Pilot Randomised Controlled Trial Evaluating a One Stop Vein Clinic

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FULL TITLE

Pilot Randomised Controlled Trial Evaluating the potential benefit of a One Stop Vein Clinic

DESCRIPTION

A pilot randomised controlled trial looking at the setting up of a one stop vein clinic for the treatment of varicose veins and assessing the quality-adjusted life years at 3 months of patients

This will be a pilot study which is designed to provide us with enough information for a potentially larger multicentre randomised controlled study.

OBJECTIVES

- Primary Objective
  - Measure the quality-adjusted life years (QALY) gained at 3

months (using EuroQoL's EQ-5D) & AVVQ by patients randomised to treatment in the One Stop Vein Clinic with patients randomised to treatment in the normal care pathway

- Secondary Objective
  - Patient satisfaction with the service provided using the Picker patient experience questionnaire both post-operatively and at the 3 months follow-up (One Stop Vein Clinic versus Normal Care Pathway)
  - Measure and compare the quality of life scores using CIVIQ at 0 and 3 months in patients randomised to treatment in the One Stop Vein Clinic with patients randomised to the Normal Care Pathway
  - Record the time from referral to treatment (RTT)
  - Assess the cost-effectiveness of the One Stop Vein clinic compared to the normal care pathway
  - Record the time to return to normal activities and to work
  - Assess the estimated societal costs

BACKGROUND

Varicose veins are very common conditions, affecting approximately 25% of the population[1]. Over 35,000 varicose vein procedures are currently carried out in the UK[2]. However, with the new 2013 NICE guidelines, the Department of Health has estimated that this is set to increase to 50,000 per year. Waiting for varicose vein interventions has been shown to be detrimental to the severity of the condition and the quality of life of patients[3]. Progression of varicose veins can also lead to complications such as leg ulcerations and can be costly to the health service[4]. Over the past decade, new endovenous techniques have been introduced and these are felt to be cost-effective, especially, when performed in an outpatient or 'office-based' setting[5]. At present, patients referred to the Vascular unit for consideration of management of their varicose veins have to attend the outpatient clinic at least twice prior to be listed for their procedure.

At present, patients referred to the Vascular Outpatient Clinics for consideration for varicose vein management have an initial appointment where the severity of the venous insufficiency is assessed clinically and, subsequently, have a venous Duplex scan to evaluate the extent and cause of any venous incompetence. If any treatable lesion is found, they are then added to the waiting list to come for the eventual varicose vein procedure. This means, they have to attend at least two outpatient appointments and attend another appointment for their venous scans, before actually attending for their varicose vein procedure. Waiting for varicose vein interventions has been shown to lead to worsening of their conditions both clinically and radiologically[3]. In addition, the quality of life of patients waiting for elective surgery is adversely affected[6].

In order to evaluate patients' ideas and expectations with respect to the provision of varicose vein service in our unit, we conducted a survey of patients attending the Vascular Outpatient Clinic between March and June 2014. One hundred and six patients completed the anonymous questionnaire. Most were females (62.4%) with a mean age of 51 ± 15 years. More than 90% of patients stated that the waiting time between a Vascular appointment and a venous scan should be no more than 1 month and 85% of patients believed varicose vein procedures should be received within 1 month of their Vascular clinic appointment. Ninety percent of patients were agreeable to attend a 'one-stop' vein clinic offering same day diagnosis and treatment. Patients were generally accepting of the fact that most procedures would be carried out under local anaesthetic (89%).
Hence, it appears that patients in our unit have a preference for a one stop clinic. This concept is not new and has been piloted in other specialities with good success - a one-stop carpal tunnel clinic as well as a one stop cataract clinic was shown to be feasible with good

patient satisfaction[7, 8]. Both laparoscopic and open inguinal hernia repairs, where patients received a general anaesthetic, have been carried out successfully using a one stop model offering same day diagnosis and treatment[9, 10]. There is currently already a 'see and treat' service for skin lumps operating at many NHS Trusts and there is already a one stop carpal tunnel service being provided at the Imperial College NHS Trust. It would appear that these one stop clinics have the advantage of reducing the number of unnecessary hospital visits as well as possibly leading to cost savings to the health service[7-10].

