A Decade of Endovascular Abdominal and Thoracic Aortic Aneurysm Repair

Medtronic devices and their contribution to the evolution of a therapy.
100,000 patients treated globally.

In recognition of the clinicians who helped make this milestone in EVAR possible, thank you from Medtronic.
INTRODUCTION

Physicians worldwide have now been treating aortic aneurysms using Medtronic, Inc. (Santa Rosa, CA) endovascular devices for over a decade, with more than 100,000 patients treated. This special edition to *Endovascular Today* shares some of the results from clinical trials and registries, technological advances, and techniques that have been developed along the way to address the many demands of abdominal and thoracic aortic disease.

The authors who have contributed to this edition are some of the most experienced vascular surgeons in the world, and their work illustrates not only the progress that has been made, but also the continued excellence that can be expected in the future.

CONTENTS

4 **Ten Years of Endovascular Aneurysm Repair**  
   By Juan C. Parodi, MD

6 **The Medtronic Talent™ and Valiant Devices**  
   By Ronald D. Fairman, MD

9 **Multicenter Results of the Talent™ Thoracic Device in All Comers**  
   By Rossella Fattori, MD, for the Talent Thoracic Retrospective Registry Investigators

11 **European Experience With the Medtronic Valiant Thoracic Endograft**  
   By Matt Thompson, MD, FRCS; Stella Ivaz, MBBS; Rob Morgan, FRCR; and Ian Loftus, MD, FRCS

16 **An Overview of Hybrid Procedures for TAAAs**  
   By Andrew M.T.L. Choong, MB BS, MRCS; Robert E. Brightwell, BM, MRCS; and Nicholas J.W. Cheshire, MD, FRCS

20 **EVAR Device Evolution**  
   By Peter Harris, MD, FRCS, and Richard McWilliams, FRCS, FRCR

24 **EVAR Treatment of Ruptured AAAs and TAAS**  
   By Manish Mehta, MD, MPH; John B. Taggert, MD; Andreas Spirig, MD; Yaron Sternbach, MD; R. Clement Darling III, MD; Kathleen J. Ozsvath, MD; Sean P. Roddy, MD; Paul B. Kreienberg, MD; Philip S.K. Paty, MD; Benjamin B. Chang, MD; and Dhiraj M. Shah, MD

29 **Impact of Recent Trial Data**  
   By Gregorio A. Sicard, MD
Ten Years of Endovascular Aneurysm Repair

Where we began, how the procedure has evolved, and what the future holds.

BY JUAN C. PARODI, MD

In 1976, when I was a resident at the Cleveland Clinic and began treating vascular disease, open surgical repair was the only means of treating abdominal aortic aneurysms (AAAs). Although the surgical treatment was very effective, it was also quite invasive, and considering that aneurysms are usually found in older and often more debilitated patients, many of them did not tolerate the procedure well. Even in an institution with much experience treating aneurysms, the complication rates were not very encouraging. For these reasons, I wondered if there was a way to offer a less invasive treatment for this condition.

I noticed that the arteries of aneurysm patients were often larger than normal, and I hoped there was some way we could use this advantageously in their treatment. One possibility was to compress a graft into a tube, and place it in a retrograde, catheter-based fashion from the femoral artery using the Seldinger technique. To replace the surgical suture, I envisioned using a metal component, which I called a cage, to keep the graft in position. I thought about using a friction seal with an oversized metal cage, perhaps with some small metal barbs also.

I presented this idea to my boss, and he thought it was interesting. With his encouragement, I began to construct very primitive prototypes in our engineering department. I started by welding together two pieces of stainless steel wire and covering it with Dacron graft material. I began conducting animal experiments in 1988, attempting to place the graft into the aorta using a large tube.

In the beginning, nothing seemed to work properly. This was primarily because I was not using a nose cone to facilitate introduction, and I had great difficulties advancing the tube into the aorta from the groin. In some cases, I ended up just opening the aorta and placing the graft inside. Although the first series of tests was not necessarily successful, in performing them, it became clear to me that with further development, this procedure would be possible. As the testing continued and modifications were made to the device and my technique, the results improved, and the follow-up was very encouraging.

