Impact of surgeons, patients and referral practices on recruitment in the CLASS trial

CLASS Study Group

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The CLASS Trial: Comparison of LAser, Surgery and foam Sclerotherapy

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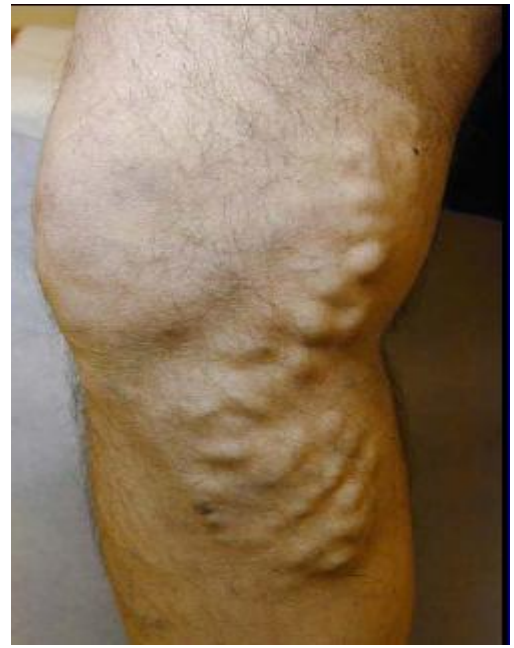
Varicose veins

- **Prevalence: up to 40% - men, 32% - women**
- **Symptoms: aching, heaviness, itching, swelling (Michaels, HTA, 2006)**
- **considerable workload**

  + cost to NHS

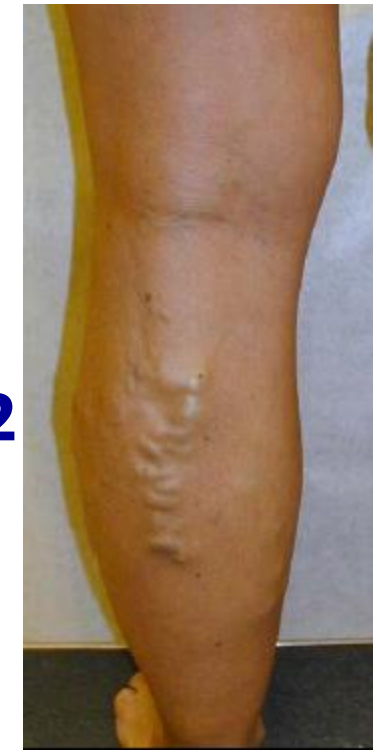
  ~95,000 operations/year

  (HES, 2004-2005)



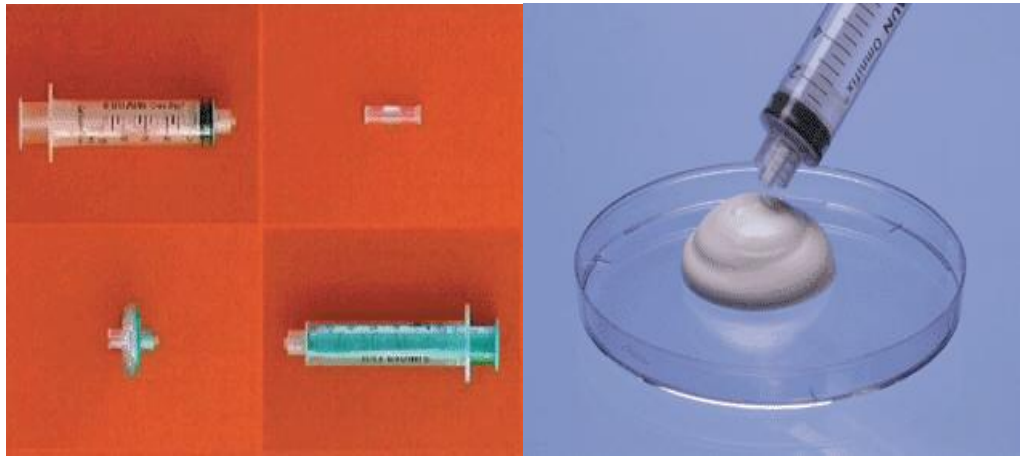
Varicose veins & Quality of life (QOL)

