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A look at what the United States and the United Kingdom can learn from each other, how to interpret the clinical trial data, and making endovascular technology more cost-effective.

How did you become involved with the project to review the provision of cardiovascular care and trauma care in London? What progress has been made so far?

Research into the outcomes of complex surgical procedures has suggested that the volume outcome relationship is crucially important. Widespread and robust evidence suggests that these complex procedures, of which major trauma and aneurysm surgery are good examples, are best performed in units that have exposure to a critical mass of cases. I believe that clinicians should be at the heart of service reorganization because there are huge opportunities in this field to improve the care of our patients. After a review of health care services in London carried out by Lord Darzi, Healthcare for London established a series of projects to look at different facets of health care and to suggest ways in which services may be delivered in a more effective way. I was lucky enough to be invited to be the clinical lead for the major trauma project that aimed to define a case for service change and then designated four major trauma centers in London. This was a great opportunity to work with a multidisciplinary project team and streamline the care of patients with major trauma in London. This project delivered a successful case for change and has now established a system of trauma care in London based on four networks. The system went live in early April, and we hope to see an improvement in outcomes over the next few years.

After the trauma project, I was asked to lead a review of complex cardiovascular services in London. This project, supported by a similar team, was given a broad remit to look into the delivery of cardiology, cardiac surgery, and vascular surgery in London. All of these specialties had their own clinical leads with Professor Nick Cheshire of Imperial College leading the vascular work stream. The project's findings were similar to that of the major trauma project, with complex surgical procedures being delivered in too many small-volume units. The case for change review has been published (www.healthcareforlondon.nhs.uk), and some recommendations for next year have been accepted (minimum volume criteria for aneurysms, lower limb revascularization, and carotid surgery, respectively, at 50, 40, and 30 per annum). The plans for future reconfiguration of cardiovascular services will be published after the UK general election.

Given the differences in the health care systems of the United Kingdom and the United States, and the resultant differences in their respective clinical trial designs, what advice do you have for physicians on both sides of the pond in interpreting and applying each other's trial data?

Interestingly, I was at the Society for Clinical Vascular Surgery in April discussing the health care systems of the US and the UK. Although the systems are different, there is a degree of commonality, and the similarities appear to be growing with health care reform on both sides of the Atlantic. The majority of clinical trials that have been performed in the last few years have delivered results that are similar whether from the UK or US. For example, the ADAM trial and the UK Small Aneurysm trial essentially delivered the same message, as did EVAR-1 and the OVER trial. Fundamentally, this set of randomized investigations gave the same broad message. Obviously, interpretation of trial data is likely to be different depending on your philosophy and in which health care system you practice. It is important to remember that randomized trials very rarely provide a single answer, but the best trials provide a set of robust data to guide practice.

What are your thoughts on these trials' conclusions about the relative cost-effectiveness of open versus endovascular repair?

I was a clinical advisor on behalf of the British Society for Endovascular Therapy to the National Institute for Health and Clinical Excellence's Health Technology Assessment (HTA) investigation of endovascular repair for the treatment of abdominal

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aortic aneurysms (AAAs). I thought the conclusions of that appraisal (that concluded that endovascular repair was cost-effective) were reasonable and took into account the likely improvements in endovascular practice that are likely to be apparent in the next few years. I believe that endovascular repair is now widely accepted to be cost-effective, but it remains likely that practice needs to improve in order to make the technology safe from any restriction in the future.

There are several areas in which endovascular practice can improve to make the technology much more cost-effective. These areas would include a reduction in the reintervention rate due to better intraprocedural imaging and better case and endograft selection; a reduction in the rate of aneurysm-related death due to better surveillance protocols, better medical management, and better indications for reintervention; and a reduction in hospital cost, which might be achieved by reducing hospital stay by total percutaneous access and fast-track protocols. These are all areas in which practice can improve to make the technology more cost-effective.

What is the current focus of your own clinical research?

The St. George's Vascular Institute integrates clinical, research, and educational activities within a single organizational structure across St. George's Hospital Healthcare NHS Trust and St. George's University of London. Our research activities may be divided into basic science and clinical investigations and is focussed on aortic aneurysms. There are four main research groups within the Institute: a basic science group, a clinical trials group, a health outcomes research group, and an endovascular group (key investigators, Mr. Ian Loftus, Dr. Gillian Cockerill, Mr. Peter Holt, Mr. Robert Hinchliffe, and Dr. Rob Morgan).

