, respectively. In 112 cases (66%) in group I, clinicians felt certain about the diagnosis and yet duplex scanning revealed they were wrong in 12% of cases. In group II, clinicians would request a duplex scan because of clinical uncertainty in 30 (81%) cases. In group III, the sensitivity, specificity, positive and negative predictive value of clinical assessment in detecting DVR was 32%, 77%, 24%, and 83%, respectively.

Conclusions. Clinical evaluation of patients with VVs is unreliable in planning their management. Clinicians can neither predict those who will require duplex scanning nor correctly identify DVR. Even experienced surgeons often “get it wrong” when assessing primary uncomplicated veins despite being certain about the diagnosis. Therefore, an “all-comers” duplex imaging policy should be implemented if optimal management is to be achieved.

Introduction

Chronic venous disease is a significant cause of morbidity. Varicose veins, in particular, represent one of the commonest vascular problems seen in daily practice.^{1–5} In the Edinburgh vein study, approximately 33% of the adult male and 26% of the adult female population were affected from this common clinical condition.¹ Recurrence rates of up to 40% have been reported following surgery for primary, uncomplicated cases and approximately 20% of patients requiring surgery have had a previous operation.^{6–8} This usually occurs as a result of inaccurate initial assessment, inadequate surgical treatment, neovascularization or disease progression.^{9,10} A thorough

preoperative evaluation leading to correct planning of surgical procedure seems to be a prerequisite for exact eradication of all sites of superficial venous disease. Physical examination and tests, such as the cough test and the Trendelenburg test have proven to be unreliable.^{11–13} Hand-held Doppler (HHD) is simple, easy to learn, and compared to duplex scanning, not time-consuming. Compared to duplex scanning, HHD assessment of the saphenofemoral junction (SFJ) has a sensitivity of more than 90%.^{14–17} However, although HHD does improve the number of correctly planned procedures compared with clinical examination alone, 9–14% of patients with primary varicose veins will still receive inadequate or inappropriate surgery when the diagnosis is based on HHD findings alone.^{17–21} HHD is of limited accuracy in evaluating the saphenopopliteal junction (SPJ) and cases of recurrent varicose veins.^{17,22} Finally, patients with significant skin changes and/or ulceration, require detailed assessment of the deep venous system. Such patients are not easily evaluated with HHD and are usually excluded from studies examining the HHD value.²⁴

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Currently, colour-flow duplex scanning is considered the "gold standard" method for non-invasive anatomical and functional assessment of venous reflux.^{25,26} It is also particularly useful in the assessment of varicose vein recurrence and complex venous disease. However, duplex examination is often criticized for being expensive, time-consuming and requiring experienced technologists. As a result, it has been suggested that duplex scanning should be performed selectively in patients with suspected SPJ incompetence, recurrent varicosities, anatomical variations, and post-thrombotic changes.^{7,14,17,21} In contrast, others favor duplex scanning in all patients presenting with venous disease – even those with primary varicose veins.^{18,22–24} The aim of this prospective study was to determine whether clinical assessment by a vascular surgeon could predict the correct management of consecutive patients attending a single-visit outpatient clinic with varicose veins, select those patients who would need duplex scanning, and identify deep venous insufficiency.

Methods

Between February 2002 and January 2005, a prospective study was undertaken of all new consecutive patients with varicose veins referred to a single-visit outpatient vascular clinic. A total of 271 patients and 342 limbs were enrolled in this study. There were 113 men and 158 women, with a median age of 51 years (range 13–88). The presence or absence of "skin changes", defined as haemosiderin deposition, eczema, lipodermatosclerosis, and healed or active ulcer, was recorded. Patients were divided into three groups. Group I consisted of 170 (50%) limbs with primary varicose veins without skin changes, group II included 37 (11%) with recurrent varicose veins without skin changes, and group III 135 (39%) limbs with either primary or recurrent varicose veins with skin changes. In the latter group, the varicose veins were primary in 104 limbs and recurrent in 31. Thirty-two limbs in group III had active ulceration. According to CEAP classification, there were 207 limbs classified as C2 and C3 (i.e. all limbs belonging in group I and II), whereas in group III, 86 limbs were class C4, 17 C5, and 32 C6.

