EDITORIAL

What is the Future for Registries on Endovascular Aortic Aneurysm Repair and Who Should be Responsible?

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A recent article by Mike Wyatt, published in the European Journal of Vascular and Endovascular Surgery,1 has highlighted the important contributions made by EUROSTAR and the UK RETA registries to our understanding of the pitfalls as well as the potential clinical benefits of endovascular aneurysm repair (EVAR) during its early developmental phases. In the decade, since these registries started recruiting patients they have recorded a rapid uptake of the procedure in Europe, despite the absence of definitive evidence of superior efficacy in comparison to the established methods for treating aortic aneurysms. But, this year we have seen further highly notable European contributions to knowledge in this area with publication of the UK EVAR and Dutch DREAM Trial results2,3 and we do now have level 1 evidence in support of EVAR for relatively fit patients. Somewhat counter intuitively, the UK EVAR 2 trial showed no benefit for EVAR over non-interventional conservative management in patients deemed unfit for conventional open repair4 and it would seem that strenuous measures to address their co-morbidities, as effectively as possible, is to be preferred to early EVAR for these individuals.

Given the present state-of-play it is timely to consider the future of the EVAR Registries. Some may question whether they have any useful role at all following publication of the randomised trial results. On the contrary, it is our case that not only do the EVAR registries have a future but that, far from being diminished, their value to the vascular community may be enhanced considerably in the post-randomised trial era. There are three reasons for this. First, there is clearly a need for continued tracking and clinical evaluation of endograft technologies, which may well evolve at an even faster rate given scientific proof of efficacy, which is likely to boost the confidence of industrial companies and encourage increased investment in research and development. Secondly, there are applications of EVAR technology that have not been subjected to the test of randomised trials, for example endovascular repair of thoracic aneurysms and the application of fenestrated and branched endografts for treatment of complex juxtarenal and thoraco-abdominal aneurysms. Endovascular repair of thoracic aneurysms is already well-established treatment, which, by common consent, should probably not be subjected to a randomised controlled trial (RCT) because the perceived benefits over open repair in terms lower operative mortality and morbidity are such that few, if any clinicians are left in any doubt about its advantages, i.e. equipoise does not apply. However, especially in the absence of data from any RCT, careful monitoring of the outcomes of treatment is essential and should probably be a mandatory regulatory requirement. Both EUROSTAR and RETA have ongoing thoracic registries, which must be continued. Thirdly, the dissemination of EVAR as mainstream treatment in most vascular units throughout Europe raises serious issues about quality control. Issues that the registries could, and in our view should, be adapted to address.

Although, the randomised trials have shown statistically significant benefit for EVAR when compared to open repair it is important to appreciate that the margin of benefit was relatively small and attributable, entirely, to a difference in operative mortality rates. There was a survival advantage for EVAR over conventional open repair (OR) of just three percent at 30 days (EVAR 1; 1.7 versus 4.7%). And this
survival advantage was neither enhanced nor diminished after 4 years of follow up. Such a small margin is at risk from being cancelled out by any relaxation of clinical standards, specifically relating to patient selection and technical performance of the procedure itself. Therefore, there are requirements for benchmarking and comparative audit as tools for quality control that are both essential and urgent. The EUROSTAR and RETA registries have always served to provide these to their contributors, but as a secondary rather than a primary function and on a voluntary rather than a mandatory basis.\textsuperscript{5,6}

In the USA, the value of registries for quality control has been recognised and is being acted upon. Both the lifeline EVAR registry and the recently initiated ASVS registry on carotid artery stenting and endarterectomy are being adapted for this function. We propose that EUROSTAR and other European national EVAR registries, such as RETA should be similarly utilised. To render EUROSTAR ‘fit for purpose’ in this context, the following three essential prerequisites will need to be satisfied.