- **Patients with varicose veins have ↓ QOL**
  - **improves following surgery**
    (Subramona, JVS, 2005; Mackenzie R, JVS, 2002x2; Smith JJ, JVS,1998).
- **Surgery is cost-effective in terms of QOL**
  - **HTA RCT of surgery versus conservative management**
  - **Incremental cost per QALY gained: £4682**
    (Ratcliffe, BJS, 2005)
- **Increasing use of minimally invasive treatments**



Background

- August 2006
- HTA priority area 06/45 Foam sclerotherapy for varicose veins
- Primary outcome : Quality of life at 6 months



Primary objectives

To compare conventional surgery with

- **Foam sclerotherapy**
- **Endovenous laser ablation (EVLA) of main trunk + foam sclerotherapy of non-trunk varicosities**

Quality of life at 6 months (to 5 yrs)

Cost-effectiveness as cost per quality adjusted life year (QALY) gained

Secondary objectives

- **Cost**
  to health service and patients of each intervention and any subsequent care

- **Technical success**
  duplex scan verified reflux/partial or complete ablation of the long/short saphenous

- **Clinical success**
  residual varicose veins, Venous Clinical Severity Score, CEAP, complication rates and return to normal activities

Inclusion/Exclusion criteria

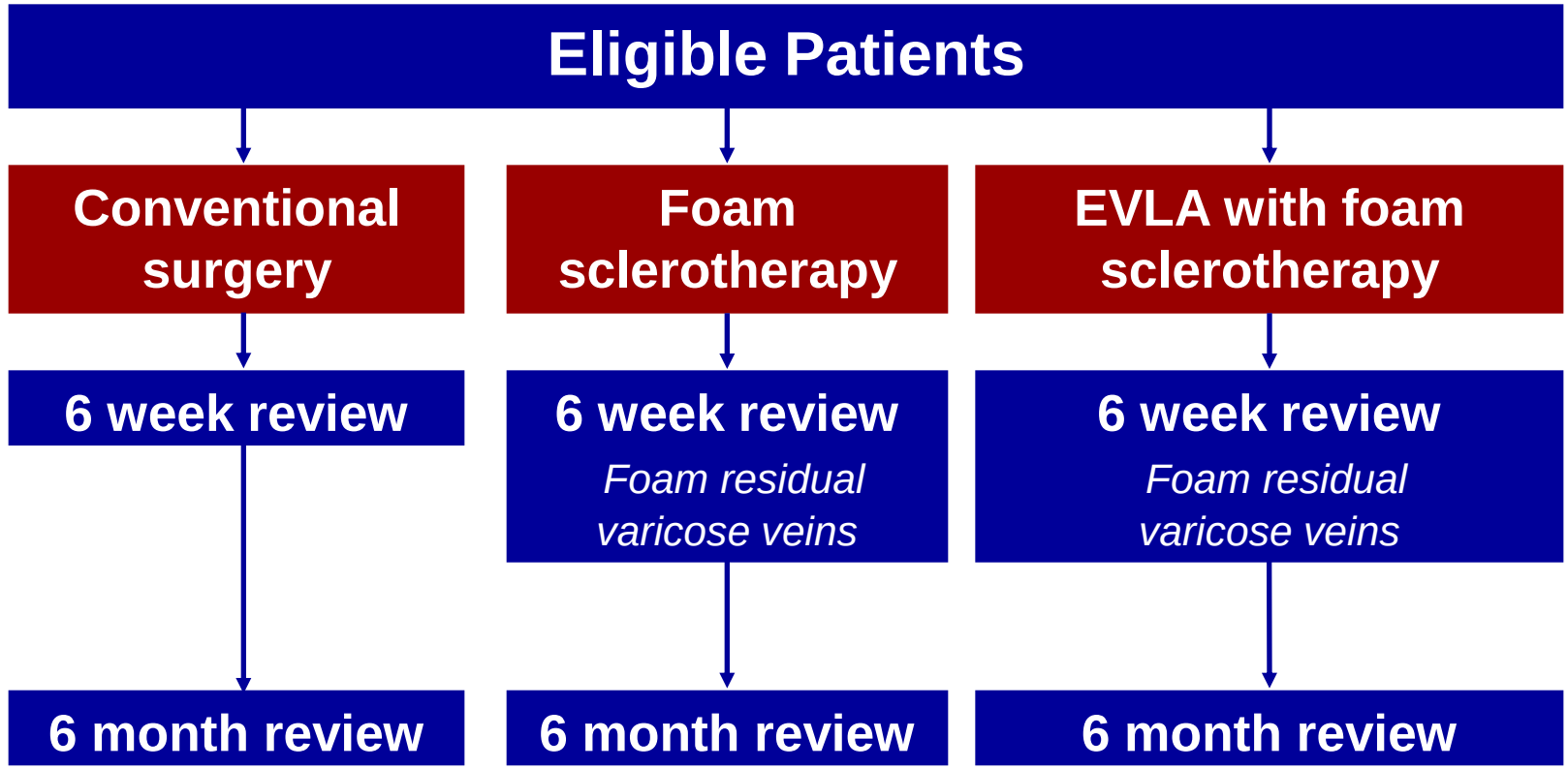
Inclusion

- adult patients (>18 years old)
- primary long or short saphenous varicose veins
- symptomatic (CEAP grade 2 or above)
- reflux >1 second on duplex scanning
- vein diameter >3mm, <15mm

Exclusion

- current thrombosis- deep or superficial
- allergy to sclerosant or other contraindication to Fibro-Vein
- pregnancy or breast feeding
- ankle brachial pressure index <0.8
- inability to mobilise post-procedure

Overview of trial design



Trial sites

- **Original sites: Gloucestershire & Cheltenham Hospitals, NHS Grampian, Hull Royal Infirmary, Leeds Teaching Hospitals NHS Trust, Royal Devon and Exeter Hospital**

- **New sites: Blackburn, Bournemouth, Newcastle, Sheffield, Worcester, Sherwood Forest**

Recruitment process

Out-patient appointment + 1 page study summary

↓

Receive PIL on arrival at clinic

↓

Seen by surgeon – study discussed (if eligible)