THE FIRST PATIENT

I treated the first endovascular aneurysm repair (EVAR) patient in September 1990. He was referred to me by the president of Argentina, who had learned that I was doing animal studies, attempting to treat this condition with a minimally invasive procedure. The patient’s general condition was very poor; he had significant back pain and severe COPD. When I showed him the before and after pictures from the previous procedures I had done, he was very confident, but when I told him that the pictures were not from human beings, that they were dogs, he was a little disappointed. I told him that I had not yet done any human studies, and that if he accepted, he would be the first.

After some trepidation, he consented, and we performed the procedure. I invited Julio Palmaz, MD, to be in the room with me. Amazingly, the procedure went very well. I will never forget that on that same day, we performed an open surgical repair on another aneurysm patient. After both were complete, Dr. Palmaz and I went to dinner. When we returned to the hospital to check on the patients, the patient who had undergone the endovascular treatment was having dinner, and the surgical patient was still intubated. Seeing this, I said to Dr. Palmaz, “We don’t have any evidence that this is going to work, but if it does, there will be a revolution in the treatment of aneurysms.”

RESISTANCE TO CHANGE

After the success of the first several procedures, I attempted to publish a paper summarizing my work in the Journal of Vascular Surgery, but it was rejected. They thought that it was a crazy idea, and one of the editors even expressed anger with me. He asked me why we needed this procedure when we already had a perfect treatment for aneurysms. I was disappointed, but not discouraged, and I continued to perform cases and collect information. Finally, I presented my results at a meeting, where John Bergan, MD, told me that he very impressed; he asked me to submit my paper to the Annals of Vascular Surgery. I did, and it was published in 1991.

A TURNING POINT?

This publication made a big impact in the vascular com-
munity. I received letters from all over the world, with physicians from many countries expressing mixed opinions on the new procedure. In a way, I think this was a very important transition milestone for vascular surgery. At that time, angioplasty and procedures involving the Seldinger technique were being performed only by radiologists, and stenting had only just come about in 1990 and was not yet a part of regular clinical practice. For a large number of vascular surgeons, the publication of this new method for treating aneurysms was a sign of things to come, and perhaps that we needed to change the way we viewed the treatment of vascular disease.

Although there was some resistance, I think the fact that this procedure was developed by a vascular surgeon helped make the concept of endovascular aneurysm repair more palatable to other vascular surgeons. If the article had been written by a radiologist, its acceptance might have been quite different. At that time, many vascular surgeons were ignoring the validity of the radiology literature, with some even refusing to accept angioplasty as a possible treatment option.

Industry acceptance of EVAR took some time as well. It was 4 or 5 years after the publication before a commercially made endograft was ready to be entered into clinical trials. All of the companies who were interested in manufacturing a stent graft called me, and I tried to help them by showing them our failures and the way to solve them. One mistake I made was establishing an exclusive partnership with one of these companies, under which I was not free to be a consultant or partner with any other company. The relationship turned out to be a failure, and to make matters worse, it immobilized my ability to help develop this technology for several years. It would have been much more productive to collaborate with several groups during that early period.

COLLABORATION FOSTERS EVOLUTION

The initial stent graft systems were very large in profile and rigid by today’s standards. The industry did a great job in improving the technology, evaluating initial problems, and coming up with solutions. It was very encouraging to see the devices evolve and develop due to the collaboration of physicians and industry. As a result, today we have several systems that have lower profiles and are much more flexible.

Advances in imaging have also been a crucial factor in making endovascular aneurysm repair into a first-line therapy. Especially with complex cases involving difficult anatomy, it is clear that highly sophisticated, reliable imaging and innovations such as 3-D reconstruction have allowed us to accurately measure angles and dimensions, ensuring proper device delivery.

Today, EVAR has been shown by level 1 evidence to be comparable to, and even have advantages over open surgical repair. There is still a place for surgical repair in some cases, but in the near future, we will be treating 80% to 90% of our patients using EVAR. In fact, many of the larger centers that have more EVAR experience are already treating at approximately this percentage. This trend has increased due to patient preference and also the growing experience of clinicians. Even the most complex aneurysms and difficult cases, such as ruptures, are now being successfully treated endovascularly.

