EVRA (Early Venous Reflux Ablation) ulcer trial:

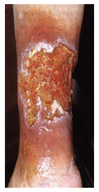
The issues of recruiting to a multicentre trial in patients with venous ulceration

F.Heatley[1], A.W.Bradbury[2], R.A.Bulbulia[2], N.Cullum[2], D.Epstein[2], M.Gohel[2], K.R.Poskitt[2], J.Warwick[2], A.H.Davies[1]

INTRODUCTION

The timing of offering superficial venous intervention to patients, in terms of leg ulcer healing is controversial.

A multi-centre, prospective, randomised controlled trial has been designed to clarify this issue.



METHODS

According to the published literature, the 24-week healing rate in patients randomised to compression alone is approximately 60%. For a meaningful clinical difference it is estimated that a 15% improvement in ulcer healing is required from early intervention.

Patients with a history of leg ulceration between 6 weeks and 6 months in duration, with no significant arterial disease and who are considered suitable for endovenous ablation are randomised to either early endovenous treatment of superficial venous reflux in addition to standard care compared to standard care alone. All patients are examined clinically at 6 weeks, with monthly telephone follow-ups to document resource use and monitor patient safety. 4, weekly ulcer healing verification visits are performed upon notification of healing. Quality of life is measured at baseline, 6 weeks, 6 and 12 months (Figure 1).

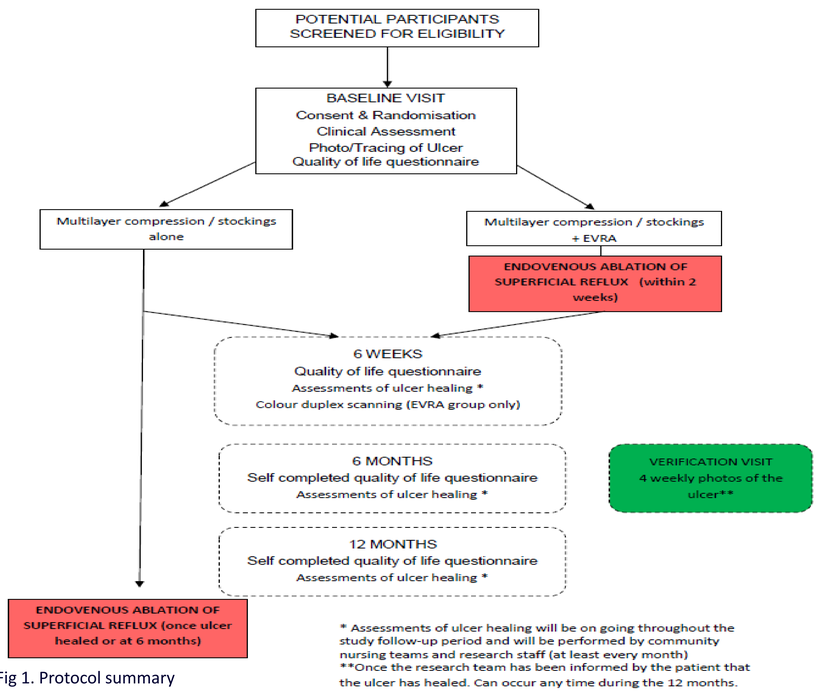


Fig 1. Protocol summary

RESULTS

The primary endpoint of this study is time from randomisation to ulcer healing. Over 4700 patients (51% men; 49% women, mean age 71) have been screened to date (Figure. 2, with a 8% inclusion rate (55% men; 45% women, mean age 68). 30% of patients screened were ineligible with respect to ulcer duration and 6% declined to take part (Figure 3).

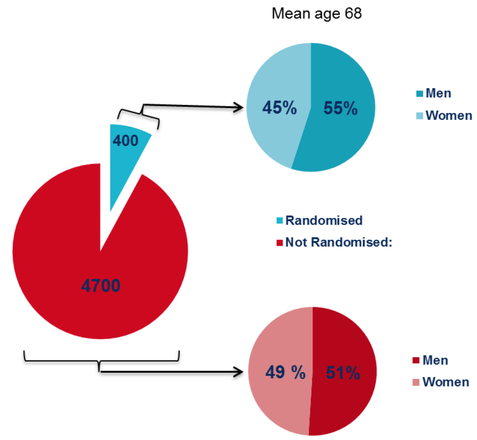


Fig 2. Randomised vs. screened population

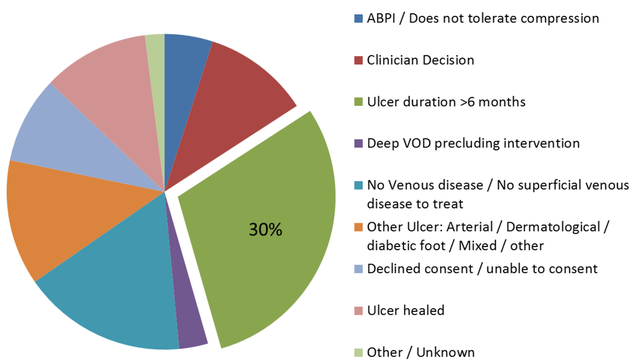


Fig 3. Breakdown of non-randomised population

To date 400 patients have been randomised, the pattern of venous incompetence in these patients was: - 53% had GSV incompetence alone, 12% had SSV incompetence alone and 26% had both GSV and SSV incompetence combined; 28% had evidence of deep venous incompetence (Figure 4). In the early arm, the interventional treatment strategy employed was: - 52% were foam alone, 33% with endothermal ablation alone and 15% by a combination of therapies (Figure 5).

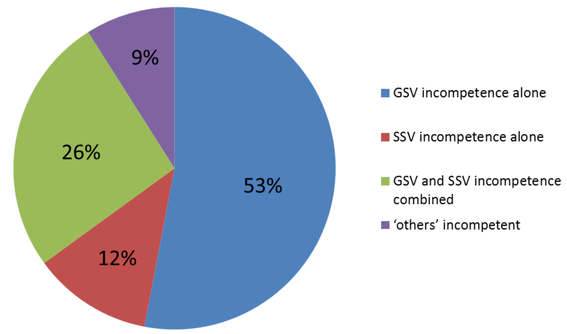


Fig 4. Baseline venous incompetence patterns

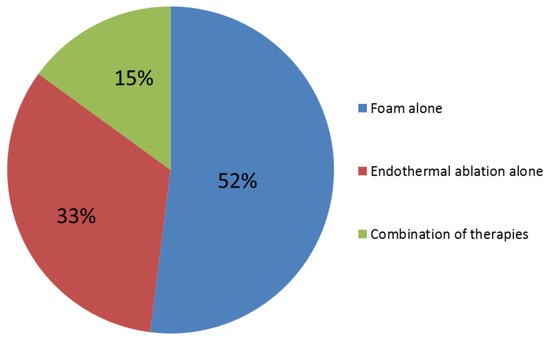


Fig 5. Interventional treatment strategy in the early arm

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CONCLUSIONS

This study will be the first large randomised multicentre trial to report on the clinical, quality of life and cost effectiveness of treating patients with venous ulcers by early superficial venous intervention.

Screening data indicates that patients are not being referred in line with the UK national guidance.

[1]Academic Section of Vascular Surgery, Imperial College London [2]A.W.Bradbury, University of Birmingham; R.A.Bulbulia, University of Oxford; N. Cullum, University of Manchester,; D.Epstein, University of Granada; M.Gohel, Cambridge University Hospitals NHS Foundation Trust; K.R.Poskitt, Gloucestershire Hospitals NHS Trust; J.Warwick, Imperial College, London