As a result, we intend to evaluate the one stop model within our own varicose vein service. We will assess the feasibility of having a one-stop vein clinic, where patients will be assessed, have their venous Duplex scans and, depending on the lesions shown, have their venous treatment on the same day.

The hypothetical benefits of such a stratagem are an improvement in patient satisfaction, a reduction in the number of appointments, the abolition of any waiting times as well as cost savings to the health savings.

METHODS

GP referrals will be screened and patients meeting the inclusion criteria will be invited to take part in the trial .

They will be sent an information pack containing:

- Information leaflet about the trial
- Information about varicose veins, their treatments and a telephone number as a helpline
- The Aberdeen Varicose Vein Questionnaire (AVVQ), the Chronic Venous Disease Quality of Life Questionnaire (CIVIQ) and EuroQoL's quality of life questionnaire (EQ-5D)
- Consent form to participate in the study

Patients agreeing to be part of the trial will be consented and randomised either to:

- The One Stop Vein Clinic (offering same day diagnosis and treatment); or
- The normal care pathway

Once patients indicate their consent to participate, their General Practitioners (GP) will be sent a letter informing them of the patient's participation in this study.

Patients declining to partake in the randomised part of the study, but agreeable to complete study questionnaires while continuing down the normal care pathway, will also be consented. Further information will be provided to them when they attend for their clinic appointment and the consenting process will take place when they attend for their subsequent procedure

One Stop Vein Clinic Pathway

Patients attending the One Stop Vein Clinic will be reviewed by the Vascular Surgeon, who will confirm the patient's consent in the trial, then assess the degree of venous disease and fill in the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification and Varicose Clinical Severity Score (VCSS). If the patient's symptoms are deemed secondary to venous disease, they will be sent to have a Duplex scan to confirm the presence of the venous disease. The results will be reviewed by the Vascular Surgeons, and if the patients are suitable for endovenous ablation +/- avulsions or UGFS, they will be informed of the findings of the scan and proposed treatment. If they are happy to go ahead with the proposed intervention, they will be consented and transferred to the waiting area to wait for their intervention. If, however, they decline same day treatment, they will be put onto the conventional care pathway.

Another Vascular Surgeon will be carrying out the interventions in an 'office-based' environment under local anaesthetic. Once done, the patients will be asked to fill the Picker patient experience questionnaire. They will subsequently be discharged, similar to current practice, and will be given a diary card to fill for when they return to their normal activities

and work.
Three (3) months post-operatively, they will be asked to fill the AVVQ, CIVIQ, EQ-5D and Picker patient experience questionnaires once more. This will be done by sending them the questionnaires by post.

The Normal Care Pathway (NCP)

In the normal care pathway, patients referred by their GP are seen in the outpatient clinic and, if their symptoms are suggestive of varicose vein disease, they are sent to have a venous duplex scan. This usually happens on a different day. Afterwards, they are seen back in the clinic (again on a different day) and, if the scan result suggests venous incompetence amenable to day case treatment, they are added to the waiting list. The eventual procedure takes place some time later (within 18 weeks from referral to treatment). After their procedure, they will be asked to fill a Picker patient experience questionnaire. On discharge, they will be given a diary card to fill for when they return to their normal activities and work.
At 3 months post intervention, patients randomised to the normal care pathway will be sent the QoL questionnaires again and asked to fill the AVVQ, CIVIQ, EQ-5D and Picker patient experience questionnaires. As there will be an inherent delay in the NCP pathway we can not use the time from randomisation as many patients will not have received their interventional treatment by then.