The clinical and duplex examinations were performed at a single-visit outpatient clinic. All patients underwent a thorough clinical assessment (history and clinical examination) without the use of HHD by either a consultant vascular surgeon ($n = 253$ limbs, 74%) or a senior trainee ($n = 89$). Clinical examination included inspection, palpation, and the tap

test, i.e. with the patient in the upright position, the presence of a palpable transmitted impulse over the saphenous opening on percussion of a distal varix was indicative of tested saphenous vein incompetence. Traditional clinical examination based on the cough test and the Trendelenburg test was not performed since this has proven to be unreliable. Similarly, HHD was not routinely used in our clinical practice when assessing varicose vein patients. The structure of the clinic is such that one or two vascular technologists are always present. They have access to a Duplex scanner based permanently in a dedicated scanning room located next to the clinic space, facilitating a one-stop service. Therefore, as part of our routine, all patients were directly assessed by Duplex scanning following clinical examination without interim HHD assessment. Opinions about the appropriate diagnostic pathway and plan of subsequent treatment were recorded. The examiners were specifically asked to document what operation they would perform if duplex scanning were unavailable, based only on clinical findings. They were also asked 1) whether they would normally request a duplex scan in case of clinical uncertainty (in groups I and II only, as a duplex scan was considered essential for accurate diagnosis in group III), 2) whether they suspected deep venous reflux (DVR), and 3) whether this was a patient for whom they were considering surgery. They were then asked to commit themselves to either no surgical treatment or to one or more of the following surgical procedures: 1) SFJ junction ligation, great saphenous vein (GSV) stripping and avulsions; 2) SPJ ligation and avulsions; 3) stab avulsions only; 4) mid-thigh perforator ligation and avulsions; 5) redo SFJ surgery; and 6) redo SPJ surgery. No sclerotherapy, radiofrequency ablation or endovenous laser options were available during the study period.

Each patient was subsequently assessed with a colour duplex scan performed by an experienced vascular technologist using either an ATL Ultramark 9 (Advanced Technology Laboratories Ltd, Letchworth, UK) or a Diasonics Masters (Sonotrom, Bedford, UK) scanner. The superficial and deep venous systems were examined using 5-MHz and 10-MHz linear array probes respectively, with the limb dependent. The entire superficial venous network, i.e. SFJ, SPJ, GSV, small saphenous vein (SSV), and perforators of the femoral canal, and the deep venous system were examined. No routine assessment for calf perforator incompetence was performed during duplex scanning, however, any prominent incompetent calf perforator sites were marked in patients in whom no other obvious incompetence was found. Venous duplex findings were recorded on a standard diagram accompanied

by a written description. Venous reflux was defined as the presence of reversed blood flow for more than 0.5 sec on release of calf squeeze distal to the segment of vein under examination. The GSV and SSV were examined at their origins and distally at sites of perforating veins. The superficial femoral and below knee popliteal segments of the deep venous system were also examined. Segmental DVR was defined as deep venous incompetence in the presence of at least one competent deep vein valve either above or below the refluxing segment. The median time taken to perform a duplex scan was 10 min (range 4–20 min) and was approximately the same in all three groups.

After duplex scanning, the clinicians were asked again whether or not they would recommend surgery and to choose what operation they would perform, this time based on the reflux pattern. No surgery was considered when venous disease was proved to be minor or in patients with documented full-length DVR. Segmental DVR in the presence of superficial venous insufficiency did not preclude surgery, as many such patients have their DVR corrected after superficial venous surgery. A comparison of the decision-making based on clinical assessment and duplex scanning was then performed. Failure of clinical judgement usually referred to three outcomes: an unnecessary, an inadequate, or an inappropriate procedure. Unnecessary operations were considered those where no operation should have been performed or where a more extensive surgical procedure was performed dealing with both refluxing and non-refluxing sites of superficial veins. Such an example was performing SFJ ligation and GSV stripping in the absence of SFJ reflux, instead of stab avulsions only. Inadequate operations referred to those where failure to detect and deal with a second refluxing site was noticed. Such an example was performing only SFJ ligation and GSV stripping and missing SPJ reflux in a patient with both SFJ and SPJ reflux. Finally, inappropriate operations referred to those where a non-refluxing superficial venous system was eliminated instead of dealing with the truly refluxing superficial venous system. For example, operating on either the GSV or SSV when the operation should have been to deal with the other saphenous vein, just operating on tributaries and failing to operate on the saphenous vein, or perforators alone rather than saphenous veins or vice versa.

Statistical analysis was performed using the SPSS version 12.0 (SPSS, Chicago, IL, USA) and the StatsDirect (CamCode, Ashwell, Herts, UK, www.statsdirect.com) statistical software. Categorical data were compared using the chi-square test. A $p < 0.05$ was considered statistically significant.