With regard to clinical research, the outcomes group is concerned with investigating the optimum configuration for the delivery of clinical services in the UK and defining risk stratification scores for patients undergoing endovascular therapy for AAA or thoracic aortic aneurysm. In the last few years, this group has published extensively on the relationship between caseload and surgical outcome and has defined the evidence for current models of clinical care. At present, there is a considerable focus on defining subgroups that have disparate outcomes with endovascular techniques. These data will then be used to formulate scoring systems.

St. George's Vascular Institute has one of the largest endovascular practices in the UK. Research underpins this practice with contemporary investigations into

endovascular repair of infrarenal aneurysms, thoracic aortic disease, and fenestrated graft technology. There is an ongoing program of research that at present is focusing on quality control during endovascular procedures, the indications and results of treatment for thoracic dissections, and hybrid procedures for aortic arch and thoracoabdominal aneurysms. I am one of the lead clinicians for the HTA-funded IMPROVE trial, which will define the role of endovascular therapy in the treatment of ruptured aneurysms. I also act as principal investigator for the VIRTUE study, which investigates type B aortic dissection.

Which advances do you believe are the most necessary in abdominal and thoracic endovascular aortic repair technologies?

My current opinion is that the available endovascular devices for aortic and thoracic endovascular repair are in different stages of evolution. With endovascular repair for AAAs, there have been a significant number of graft design changes, but most manufacturers now have a settled endograft, which has been shown to perform well in the long term. One of the biggest challenges facing endovascular repair for AAAs is to define the patients and the types of aneurysm morphology that predict good and poor outcomes. I suspect that the best results for a population of patients with AAAs will be obtained by a mixture of open and endovascular procedures, with the endovascular technique being used in the vast majority. Risk stratification and subgroup analysis of the large trials and registry data will provide good data that should allow us to stratify patients by their physiological characteristics and aneurysm morphology. A scoring system that allows outcome prediction with open and endovascular techniques is overdue and should be achievable with appropriate data modeling.

In addition, I believe that we need to work hard to define the optimum follow-up regimen for patients with endovascularly treated AAAs. At present, most patients go on the same follow-up protocols, and there is a degree of inconsistency as to ultrasound and computed tomography usage. If endovascular repair is going to become truly cost-effective and widely accepted by patients, we need rational follow-up protocols. This must be done by analysis of long-term data and risk stratification.

Obviously, there will be a number of technological improvements in endovascular repair for AAAs, and I think this will include lower-profile devices and "off-the-shelf" fenestrated grafts.

With regard to thoracic endovascular repair, I believe that the grafts are still in evolution. There have been considerable improvements in the current iteration of thoracic endografts, with W. L. Gore & Associates, Cook Medical, and Medtronic, Inc., all recently releasing new and improved graft iterations. However, there still appears to be a gap between the available technologies and the pathologies treated in the thoracic aorta. It seems inevitable that pathology-specific devices will be required in the long term, as the essential graft characteristics must differ between a thoracic aneurysm and an acute type B dissection. Additionally, branch technology is required for the arch vessels, although this will pose a formidable challenge due to the difficult hemodynamics and movement in this region.

How would you describe your treatment paradigm for patients with acute type B thoracic dissection? How have the results of studies such as INSTEAD and IRAD, as well as your work in the VIRTUE registry, had an impact on your paradigm?

I think that endovascular technology has revolutionized the treatment of patients with acute type B dissection. In our practice, all patients with a complicated acute type B dissection are considered for treatment with an endograft, with the selected use of a specialized dissection device (bare stent) if they have signs of malperfusion. I think that this practice is well accepted, and I cannot see that open surgery should be considered any more for this condition in the overwhelming majority of cases.

The more difficult area is treating patients with uncomplicated dissection or patients with a chronic dissection. For uncomplicated acute dissection, the clear need is to be able to identify patients at high risk of progressing to complications or to a rapidly expanding chronic dissection. If we were able to identify these patients during their acute presentation, we would be able to offer treatment in the acute phase of the disease when the aorta is capable of remodeling. This sort of information should come out of the current trials investigating aortic dissection: INSTEAD, ADSORB, and VIRTUE, in which subgroup analysis should allow identification of the patients at high risk of rapid disease progression.

At present, one of the knowledge gaps in the endovascular treatment of dissections is the long-term outcome of patients treated for chronic dissections using endovascular techniques. The reports in the literature are quite mixed, and I am not sure at present that endovascular repair of chronic dissections is widely accepted as an effective technique. Further information regarding chronic dissections should come from VIRTUE and other long-term trials. ■