Inclusion and Exclusion Criteria

The inclusion criteria are:

- Adults over the age of 18 years
- Unilateral lower limb symptoms suggestive of venous disease on the referral letter

The exclusion criteria are:

- Recurrent varicose veins
- Known arterial disease or ABPI<0.8
- Current deep vein thrombosis
- Patients who withdraw their consent
- Inability to complete the questionnaire or attend follow up appointments
- Currently enrolled in other venous study

PATIENT SELECTION

This is a pilot randomised controlled study and patients will be selected following screening of the GP referral letter.

CONSENT

As part of the consenting process, patients will be given three options.
1.Patients wishing to attend the One Stop Vein Clinic and participate in the study will be asked to indicate their consent by signing a consent form and filling in a reply slip. Patients will be randomised either to the One Stop Vein Clinic group or to the Normal Care Pathway (NCP) group.
2.Patients not wishing to attend the One Stop Vein Clinic and participate in the study will be asked to indicate this by filling in a reply slip. They will instead attend the normal care pathway. They will, however, be asked, if agreeable to complete the QoL and Picker patient experience forms.
3. Patients declining either the trial or simple service evaluation will be offered the NCP.

TREATMENT ALLOCATION

Treatment received will depend on the findings on the venous Duplex scan. All treatments are minimally invasive with endovenous ablation procedures (either radio-frequency ablation, endovenous laser ablation or mechano-chemical ablation), avulsions or ultrasound-guided foam sclerotherapy. All procedures will be carried out under local anaesthetic and patients will be discharged home later that day, as is the current standard of care.

MEASUREMENT OF OUTCOMES

Primary Outcome

- Measure the quality-adjusted life years (QALY) gained at 3 months (by patients randomised to treatment in the One Stop Vein Clinic with patients randomised to treatment in the Normal Care Pathway)

Secondary Outcome

- Patient satisfaction with the service provided using the Picker patient experience questionnaire both post-operatively and at the 3 months follow-up (One Stop Vein Clinic versus Normal Care Pathway)
- Measure and compare the quality of life scores using EQ-5D, AVVQ and CIVIQ at 0 and 3 months in patients randomised to treatment in the One Stop Vein Clinic with patients randomised to the Normal Care Pathway
- Time from referral to treatment
- Assess the cost-effectiveness of the One Stop Vein clinic compared to the normal care pathway
- Record the time to return to normal activities and to work
- Assess the estimated societal costs

STUDY DURATION & SAMPLE SIZE

Following screening of their GP referral letter, patients with varicose vein disease will be invited to participate in the study. We estimate that 12-14 patients will be invited on a weekly basis to participate in the study following screening. Out of those, we are anticipating only 8 patients will agree to be randomised to the One Stop Vein Clinic or Normal Care Pathway. If the clinic is held weekly, we estimate recruiting 416 patients over the course of the year (8 patients X 52 weeks).

Statistical analysis suggests that the sample size of 208 patients per group would be able to power a potential phase 3 multicentre randomised controlled trial. Compared to a previous study conducted in our unit which involved 317 patients in total and looked at different quality of life scores and their responsiveness[11], the coefficient of variation (ratio of standard deviation to mean) was found to increase at the follow-up period and to vary among the different scores used. With a larger sample size as in this pilot study, this variability would be reduced and result in a smaller coefficient of variation when looking at the follow-up scores. Hopefully, this will enable us to identify the QoL score with the least variability and use it as the primary outcome measure in a future Phase 3 study. A primary outcome measure with little variability would provide us with enough information to estimate an adequate sample size for any future randomised controlled trials.

For example, with a sample size of 208 patients and coefficient of variation of 0.5, a 15% reduction in the geometric mean (a measure of central tendency, similar to median) would be required compared to 25% from the Shepherd et al. study. With power at 85%, this would allow us to determine an adequate sample size.

Participants will be followed-up post-procedure for 3 months, including for patients randomised to the Normal Care Pathway (with potentially longer waiting time from referral to treatment). This means that the study period will be about 18 months. With 3 months for study start-up and 3 months to write the study up, the study will last for 24 months.