Results

The examiners would normally have requested a duplex scan in groups I and II because of clinical uncertainty in 88 cases (43%) and they were considering surgery for 301 (88%) limbs across the entire 3 groups.

Treatment plans decided on the basis of clinical and duplex findings were compared in each group and the details are shown in Table 1. Agreement and mismatches between the findings in those limbs considered to “need” and those considered not to “need” a duplex scan are summarised in Table 2. No operative treatment was planned after duplex examination in 56 limbs and the reasons for such a decision are listed in Table 3. An overall agreement between clinical and duplex findings was encountered in 251 (73%) limbs. Consultant and trainees were equally likely to fail to correctly plan the treatment based on clinical assessment, i.e. 70/253 (28%) versus 21/89 (24%), respectively (chi-square test, $p = 0.4$).

In group I, the overall agreement between clinical and duplex findings was 82% (139/170). In 31 legs, duplex examination suggested a different surgical procedure than had been considered on clinical grounds. For SFJ operations only, the agreement was 89% (116/131), and 15 (11%) legs would have had an incorrect ($n = 6$), an unnecessary ($n = 4$), or an inadequate ($n = 5$) operation. The main source of the discrepancy was unsuspected SPJ reflux, a diagnosis which was missed in 9 limbs. In 11 out of these 15 limbs, no duplex scan would have normally been requested because of clinical certainty about the diagnosis. Furthermore, in 112 cases (66%) in group I the examiner seemed to be certain about the diagnosis and would not normally have requested a duplex scan; of these, the agreement with duplex was 88% (99/112). Of the 13 (12%) cases with discrepancy between clinical and duplex findings, SFJ surgery would have been offered in 11, when, in fact, based on duplex scanning, the correct decision would have been SPJ ligation in 2, stab avulsions in 4, combined SFJ and SPJ surgery in 3, and no operative treatment in 2. In the remaining 2 cases in which the clinician recommended no operation, the correct procedure would have been SFJ surgery in the first, and stab avulsions in the second. The sensitivity of clinical assessment in identifying correctly SFJ incompetence in group I patients was 94%, whereas the specificity, positive predictive value (PPV) and negative predictive value (NPV) were 69%, 92%, and 76%, respectively.

In Group II, the agreement between clinical and duplex findings was 59% (22/37). Clinicians felt uncertain about their clinical diagnosis and requested a duplex scan in the majority of cases (81%, 30/37).

Table 1. Treatment strategy decided on the basis of clinical and duplex findings in all three groups

Clinical Status	Operation based on clinical findings	Operation based on duplex findings										Total
		SFJ surgery	SPJ ligation	Stab avulsions	Mid-thigh perforator	Redo SFJ surgery	Redo SPJ surgery	No operation	SFJ + SPJ surgery	SPJ Ligation + Redo SFJ	Redo SFJ + Redo SPJ surgery	
Group I	SFJ surgery	116	4	4				2	5			131
	SPJ ligation		10					1				11
	Stab avulsions	1		5								6
	Mid-thigh perforator	5	1		2							8
	No operation	2		1				5				8
	SFJ + SPJ surgery	4	1						1			6
	Total	128	16	10	2			8	6			170
Group II	SFJ surgery	4		1								5
	SPJ ligation					1		1				2
	Stab avulsions	1	1	2	2	1	1					8
	Mid-thigh perforator				2	2	1					5
	Redo SFJ surgery			2	1	6						9
	Redo SPJ ligation						4					4
	No operation							3				3
	SPJ ligation + Redo SFJ									1		1
	Total	5	1	5	5	10	6	4		1		37
Group III	SFJ surgery	59	1		1			13	2			76
	SPJ ligation		1		1	2		1	1			6
	Stab avulsions		1	1								2
	Mid-thigh perforator				1	1		2				4
	Redo SFJ surgery			1	3	4		3			1	12
	Redo SPJ ligation							1				1
	No operation	3	1			1		23	1	1		30
	SFJ + SPJ surgery							1	1			2
	SFJ surgery + Redo SPJ				1							1
	Redo SFJ + Redo SPJ surgery						1					1
	Total	62	5	1	7	8	1	44	5	1	1	135
Total		195	22	16	14	18	7	56	11	2	1	342

Table 2. Agreement between clinical and duplex findings in those considered to "need" and not to "need" duplex scanning

Group	I (%)	II (%)	III (%)	Total
Number of limbs	170	37	135	342
Limbs considered for surgery	162 (95%)	34 (92%)	105 (78%)	301
Limbs considered to "need" a duplex scan:	56/162 (35%)	28/34 (82%)	NA	NA
- agreement between clinical and duplex findings	39/56 (70%)	13/28 (46%)		
- decision changed	17/56 (30%)	15/28 (54%)		
Limbs considered not to "need" a duplex scan:	106/162 (65%)	6/34 (18%)	NA	NA
- agreement between clinical and duplex findings	95/106 (90%)	6/6 (100%)		
- decision changed	11/106 (10%)	—		
Overall agreement between clinical and duplex findings in limbs considered for surgery	134/162 (83%)	19/34 (56%)	90/135 (67%)	243/301 (81%)

This was not examined in group III since it was the policy of the unit to scan all patients with skin changes during the study period. NA: non-applicable.