possible to recruit patient at this stage

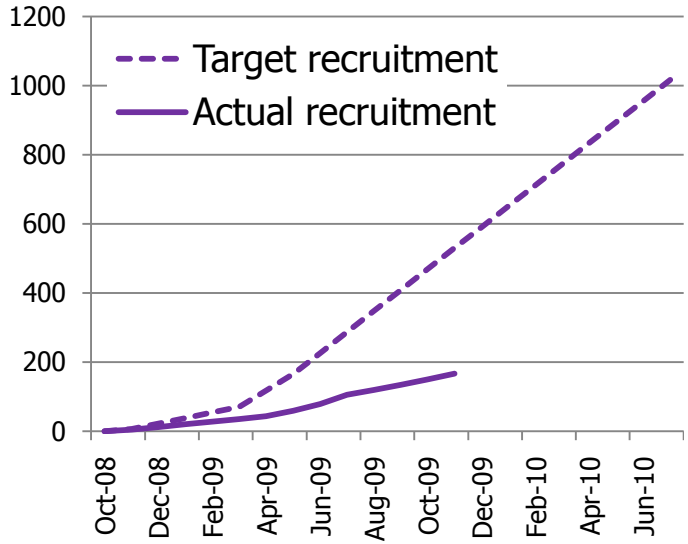
↓

If potentially interested – phoned by nurse

possible to obtain postal consent

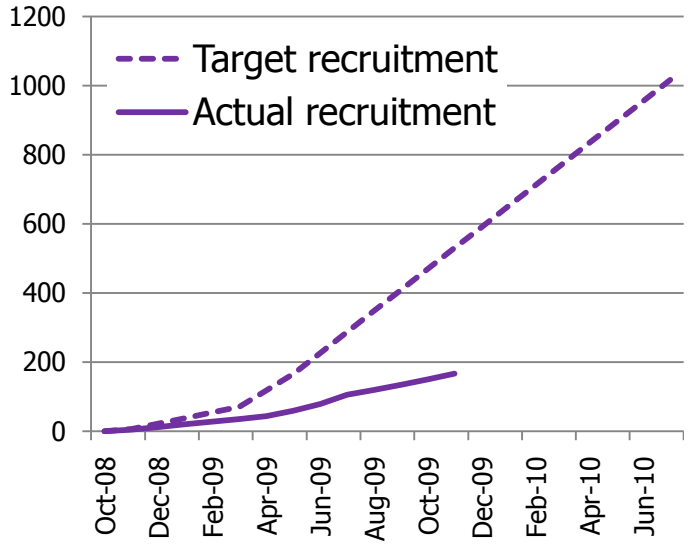
Actual versus target recruitment

original recruitment targets

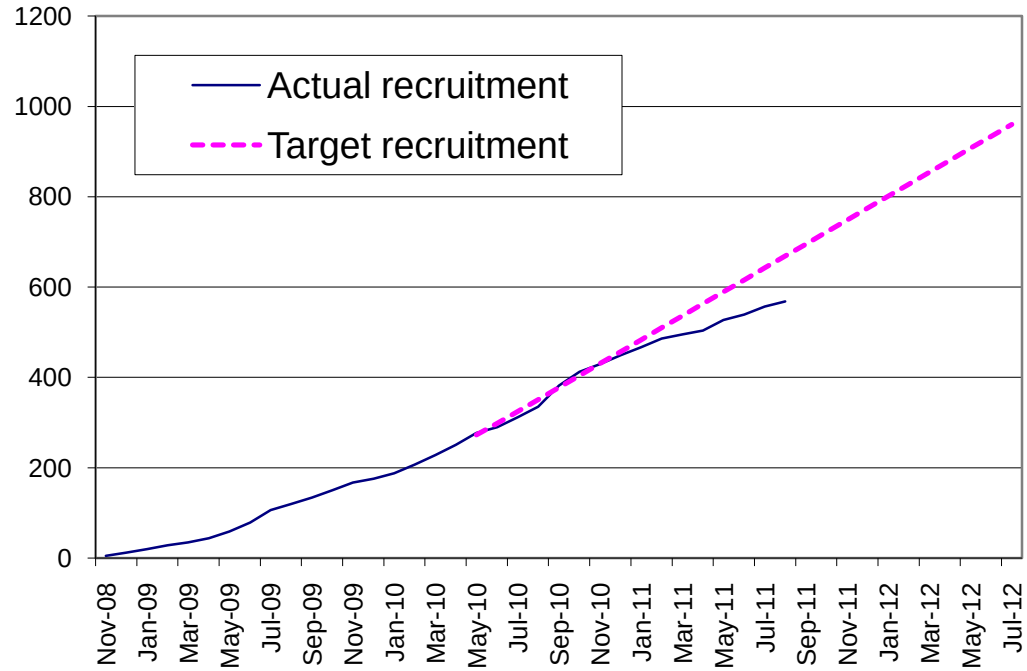


Actual versus target recruitment

original recruitment targets