Approximately 1,000 patients undergo varicose vein procedures at the Imperial College NHS Trust every year.

COST BENEFIT OF PROJECT

Our hypothesis is that along with improved patient satisfaction and improved waiting times for outpatient appointment, there will be cost savings derived from the One Stop Vein Clinic. On average, 1,000 patients are treated every year in the Imperial College NHS Trust and the cost of an outpatient attendance is approximately £93[12]. Savings could be made if patients are seen and treated at their first appointment rather than having to attend another two

appointments.
The potential cost saving is estimated to be in the order of £186,000 annually (£93 x 1,000 X 2).

Estimated societal costs.

Data will be collected on time off from work and carer's duties (child/relative/friend). Additionally, data on income, cost of attending clinic and impact on family and colleagues will be assessed to estimate the societal cost of the two pathways.

ETHICAL ARRANGEMENTS

The Chief Investigator has obtained approval from the National Research Ethics Service (NRES) Committee (**REC Ref.: 14/LO/1295**).
Patients will be screened and patients thought eligible will be sent an information pack with information about the trial and varicose veins and its treatments. They will be invited to the clinic and would be asked to confirm their consent by providing a written consent prior to participating in the trial. The National Health Service (NHS) Trust Research and Development approval will also be sought prior to starting the trial.

DATA HANDLING & DISSEMINATION OF RESULTS

All patient data will be anonymised and stored on a password protected access database under the guidelines of the Data Protection Act 1998. Patient records will be kept on paper in the form of the diary card questionnaires and clinical scoring sheets, which will be kept in a locked filling cabinet at Charing Cross Hospital for 10 years in accordance with the Imperial College Trust Policy.

DISSEMINATION OF RESULTS

For Patients/Public

We will produce a short, easy to understand summary of our research findings that will be available from our website or that can be sent to interested parties. There will also be significant patient and public engagement through new and existing conferences and open days.

For academics

Knowledge will be disseminated through peer-reviewed scientific publications in leading international, high impact journals (e.g. Lancet, BMJ, Annals of Surgery; Health Affairs; or relevant open access journals, where possible and appropriate), and presentations at local, national and international conferences. A balanced approach will be adopted to maximise the impact and output of the studies. In line with all research funded by the NIHR, we will produce a full and complete account of the research ensuring that the work is reported fully and publicly available.

For Health Managers

We will disseminate findings to a specialist audience, including health care commissioners, policy makers, Department of Health, and specialist providers. The study results will be presented to healthcare commissioners and policy makers at appropriate meetings and publications. A summary of results, in language appropriate for lay persons, will be sent to all relevant patient groups. We will provide details of simulations on a web based platform to facilitate the adoption of our model and methodology in other fields. The dissemination strategy for our findings will be aimed at reaching the largest possible stakeholder audiences.

CRITERIA FOR ELECTIVELY STOPPING THE TRIAL OR OTHER RESEARCH PREMATURELY

The trial may be stopped prematurely due to loss of equipoise or any major adverse effect as a result of treatment in any of the treatment arms.

Adverse events

No significant adverse events are expected.
Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

REPORTING PROCEDURES

All adverse events should be reported to the trial management committee via the CI and via the trust datix system.

Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

Adverse Events (AE)

All such events, whether expected or not, should be recorded.

Serious Adverse Events (SAE)

An SAE form should be completed and faxed to the Chief Investigator within 24 hours.

All SAEs should be reported to the Sponsor where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

In the event of any harm to participants in the trial, Imperial College holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies, which apply to this trial. All issues will be reviewed by the TMC (AHD/CB/KD/RB), Prof Andrew Bradbury (Professor of Vascular Surgery) will be available as an independent advisor.