Venous duplex findings confirmed that clinical assessment alone would have led to inappropriate surgical procedures in half of these limbs (15/30). Surprisingly, there was 100% agreement between clinical and duplex findings in all seven cases where a duplex scan would not have been requested.

In Group III, clinical assessment correctly introduced the appropriate treatment plan in 67% (90/135) of cases. In particular, the agreement between clinical and duplex findings was 78% (81/104) in the subgroup with primary varicose veins and 29% (9/31) in those with recurrent.

A total of 274 limbs presented with primary varicose veins regardless of the presence of skin changes, i.e. all group I and 104 group III patients. In this population, agreement between clinical and duplex findings was achieved in 80%. The main source of disagreement was the detection of SFJ reflux with 23 false positive and 13 false negative diagnoses. The sensitivity, specificity, PPV and NPV of clinical assessment in identifying SFJ incompetence were 93%, 69%, 89%, and 80%, respectively.

The presence of DVR was suspected in 33 (24%) limbs in group III due to history of previous DVT in 8, clinical appearance in 25, and obesity in 3 (two or more reasons were present in 3 patients). However,

in only 8/33 (24%) was our suspicion confirmed by the duplex findings (5 limbs with DVR and 3 with post-thrombotic damage). On the other hand, in 17 out of 102 (17%) limbs, duplex scanning revealed DVR despite the absence of any clinical suspicion. Therefore, in limbs with skin changes, the sensitivity of clinical assessment in detecting DVR was 32%, whereas the specificity, PPV and NPV were 77%, 24%, and 83%, respectively. Patients with a positive history of previous DVT were more likely to have DVR on duplex scanning than those without a history of DVT (6/9 versus 19/26, $p = 0.001$).

Finally, in 43 out of 274 (16%) legs with primary varicosities, significant anatomical variations were identified with duplex scanning (Table 4).

Discussion

Debate continues regarding whether or not routine preoperative duplex imaging should be performed in all patients with varicose veins. The present series is unique in that it is a prospective study recruiting a large number of consecutive patients referred to a single-visit outpatient vascular clinic with a venous complaint. There were no exclusion criteria and an "all-comers" policy was adopted incorporating patients with primary or recurrent varicosities with or

Table 3. Main reasons for deciding against operation in the 56 limbs based on duplex findings

Reasons for non-operative treatment	N
Deep venous reflux (full-length)	31
Active ulcer with normal duplex findings	6
Minor varicosities and/or reticular veins with normal duplex findings	8
Limb swelling with normal duplex findings	2
Eczema with normal duplex findings	6
GSV thrombosis	1
Obesity and minor varicose veins	2
Total	56

Table 4. Anatomical variations in the 274 limbs with primary varicosities

Anatomical variations	N
Anterior thigh circumflex vein feeding distal varicose veins	27
Double GSV	7
SSV-GSV communicating branch	6
Pudendal veins feeding varicosities	2
SFJ in between superficial femoral and profunda femoris arteries	1

without skin changes (class C2-C6 of CEAP classification). Assessing this large, mixed group of patients provided a first-class opportunity to answer whether vascular surgeons could predict surgical management, select those who need scanning, and correctly suspect DVR. In contrast to other authors, we relied solely on clinical assessment rather than the use of HHD.

