

AN INTERVIEW WITH...

Prof. Alun H. Davies

Prof. Davies shares his thoughts on how the recent EVRA trial results will impact patient care and provides a look into how national guidelines are created.



Congratulations on the recent publication and presentation of the EVRA results. Could you please share with us how the trialists determined the endpoints for this trial?

The trialists took part in patient public consultation to determine the endpoints. The key outcome measure that was decided on was freedom from leg ulceration. Various secondary measures were then developed, such as ulcer-free time, quality of life, and the cost-effectiveness of the interventional strategy. A leg free from ulceration is key, as the presence of an ulcer is known to decrease the quality of life of patients and is the principal outcome in most leg ulcer trials.

How should the results from EVRA influence clinical decision-making?

The EVRA trial gives the first level 1 evidence that early intervention on incompetent veins improves leg ulcer healing. This key fact should influence community practitioners to refer patients to a vascular specialist as soon as possible, and following the National Institute for Health and Care Excellence (NICE) guidance, this should be within 2 weeks. The results should change global guidelines so that patients receive improved care that is cost-effective.

As previous Chairman of various guidelines groups, what do you predict will be the impact of EVRA on guidelines, both in the United Kingdom and elsewhere?

As previously mentioned, I believe that these results should update global guidelines so that we are better able to offer patients improved, timely, and cost-effective care. With respect to the Society for Vascular Surgery/American Venous Forum guidance, it should see a change in the recommendation from a 2C recommendation to a level 1.

What is the logical next question for a major randomized trial to explore in the area of superficial venous reflux?

The key questions to be addressed are whether both the truncal and tributary veins should be treated in order to provide symptomatic relief, as well as the optimal treatment modality to accomplish this. The NICE guidelines set some key recommendations for further research. There is also a need to evaluate the management of patients with superficial venous reflux and iliac vein disease.

What trends do you anticipate seeing in the treatment of carotid artery disease in the next 5 to 10 years?

I believe that we will see a further decrease in interventions for carotid artery disease. This decreasing trend has been seen in many countries over the last couple of years. The reason for this may be better medical management and the decrease in smoking prevalence. However, we are not seeing an overall reduction in patients presenting with stroke.

Just after this edition of *Endovascular Today* is published, we will learn the full NICE guidelines pertaining to treatment of abdominal aortic aneurysms (AAAs). Reserving discussion of the recommendations themselves until after dissemination, can you tell us about the process by which these guidelines are generally arrived upon?

The NICE guidelines are written based on the best evidence available, expert input, patient and caregiver involvement, independent advisory committees, genuine consultation, regular review, open and transparent processes, and social values and equity considerations. First, a topic is identified and then NICE appoints a chairman and committee members by open

(Continued on page 105)

(Continued from page 106)

advert. The AAA guideline committee consisted of vascular surgeons, a radiologist, a general practitioner, a care-of-elderly doctor, an emergency department physician, an anesthesiologist, a vascular scientist, a nurse, paramedics (advanced ambulance practitioner), patients (one who underwent open repair and one who underwent endovascular aneurysm repair), as well as a team of NICE expert analysts, health economists, and a statistician (up to 10 individuals).

Next, the key areas for consideration are identified, and these go out for stakeholder consultation and a subsequent caseholders meeting. Stakeholders (eg, Vascular Society, British Society of Endovascular Therapy, British Society of Interventional Radiology, Vascular Anaesthesia Society, industry, public) then identify and approve the key questions. The committee meets regularly to discuss relevant topics and evidence is reviewed. Randomized controlled trial data are key in these discussions, especially outcomes regarding cost-effectiveness at a certain cost threshold. The guideline draft is then released for public/stakeholder consultation. After a final meeting occurs, the guideline is published.

To what degree are comments received during public comment periods considered and incorporated?

All comments from stakeholders are reviewed by the NICE team and are discussed among the guideline committee.

As Editor-in-Chief of the journal *Phlebology*, what is one tip you would share with every potential author before they submit a manuscript to increase the chances for acceptance?

I would recommend that all authors ensure that they have thoroughly read the guidelines for submission and follow them. If there are any questions along the way, you can always direct queries to the editorial office for the best chance at manuscript acceptance. ■

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Disclosures: None.