CO-APPLICANTS & RELEVANT EXPERTISE

Professor Alun Davies was the Chairman of the NICE Guideline Development Group on varicose veins, and a past president of European and UK Venous Forums. He has experience of running large multicentre trials including the Vein Graft Surveillance Trial. He is presently Chairman of the trial steering committee for the HTA CLASS trial, Chief Investigator of the NIHR funded EVRA trial and co-applicant on BASIL 2 and 3 trial. He is co chair of the European Venous Guidelines Committee.

Mr Colin Bicknell is Senior Lecturer and a Consultant Vascular Surgeon at Imperial College Healthcare NHS Trust. He has significant trial experience and is PI of the IDEAS trial, investigating incentive for diabetic eye screening, co-investigator of the AARDVARK trial for small abdominal aortic aneurysms and the 15-year aneurysm-related mortality evaluation of EndoVascular Aneurysm Repair randomised controlled trial – all NIHR funded trials. He works with AHD clinically and on a number of research topics.

Miss K Sritharan is Consultant Vascular surgeon with experience of recruiting to randomised controlled trials and performing venous interventions.

Dr David Epstein is an experienced health economist from the Department of Applied Economics at
the University of Granada, Spain.

Dr Rosalind Herbert is an academic GP at the Imperial College London with previous trial experience.

Mr Tristan R. A. Lane is a Vascular Trainee in the London Deanery and Post-doctorate Honorary Research Fellow in venous disease who has previously been involved in the AVULS and VVCVV randomised controlled trials and the eSCOPE prospective observational study.

Mr Roshan Bootun is a Clinical Research Fellow in Vascular Surgery who is currently involved in the
randomised clinical trial of VNUS versus Clarivein in Varicose Vein (VVCVV) Trial

Ms Karen Dhillon is an experienced Research Nurse who is currently involved in the NIHR EVRA randomised controlled trial. She has previously managed vascular outpatient clinics and set-up and ran the Local anaesthetic Varicose Veins Unit (LAVVU) at the Charing Cross Hospital.

Mr Paul Bassett is an experienced Medical Statistician with previous trial experience.

Mrs Corine Ward and Mr Colin Price are patients who have helped us with the design and direction of the study.

COST ESTIMATION

The estimated duration of the study is 2 years. We anticipate recruiting about 416 patients for the one stop vein clinic and, also patients who decline the one stop clinic and prefer to attend a clinic on the normal care pathway.

The salary contributions for the CI (AHD) has been calculated at 0.05 FTE to represent the increased responsibility and anticipated time commitment from the trial co-ordinating institution (Imperial College London).

The salary contribution for CB, KS, TRAL, KD and RB has been calculated at 2% FTE.

The salary of a research nurse has been included (1 FTE).

The cost for a health economist, statistician and primary care physician has been also been included.
Other costs include cost of the questionnaires, trial registration, consumables and for dissemination of the results at conferences.

CONFLICT OF INTEREST

Most of the clinical applicants have an extensive experience of treating superficial venous reflux using multiple endovenous interventions. Some of the applicants have extensive endovenous research programmes that attract research funding. Most of the applicants have given invited lectures at meetings and many of the organisers of such events will have received industrial sponsorship. However, as the intervention being evaluated in this study is a change in the service provision in varicose vein management, we do not believe that these personal interests represent a conflict of interest in this study.

regulatory issues

Ethics approval

The Chief Investigator has obtained approval from the National Research Ethics Service (NRES) Committee (REC Ref.: 14/LO/1295). The study must be submitted for Site Specific Assessment (SSA) at each participating NHS Trust. The Chief Investigator will require a copy of the Trust R&D approval letter before accepting participants into the study. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Consent

Consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Indemnity

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study/ Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study (delete as applicable)

Sponsor

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

Funding

Partial funding for the study has been provided by the Graham-Dixon Charitable Trust.

Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

Patient with varicose vein

GP Referral

Varicose Vein Treatment

Outpatient Clinic

Venous Duplex Scan

Outpatient clinic

Normal Care Pathway

Same day outpatient clinic, venous duplex scan and varicose vein treatment

One Stop Vein Clinic
Not suitable for One Stop Vein Clinic
Normal Care Pathway
(off-trial)
Suitable for One Stop Vein Clinic
Letter Screening
Randomisation

Day of Treatment:

- Picker questionnaire
- AVVQ, CIVIQ and EQ-5D
- CEAP and VCSS
- Patients given diary card to fill

Follow-up at 3 months:

- Picker questionnaire
- AVVQ, CIVIQ and EQ-5D
- CEAP and VCSS

Day of Treatment:

- Picker questionnaire
- AVVQ, CIVIQ and EQ-5D
- CEAP and VCSS
- Patients given diary card to fill

Day of Treatment:

- Picker questionnaire
- AVVQ, CIVIQ and EQ-5D
- CEAP and VCSS
- Patients given diary card to fill

Follow-up at 3 months:

- Picker questionnaire
- AVVQ, CIVIQ and EQ-5D
- CEAP and VCSS

APPENDIX 1: Quality of Life Questionnaire

EQ-5D Questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

1. MOBILITY

I have no problems in walking about

I have slight problems in walking about

I have moderate problems in walking about

I have severe problems in walking about

I am unable to walk about

2. SELF-CARE

I have no problems washing or dressing myself

I have slight problems washing or dressing myself

I have moderate problems washing or dressing myself

I have severe problems washing or dressing myself

I am unable to wash or dress myself

3. USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities

I have slight problems doing my usual activities

I have moderate problems doing my usual activities

I have severe problems doing my usual activities

I am unable to do my usual activities

4. PAIN/DISCOMFORT

I have no pain or discomfort

I have slight pain or discomfort

I have moderate pain or discomfort

I have severe pain or discomfort

I have extreme pain or discomfort

5. ANXIETY/DEPRESSION

I am not anxious or depressed

I am slightly anxious or depressed

I am moderately anxious or depressed

I am severely anxious or depressed

I am extremely anxious or depressed

Appendix 2: Aberdeen Varicose Vein Questionnaire

YOUR VARICOSE VEINS

1. Please draw in your varicose veins in the diagram(s) below:-

Legs viewed from front

Legs viewed from back

2. In the last two weeks, for how many days did your varicose veins cause you pain or ache?
(Please tick one box for each leg)

R Leg
L Leg

None at all

Between 1 and 5 days

Between 6 and 10 days

For more than 10 days

3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins?
(Please tick one box for each leg)

R Leg
L Leg

None at all

Between 1 and 5 days

Between 6 and 10 days

For more than 10 days

4. In the last two weeks, how much ankle swelling have you had?

(Please tick one box)

None at all

Slight ankle swelling

Moderate ankle swelling (eg. causing you to sit with your feet up whenever possible)

Severe ankle swelling (eg. causing you difficulty putting on your shoes)

5. In the last two weeks, have you worn support stockings or tights?

(Please tick one box for each leg)

R Leg
L Leg

No

Yes, those I bought myself without a doctor's prescription

Yes, those my doctor prescribed for me which I wear occasionally

Yes, those my doctor prescribed for me which I wear every day

6. In the last two weeks, have you had any itching in association with your varicose veins?

(Please tick one box for each leg)

R Leg
L Leg

No

Yes, but only above the knee

Yes, but only below the knee

Both above and below the knee

7. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins?
(Please tick one box for each leg)

R Leg
L Leg

No

Yes

8. Do you have a rash or eczema in the area of your ankle?
(Please tick one box for each leg)

R Leg
L Leg

No

Yes, but it does not require any treatment from a doctor or district nurse

Yes, and it requires treatment from my doctor or district nurse

9. Do you have a skin ulcer associated with your varicose veins?

(Please tick one box for each leg)

	No	Yes
R Leg		
L Leg		

10. Does the appearance of your varicose veins cause you concern?

(Please tick one box)

- No
- Yes, their appearance causes me slight concern
- Yes, their appearance causes me moderate concern
- Yes, their appearance causes me a great deal of concern

11. Does the appearance of your varicose veins influence your choice of clothing including tights?

(Please tick one box)

- No
- Occasionally
- Often
- Always

12. During the last two weeks, have your varicose veins interfered with your work/ housework or other daily activities?

(Please tick one box)

- No
- I have been able to work but my work has suffered to a slight extent
- I have been able to work but my work

has suffered to a moderate extent

My veins have prevented me from working one day or more

13. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)?

