A Management Model in Need of Revision

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The United Kingdom of Great Britain and Northern Ireland, which comprises England, Scotland, Wales, and Northern Ireland, has a total population of approximately 60.6 million. The Republic of Ireland, an independent country within the European Union, has a population of approximately 4.5 million. Statistics compiled by BIBA Medical (London, UK) from a regular survey of endovascular and vascular surgical activity in European countries (European Vascular and Endovascular Monitor) indicate that 1,655 endovascular aneurysm repairs (EVARs) and 6,400 open repairs (ORs) for infrarenal abdominal aortic aneurysms (AAAs) were performed within these two countries (The UK and Republic of Ireland) combined during the 12-month period ending September 2006. Because the registry is voluntary and not every vascular clinician contributes, these are likely to be underestimates. After the publication of results from the UK EVAR and Dutch DREAM trials,[1,2] the number of EVARs has increased, and the number of ORs has decreased. But, a large majority of approximately 80% of AAAs is still treated by OR. The annual rate of increase in EVAR activity, at approximately 12%, exceeds the rate of decrease of ORs, approximately 9%, such that the total number of patients treated for AAAs is increasing.

The National Institute for Health and Clinical Excellence (NICE) is the government agency in England that advises on the efficacy of new medicines and interventional procedures. In March 2006, having considered the results of the two European randomized trials, NICE published the following guidance: "Current evidence on the efficacy and short-term safety of stent-graft placement in abdominal aortic aneurysm appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit, and clinical governance."[3] Although this statement officially validated EVAR as a legitimate treatment for AAA in the UK, there has been considerable resistance to its widespread application by those with responsibility for the management of healthcare budgets. They point out that, despite significantly higher treatment costs, neither of the two randomized trials showed any survival advantage for EVAR in the longer term in comparison to standard OR.

Conversely, most clinicians take the view that EVAR should be made available to all relatively fit patients who have anatomically suitable AAAs, on the grounds that the operative mortality risk is significantly lower, and recovery is more rapid compared to OR. Patients who are genuinely too unfit to tolerate OR are generally managed conservatively rather than being offered EVAR, in accordance with the recommendations of the authors of the EVAR 2 trial publication.[4] Although OR is freely available in the UK to all suitable patients with AAA, accessibility to EVAR is limited by financial constraints.

Management of the National Health Service budget is devolved to local primary care teams (PCTs), albeit with instructions to deliver centrally determined healthcare targets that are strictly enforced. PCTs are administrative bodies that represent general practitioners. The concept is that general practitioners disburse public money in the best interests of patients by purchasing secondary care (ie, hospital services) on their behalf. In the UK, all patients are strongly discouraged from consulting medical specialists directly; their general practitioner must refer them. This applies even to those who opt for private healthcare. Therefore, it is local PCTs that have the greatest influence upon who can and who cannot be treated by EVAR. In most cases, some provision has been made for EVAR on a restricted basis, but a few PCTs have simply decided that EVAR is unaffordable. The result is a postcode lottery, whereby access to treatment is determined by the patient's address. Insistence by PCTs that funding for EVAR is applied for on an individual basis

inevitably delays treatment and may result in the advice of the vascular specialist being overturned. Against this background a welcome development, in some parts of the country, is the intervention of regional Specialized Services Commissioning Teams covering an area served by a number of PCTs. By coordinating the actions of PCTs, some of the unintended consequences of local decision-making, including inequality of access to EVAR, may be mitigated.

The Department of Health in England is pursuing an agenda for centralizing hospital services. The aim is to concentrate expensive, high-tech, specialized treatments into large regional centers, rather than to have them dispersed in smaller community hospitals. This policy is justified by the aim of improving the standard of care based on growing evidence of a direct relationship between throughput and clinical outcomes. However, there are strong financial drivers also related to the need to secure maximum returns from investment in expensive equipment and personnel. In keeping with this policy, there is pressure for EVAR to be concentrated into a relatively small number of high-volume centers. The result is that vascular specialists working in smaller district general hospitals are required to refer patients to a center for EVAR rather than undertaking the treatment themselves.

The regulatory authority with responsibility for control of aortic endografts for AAA repair in the UK is The Medicines and Healthcare products Regulatory Agency (MHRA), which implements European Community (EC) Devices Directives into UK law and is a government agency similar to the FDA. Medical devices are approved by private sector organizations called *Notified Bodies.* Their approval is needed before a CE (Conformité Européenne) mark can be put on a device. The MHRA audits the activities of Notified Bodies.The MHRA also monitors adverse events relating to the clinical application of clinical devices, including aortic stent grafts, and publishes reports and guidance for the information of stakeholders—clinicians included. This system of approving medical devices for commercial exploitation in the UK, and other countries of the European Union, seems to be substantially less rigorous than that employed the FDA in the US. Commercial companies can register products for a CE mark themselves. As a result, new endografts tend to become available for clinical use in Europe earlier than in the US, and vascular specialists in Europe have freer access to a wider range of endografts than their American colleagues. CE-marked endografts available for purchase in the UK include Anaconda (Vascutek, a Terumo company, Glasgow, Scotland), Aorfix (Lombard Medical Technologies, Oxford, UK), Endofit (Endomed Inc, Excluder (Gore & Associates, Flagstaff, AZ), Fortron (Cordis Corporation, a Johnson & Johnson company, Miami, FL), Powerlink (Endologix, Inc., Irvine, CA), Talent (Medtronic Inc., Minneapolis, MN), and Zenith (Cook Medical, Bloomington, IN). Currently, Zenith has a substantial marketlead, with Talent some distance behind.

Although approximately 8,000 people are treated for AAAs in the UK each year, a similar number die from previously undiagnosed ruptured aneurysms. This sad statistic is a clear indication that our approach to the management of AAAs needs radical revision. The UK is certainly not unique in this respect; the number of deaths from undiagnosed AAAs equals or exceeds that of elective operations in all similar Western countries. There is good evidence to indicate that population screening for AAAs could reverse this situation,[5] and the Department of Health in England has signaled its intention to introduce a national screening program within the next year or two. Scotland and Wales are expected to follow suit. As yet, the role of EVAR in the management of screening-detected AAAs is unclear. However, recent data from the UK EVAR and Dutch DREAM trials,[1,2] suggest that relatively fit patients benefit most from endovascular treatment, and, because the majority of the screened population is likely to fall into this category, it can be anticipated that the introduction of screening will result in a substantial increase in demand for EVAR.

At present, only 20% of patients with infrarenal AAAs are treated by EVAR in the UK. Yet data from the UK EVAR 1 study indicate that approximately 55% of the patient population have AAAs that are anatomically suitable for treatment by this approach according to accepted criteria. The discrepancy between these figures can be explained only by the restrictions placed upon the availability of EVAR within the UK healthcare system. And, if present financial constraints were lifted, it is likely that the number of procedures undertaken would double within a very short space of time. Given the present parlous financial state of the National Health Service, it is unlikely that this will happen in the immediate future. ■

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