This study confirms that clinical examination could not predict surgical management accurately. The overall agreement between clinical and duplex findings in the entire series was 73%. Had duplex scanning being unavailable, this discrepancy in operative planning of 27% would have resulted in 20 unnecessary, 34 inadequate and 37 inappropriate operations. In particular, the sensitivity of clinical examination in identifying SFJ incompetence in legs with primary varicosities, regardless of clinical status, was 93%. When considering only primary uncomplicated varicose veins (without skin changes) – a relatively "easy" group to assess in which duplex imaging is not routinely requested – this figure was almost the same (94%), surprisingly similar to the one quoted by other studies, where a HHD was used.^{14,17,27} However, the specificity, PPV and NPV of clinical evaluation of SFJ incompetence remained relatively low, in both groups of patients. That would have led to a total of 36 limbs (13%) being offered an incorrect, inadequate or inappropriate surgical procedure, resulting in high recurrence rates or worsening of chronic venous disease due to undetected and/or untreated SFJ reflux. Previous studies also demonstrated that if clinical examination alone were used for assessing primary varicose veins, inappropriate surgery would be performed in 20–29% of limbs.^{11,23}

If a policy of selective duplex scanning is to be adopted, can the clinician select those who need scanning? Based on clinical grounds, the examiners in this series would request 88 scans because of clinical uncertainty, i.e. in the 43% of patients in groups I and II. Nevertheless, they still got it wrong in 11% of cases they felt clinically certain of the diagnosis. On the other hand, if one opts to offer duplex imaging to all recurrent varicose veins and/or those with skin changes (i.e. groups II and III) and selectively to those in group I with uncertain diagnosis, 67% of the entire population would have had the investigation. This would still leave a 12% of legs (13 out of 112) with an incorrect diagnosis. The main source of this discrepancy between clinical and duplex findings was an unrecognised SPJ reflux, a finding in keeping with previous studies which suggested that assessing the presence or absence of reflux at the popliteal fossa by means of clinical examination alone is inaccurate. Therefore, selection of patients for duplex scanning based on clinical grounds is unsatisfactory, even in

primary varicose veins and when the clinical diagnosis seems certain.

The agreement between the clinical and duplex findings was only 59% in patients with recurrent varicose veins without skin changes and 29% in the subgroup with recurrent varicose veins and skin changes. Equally, a thorough investigation of both superficial and deep vein systems is of great importance in limbs with skin changes, since clinical assessment is notoriously unreliable. In both groups of patients, duplex imaging is, therefore, mandatory. In limbs with suspected DVR, a history of deep vein thrombosis may point towards the underlying problem, although other factors, such as clinical appearance, recurrence, and obesity, may easily result in false positive estimations. In our series, duplex scanning revealed DVR in one in five limbs with skin changes, in keeping with previous reports.^{28,29} In all 3 groups, the examiners were not able to predict DVR (poor sensitivity and PPV), although they could exclude DVR with greater success (high specificity and NPV). Clinicians, therefore, usually fail to predict DVR, and, as a result, all patients with skin changes should be assessed by duplex scanning.

One might argue that adopting an "all-comers" venous duplex policy would be impractical, time-consuming and expensive. In limbs with LSV incompetence, whether reflux is confined to the trunk alone or extended up to the SFJ seems to be more of an academic interest.¹⁷ Nevertheless, as seen in 16% of limbs in our series and in 25% of limbs in the study by Jutley *et al.*, duplex scanning can also reveal anatomical variations, information which would have not been detected with clinical examination and/or HHD.¹⁸ The majority of these variations may not alter the surgical management of an "open" procedure, however, if an endovenous ablation practice were to be instituted, their detection would have been of paramount importance.³⁰ Duplex scanning in this single-visit vascular clinic has not been time-consuming. Our experienced vascular technologists could perform a detailed venous scan in approximately 10 minutes. Finally, the issue of cost is a difficult one. Jutley *et al.* calculated that the cost of a venous duplex scan in the National Health Service was £40 per limb.¹⁸ This figure is similar to the £50 price a duplex scan costs in our unit. In this era of clinical governance and cost-effectiveness, the costs of an "all-comers" duplex policy should be compared with the costs of treating recurrent varicose veins. In pure financial terms, this could only be answered by a randomized controlled trial designed to delineate the financial implications of such a policy. In the overall context of varicose vein surgery, however, if duplex imaging

could be proven to reduce the recurrence rates, its routine use might be justified irrespective of cost. This has been very elegantly shown by a recent Swedish trial.³¹ Patients randomised to routine pre-operative duplex imaging had a significantly lower recurrence rate two years after surgery.

In conclusion, this study confirms that clinical evaluation of patients with venous disease is inaccurate in planning their management and clinicians can neither predict those patients that will require duplex scanning nor correctly identify deep venous insufficiency. Even experienced surgeons often "get it wrong" in assessing primary uncomplicated veins despite being certain about the diagnosis. Therefore, an "all-comers" duplex imaging policy should be implemented if optimal management of patients with venous disease is to be achieved. Naturally, this would have significant financial and manpower implications, however, there is now evidence from a randomised trial that such a policy would reduce the recurrence rates after varicose vein surgery.

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