(Please tick one box)

No

Yes, my enjoyment has suffered to a slight extent

Yes, my enjoyment has suffered to a moderate extent

Yes, my veins have prevented me taking part in any leisure activities

Appendix 3. Societal Questions

The following questions is to try assess the possible impact on society of patients having to take time off work or caring duties to attend a varicose vein appointment.

What is your total family income?

What is your highest level of education attained?

- Less than £20,000
- £20,000 - £39,999
- £40,000 - £59,999
- £60,000 - £99,999
- £100,000 and over

- None
- Primary education
- Secondary education
- Tertiary education

- Post-graduate degree

- Did you need to take time off work to attend your varicose vein appointment?

☐ Yes ☐ No (Go to Question 3)

- Did you have to take half a day or full day off?

☐ Half-day ☐ Full day

- What is your hourly rate of pay at work?

……..

- Do you have care commitments (e.g., children or relatives)?

☐ Yes ☐ No

- Did you have to ask someone to look after your child/relative so you could attend your appointment?

☐ Yes ☐ No

- Who did you ask?

……..

- How much did you have to pay them?

……..

Appendix 4: **Clinical assessment of Varicose Veins**

Hospital Number---------- **MALE** **FEMALE**

Number of Pregnancies

Weight/ Kg

BMI>30
Yes
No
OCP or HRT
Yes
No
Smoker
Yes
No
Date of birth----------

Age **----------**

Occupation----------
Date----------

Past Medical History

	Yes	No		Yes	No
Bleeding disorder	☐	☐	IHD	☐	☐
DVT/PE	☐	☐	Leg ulcers	☐	☐
Diabetes	☐	☐	Hypertension	☐	☐

Medications

Previous treatment to Varicose Veins

Side
Site
Date
Treatment type

Appendix 5: Pre Operative Clinical Assessment

Score	Definition
0	Asymptomatic
1	Symptomatic, but able to carry out usual activities with out compressive therapy
2	Able to carry out usual activities only with compressive therapy and/or limb elevation
3	Unable to carry out usual activities even with compression and/or elevation

Usual activities = patients activities before the onset of disability due to venous disease

Appendix 6: Venous Clinical Severity Score (VCSS)
Please indicate right or left leg or bilateral (R, L or B)

Absent
Mild
Moderate
Severe
Pain
None
Occasional, non/ no analgesia restricting
With moderate activity, occasional analgesia
Daily, severe limitations, regular analgesia
Varicose veins>4mm
None
Few
Multiple GSV
Extensive GSV and LSV
Venous oedema
None
Evening/ankle
Afternoon/ above knee
Morning/requiring elevation
Skin pigmentation
None
Limited and old/brown
Diffuse lower third/ purple

Wide/ purple

Inflammation
None
Mild cellulitis in marginal area
Moderate involving most of gaiter area
Severe cellulitis or significant eczema
Induration
None
Focal <5cm
Medial or lateral less than lower 1/3
1/3 of lower leg or more
Number of active ulcers
0
1

2

3

Active ulcer duration
None
<3 months
>3 months
<12 months

>12 months
Active ulcer diameter(cm)
None
<2
2-6
>6
Compression
Not used or non compliant
Intermittent use
Stockings worn most days
Stockings worn daily

Total

Appendix 7: Clinical-Etiology-Anatomy-Pathophysiology (CEAP Classification)
Clinical