Endovascular repair has also become a widely accepted treatment for thoracic aortic aneurysms. In relative contrast to the surgical alternative for abdominal aortic aneurysms, open repair of thoracic aortic disease is associated with significant morbidity and mortality, high complication rates, and prolonged hospital stays. Over the past several years, clinical trials have shown the dramatic benefit of endovascular repair over open surgery in these areas, and many physicians have embraced the endovascular alternative, as have their patients.

There is, of course, still room for enhancements that will further enable us to treat patients with difficult anatomies. In the future, we hope to have lower-profile systems and perhaps the ability to modify the axis of devices during the procedure to better treat short, angulated necks. New concepts for addressing fixation issues are also currently being explored.

NEW DIRECTIONS

The future of EVAR is very promising. For many years, the debate has focused on open surgery versus EVAR, but soon, I believe it will be EVAR alone versus EVAR plus biological treatment, which I believe will be the next step in treating aneurysmal disease. In performing mechanical treatments, we have learned a great deal about the mechanisms of aneurysmal formation and growth, and in the near future, this knowledge will likely be a critical element in how we treat it.

This is an exciting time in the history of EVAR. Many significant milestones have already been reached, including the 100,000th patient to be treated using an EVAR device manufactured by Medtronic, Inc. (Santa Rosa, CA). Medtronic has been the industry leader, with its AneuRx device as the first product to be approved for use in the US. I had the honor of collaborating with Tom Fogarty, MD, in the early stages of designing that stent graft, and it has been a pleasure to see how the line of devices has improved since that time. The company has continued to work hard to innovate, with the ultimate goal of providing physicians and patients with the ideal device. I congratulate Medtronic on this achievement, and I thank the company for its commitment to endovascular aneurysm repair.

Juan C. Parodi, MD, is Professor of Surgery at the University of Miami, in Miami, Florida. He has disclosed that he is a stockholder in ArteriA. Dr. Parodi may be reached at (305) 585-5284.
with the recent completion of enrollment in the three arms of the VALOR trial (Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms), Medtronic, Inc. (Santa Rosa, CA) introduced into US clinical trials their next-generation thoracic aortic endovascular stent graft, called the Valiant device. This technology has already been introduced in Europe and has become widely accepted. The Talent stent graft system evaluated in the VALOR trial has been used extensively outside the US for many years. In addition, physicians have gained considerable experience with the Talent stent graft since the feasibility phase 1 high-risk trial was performed in the US in 1998. The evolution of the Talent stent graft to the Valiant design is a result of accumulated feedback from thousands of implants worldwide.

DESIGN EVOLUTION

Engineers at Medtronic have enhanced both the delivery system and the stent graft itself, creating a product that promises to be vastly superior to the original Talent stent graft. The original Talent stent graft was the first endovascular device available to treat thoracic aortic pathology when we began our thoracic endovascular program at the Hospital of the University of Pennsylvania in 1998. The customization features of the first-generation Talent device presented us with our first opportunity to offer novel endovascular options to patients who were being managed with “watchful waiting.” The preliminary outcomes in our first 50 patients using the early Talent design were largely extraordinary. Minor changes to that original Talent device culminated in the Talent Stent Graft System used in the VALOR trial (Figure 1). The system is composed of a preloaded stent graft and the CoilTrac delivery system. For the purposes of the VALOR trial, the delivery system was redesigned without the balloon in the tip. This change was made based on previous clinical trial experiences. Elimination of the integral balloon served to reduce the potential for kinking, thereby reducing the deployment forces. The implanted Talent Thoracic endoprosthesis is composed of a polyester graft fabric sewn to a self-expanding nitinol wire frame. The design concept is modular and, although the Talent Thoracic stent graft has been viewed as a customized device, only catalog sizes were available in the VALOR trial. Proximal and distal stent graft diameters range from 22 mm to 46 mm, and the total covered length of the device ranges from 112 mm to 116 mm. Bare Spring (proximal device diameter <24 mm) and Freeflo (proximal device diameter >24 mm) configurations are available proximally, which have a terminating spring without fabric coverage. Bare spring configurations are also available distally. Both proximal and distal bare spring configurations allow for crossing the great vessels of the arch and the celiac artery respectively. An accessory Reliant stent graft balloon, packaged separately, is intended for use after stent graft deployment to facilitate modeling of the covered springs and to remove fabric pleats from the graft material.