**An Authoritative and Stable Administrative Structure**

To date EUROSTAR has depended entirely upon the efforts and goodwill of a small number of committed individuals, but this arrangement cannot be sustained indefinitely and is, therefore, inherently unstable. Just as the ‘Lifeline’ registry is maintained under the auspices of the American Society for Vascular Surgery, we propose that the EUROSTAR registry should be placed under the governance of the European Society for Vascular Surgery. In our view it would be an asset to The Society by enabling it to offer additional important services to its members, and to the European vascular community at large. RETA, which was established originally under the joint auspices of the British Society for Interventional Radiology (BSIR) and the Vascular Society of Great Britain and Ireland (VSSGBI) has always benefited from some financial and administrative support provided by these national representative organisations.

**Secure Funding**

EUROSTAR currently has two sources of funding; (i) income from contracts agreed with commercial companies in return for the provision of confidential ‘device-specific’ analyses, and (ii) a fee paid by the Belgian RIZIV (Rijksinstituut voor ziekte- en invaliditeitsverzekering) in connection with a contract to maintain the Belgian national EVAR registry. As far as the commercial companies are concerned, it has been possible to agree short-term contracts only and continued income from this source cannot be guaranteed. Also a reduction in the number of companies with commercially successful EVAR products has had negative impact upon the finances of EUROSTAR. The Belgian RIZIV contract terminates early in 2006 and, with it, all income from this source. There is a strong case to be made for continued funding by commercial companies. But, without compulsion, this alone is unlikely to secure the financial stability required. In the USA there are moves, by the Food and Drugs Administration (FDA) to make the commercial companies directly responsible for the funding of statutory data collection. Perhaps similar demands could be made by the regulatory authorities in Europe. The ESVS could give security to EUROSTAR by underwriting financially the registry programme, without necessarily providing direct funding under normal circumstances. Additionally, given its position as a bone fide international EUROPEAN organisation with a large membership representing all EU states, the ESVS could add considerable weight to applications for EEC funding in support of the EUROSTAR programme, which is, after all, a valuable source of specific health care information for European populations.

**Comprehensive and Complete Data Collection**

Because participation in the EUROSTAR project is entirely voluntary, data collection is neither comprehensive nor complete. The best we can hope for is that the data submitted are reasonably representative of practice in European Hospitals as a whole. For effective benchmarking this is not good enough. Data collection needs to be both comprehensive and complete, i.e. all centres undertaking EVAR should be required to submit all relevant data on all eligible patients. Electronic data transmission facilitates this process considerably and EUROSTAR provides this to its contributors. Compulsory data submission is not a universally popular concept and is difficult to enforce. However, it is in the interests of national healthcare systems to ensure that all EVAR data are collected and analysed and perhaps other countries could follow the Belgian example by making verifiable data submission a prerequisite for reimbursement of the procedure. Whether or not compulsion is considered practical universally, the ESVS could do a great deal to influence its members to comply with basic requirements for...
quality assurance through comparative audit by setting and monitoring standards, utilising the facilities of EUROSTAR.

The point about individual countries needing to collect and analyse nationally derived data is an important one. EUROSTAR even under the auspices of the ESVS would have difficulty in servicing this need. In the post-randomised trials era surely those countries that have not done so already will wish to establish a national EVAR registry. National authorities are in the best position to ensure that data collection is as comprehensive as possible, which is an important advantage associated with this approach. One option for meeting everyone’s needs might be for European national registries, like RETA, to be linked through EUROSTAR under the auspices of the ESVS. By this means vascular centres could submit just one set of data that would serve several purposes. Issues of confidentiality and governance, especially in respect of under-performing centres, arise and will need to be dealt with effectively and with appropriate sensitivity. But, these should not be accepted as obstacles to sensible progress.

A recent survey of all EUROSTAR participants revealed that 87% of respondents supported continuance of the programme in the post-randomised trial era. There are many other individuals and organisations around the world, without direct involvement in the programme, who have benefited from it and who also wish to see it continue. Certainly, a change of emphasis is necessary if it is to respond adequately to the challenges of benchmarking and comparative audit that apply today. And, most importantly, it must ‘move on’ in respect of its infrastructure if it is to endure. Early incorporation into the ESVS is possibly the only realistic option for securing a viable future for the EUROSTAR programme.

References


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