0
1A
1S
2A
2S
3A
3S
4aA
4aS
4bA
4bS
5A
5S
6
Etiology

Congenital
Primary
Secondary
No venous cause identified
Anatomy

Superficial
Deep
Perforating
No venous location identified
Pathology

Reflux
Obstruction
Both
No venous pathology identified

Class 0 No visible or palpable veins
Class 1 Telangiectasia, reticular veins
Class 2 Varicose Veins
Class 3 Oedema without skin changes
Class 4 Skin changes ascribed to venous disease
4a) Pigmentation or eczema
4b) Lipodermatoscerosis or atrophie blanche
Class 5 Skin changes and healed ulceration
Class 6 Active venous ulcers

A= Asymptomatic
S= Symptomatic

Appendix 8. CIVIQ-14 Questionnaire

C I V I Q-14

SELF-QUESTIONNAIRE PATIENTS

In English language for UK

Many people complain of leg pain. We would like to find out how often these leg problems occur and to what extent they affect the everyday lives of those who suffer from them.

Below you will find a list of symptoms, sensations or types of discomfort that you may be experiencing and which may make everyday life hard to bear to a greater or lesser extent. **For each symptom, sensation, or type of discomfort listed, we would like you to answer in the following way:**

Please indicate if you have experienced what is described in each sentence, and if the answer is 'yes', how **intense** it was. There are five possible answers, and we would like you to circle the one which best describes your situation.

- Circle 1if you feel the symtom, sensation of discomfort described does not apply to you
-
-
- Circle 2, 3,

4
or
5

if you have felt it to a great or less extent

-
-
-

QUALITY OF LIFE WITH VENOUS INSUFFICIENCY

1) During the past four weeks, have you had any **pain** in your **ankles** or **legs**, and how severe has this pain been?
Circle the number that applies to you.

No pain	1
Slight pain	2
Moderate pain	3
Considerable pain	4
Severe pain	5

2) During the past four weeks, how much trouble have you experienced at **work** or during your **usual daily activities because of your leg problems**?
Circle the number that applies to you.

No trouble
Slight trouble
Moderate trouble
Considerable trouble
Severe trouble

1
2
3
4
5

3) During the past four weeks, have you **slept badly** because of your leg problems, and how often?
Circle the number that applies to you.

Never
Rarely
Fairly
often
Very
often
Every
night
1
2
3
4
5

During the past four weeks, how much **trouble** have you experienced **carrying out the actions and activities** listed below b**ecause of your leg problems**?

For each statement in the table below, indicate how much trouble you have experiened by circling the number chosen.

No trouble
Slight trouble
Moderate trouble
Considerable trouble
Could not
do it

4) Climbing several flights of stairs
1
2
3
4

5

5) Crouching,

Kneeling down

1
2
3
4
5

6) Walking at a brisk pace

1
2
3
4
5

7) Going out for the evening, going to a wedding, a party, a cocktail party…

1
2
3
4
5

8) Playing a sport, exerting yourself physically

1
2
3
4
5

Leg problems can also affect your mood. How closely do the following statements correspond to what you have felt during the past four weeks?

For each statement in the table below, circle the number that applies to you.

Not at all

A little

Moderately

A lot

Completely

9) I have felt nervous/tense

1
2
3
4
5

10) I have felt I am a burden

1
2
3

4
5

11) I have felt embarrassed about showing my legs

1
2
3
4
5

12) I have become irritated easily

1
2
3
4
5

13) I have felt as if I am handicapped

1
2
3
4
5

14) I have not felt like going out

1
2
3
4
5

Appendix 9. Patient Diary

Please indicate at what stage you were able to return to work and your normal daily activities (the activities you were able to do prior to your treatment)

Day I was able to resume my normal activities (please tick one box)
Day I returned to work (please tick one box)

Day of surgery

Day after surgery

2 days after surgery

3 days after surgery

4 days after surgery

5 days after surgery

6 days after surgery

7 days after surgery

8 days after surgery

9 days after surgery

10 days after surgery

>10 days after surgery

-

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