August 2011 – revised recruitment targets; with extension to recruitment



Recruitment Issues

- Time taken to establish new sites

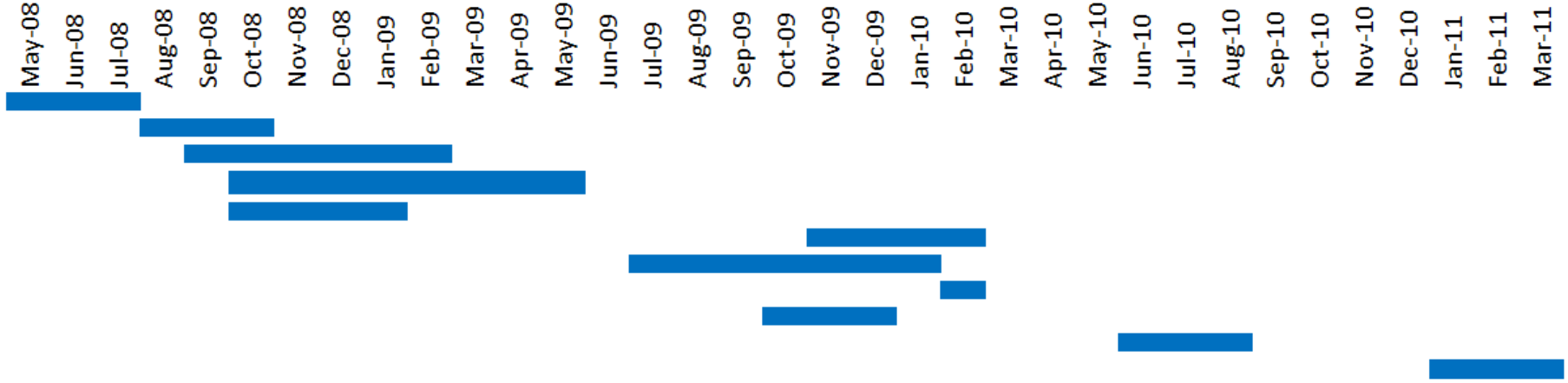
- Rationing by PCTs
- Variation in proportion of patients eligible

- Patient/centre/surgeon preferences

Delays in establishing new sites

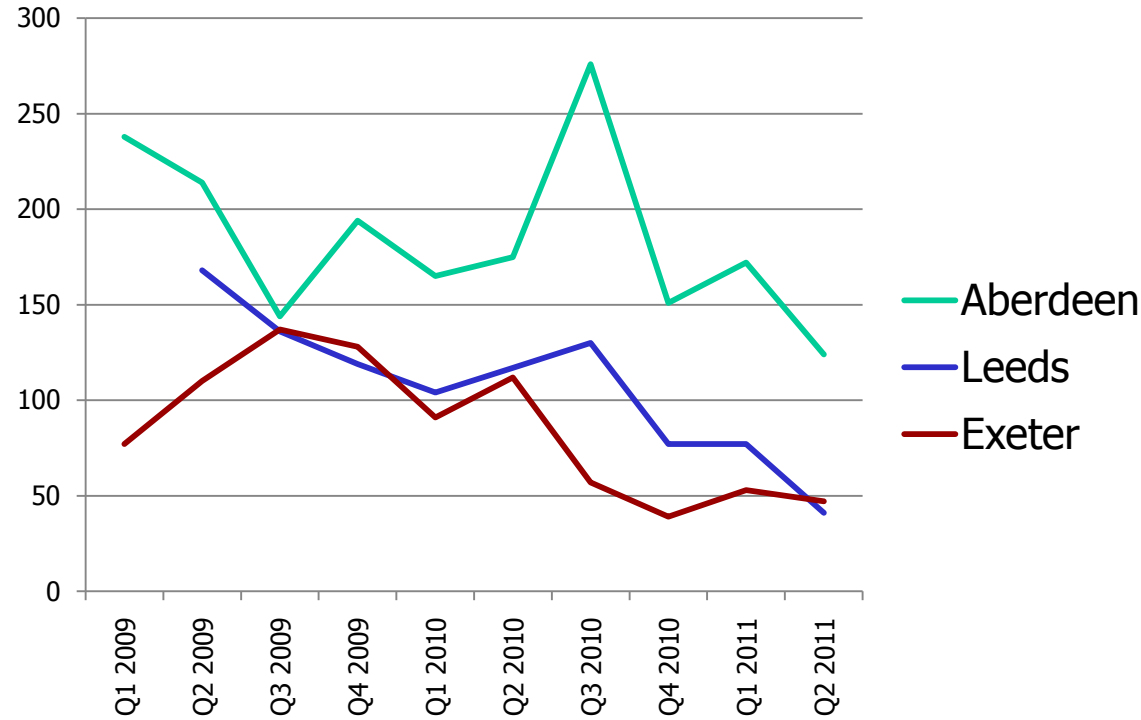
- **Median time for R&D approval: 4 months**
- **Range: 1-8 months**

Time taken for R&D Approval



Changes in PCTs referral practices

- **Number of new patients seen, by quarter, over time**



Clinic log & Patient eligibility

Clinic log

- Total number of patients attending clinic
- Reasons for non-eligibility

Eligibility

48% of screened patients (range 12-72%)

- Variation in case-mix
- different application of eligibility criteria

Non-eligible patients

	Overall	Range
No varicose veins, thread veins, asymptomatic	12%	1 - 18%
No truncal reflux	17%	2 - 38%
Recurrence	23%	17 - 55%

Surgeon bias

Proportion of eligible patients who agree to take part in CLASS, by surgeon within centre (min, max)

Hospital 1	**12.7% - 19.5%**
Hospital 2	**4.7% - 20.4%**
Hospital 3	**2.9% - 55.6%**

Overall – 24% of eligible patients agree to take part

Patient/Centre Preferences

Of those declining to take part in CLASS who express a preference for one of the treatments (%)

Hospital	1*	2*	3	4	5
Preference surgery	43.9	78.1	13.3	65.5	40.4
Preference foam	56.1	20.8	13.3	0.0	6.4
Preference laser	0	1.0	73.3	34.5	53.2

*** Laser not offered by centre**

Qualitative study: audio-recorded recruitment consultations & patient interviews

- **Surgeons**

Balanced presentation of interventions

But: Assumption that patient had preference

Asked patient to take part if no preference

- **Patients**

Many did not express a clear preference

Felt obliged to express a preference

MRCS ConDuCT Hub, Jane Blazeby, Jenny Donnovan, Sangeeth Paramasivan

Summary: recruitment in CLASS

- ↓ in referrals & types of patients referred by PCTs
- Varying surgeon enthusiasm
- Equipoise between centres on treatment received by eligible patients who decline
- Patients reasons for non-participation require further evaluation

CLASS Study Group

- Aberdeen: Paul Bachoo, Marie Balment, Julie Brittenden (Chief Investigator), Jennifer Burr, Marion Campbell, Seonaidh Cotton, Janice Cruden, Tracey Davidson, Jill Frances, Alison McDonald, Gladys McPherson, Euan Munro, Craig Ramsay, Vas Revanur, Michael Sharp, Lynne Swan, Laura Ternent, Luke Vale, Emma Wilson
- Blackburn: Simon Hardy (clinical lead)
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- Exeter: Bruce Campbell (clinical lead), Andrew Cowan, Jackie MacIntyre, Philip Niblett, Linda Park, Audrey Peters, Frank Summers, John Thompson
- Gloucester: David Cooper, Jonothan Earnshaw (clinical lead), Donna Parkin, Caroline Rodd, Julie Stephens
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- Hull: Bankole Akomolafe, Barbara Berry, Dan Carradice, Ian Chetter (clinical lead), Josie Hatfield, Brian Johnson, Peter McCollum, Paul Renwick, Vicky Lowthorpe, Samuel Nehemiah
- Newcastle: Tim Lees (clinical lead), Noala Parr, Lesley Wilson, Vera Wealleans
- Sheffield: Dominic Dodd (clinical lead), Julie Sorrell, Nathanial Mills
- Sherwood Forest: Khalid Makhdoomi (clinical lead), Caroline Wearn
- Worcester: Isaac Nyamekye (clinical lead)