THE VALOR TRIAL

The VALOR trial is a prospective, multicenter, nonrandomized evalua-
tion of the safety (rate of “all-cause” mortality) and efficacy (successful aneurysm treatment at 1 year) of the Talent Thoracic Stent Graft System when used in patients with thoracic aortic aneurysms (test arm). The test arm consists of patients diagnosed with thoracic aortic aneurysms that are considered candidates for open surgical repair, whom are low-to-moderate risk based on SVS/ISCVS criteria. Additionally, two observational treatment group registries were conducted concurrently, serving to record descriptive information that may serve as the basis for future clinical investigations. The registry and high-risk arms include patients diagnosed with dissections, traumatic injury, pseudoaneurysms, and aneurysms without a distinct proximal or distal aneurysm neck of 20 mm or greater in length.

Although there were 40 active sites in the VALOR trial, eight sites in the US trial enrolled 57% of the test group patients and 66% of the high-risk/registry arm. At the time of this trial, thoracic stent grafting was performed largely in a handful of centers. Most of the pathology treated throughout all arms of the trial consisted of fusiform or saccular aneurysms; in the high-risk arms, this pathology was present in 76% of the patients enrolled. The demographics revealed that 40% of the patients enrolled were females, a percentage not dissimilar from the phase 2 multicenter trial of the Gore TAG (Gore & Associates, Flagstaff, AZ) thoracic endoprosthesis. With a greater percentage of female patients compared to abdominal aortic aneurys-

<table>
<thead>
<tr>
<th>TABLE 1. COMPARISON OF THE TALENT AND VALIANT STENT GRAFTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Features</strong></td>
</tr>
<tr>
<td>Diameters available</td>
</tr>
<tr>
<td>Graft material</td>
</tr>
<tr>
<td>Suture</td>
</tr>
<tr>
<td>Body spring</td>
</tr>
<tr>
<td>Body spring attachment</td>
</tr>
<tr>
<td>Connecting bar</td>
</tr>
<tr>
<td>Proximal end configurations</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Distal end configurations</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Proximal radiopaque markers</td>
</tr>
<tr>
<td>Distal radiopaque markers</td>
</tr>
<tr>
<td>Sterilization method</td>
</tr>
</tbody>
</table>
mal disease, issues of iliac access assume critical importance. In the VALOR trial, surgically placed conduits were necessary in upward of 15% of patients, demonstrating the need for delivery systems smaller than 22 F to 25 F (outer diameter). The bare spring or Freeflo proximal design and the availability of stent graft devices with diameters as large as 46 mm opened the door to endovascular thoracic aortic options for a broader range of patients in VALOR than with any other industry-sponsored thoracic device trials (Figure 2). Due to device sizing constraints based on thoracic aortic anatomy, 35% of the patients treated with the Talent Thoracic stent graft in the high-risk arm of VALOR could not be treated with any other industry-sponsored device. The preliminary results of the high-risk arm were presented in June, 2005, at the Vascular Annual Meeting in Chicago.

OBSERVATIONS

The Talent thoracic experience has resulted in many consistent observations that are relevant to not only the Talent Thoracic device but to all endovascular therapies in the thoracic aorta. Although rigid stent grafts can function well in the abdominal aorta, flexible designs that conform to the aorta are paramount in the thoracic aorta (Figure 3). Thoracic devices need to conform to the aortic arch and the tortuosity inherent in the atherosclerotic thoracic aorta. Although one can accurately deploy a Talent thoracic device in the proximal descending thoracic aorta, controlled deployment in an angulated arch or in an area of marked tortuosity is difficult. These issues are addressed with the Xcelerant delivery system (Figure 4), which has been available to physicians in the US for the AneuRx AAA stent graft and has been modified for the Valiant device. The new thoracic version of the delivery system has a slightly smaller profile than CoilTrac (and tapers near the handle) and allows for controlled, ratcheted, precise deployment. Stabilization of the delivery system when deploying in the arch is of fundamental importance in preventing embolic stroke. To optimize ease and accuracy of deployment and conformability, the long connecting bar of the Talent Thoracic device has been removed in Valiant, while columnar support has been optimized through stent spacing in the exoskeleton. The removal of the connecting bar has eliminated the need to orient the device in vivo and results in improved flexibility. The proximal uncovered bare spring has been increased from five to eight peaks, which distributes the force of the spring over more apexes, and the proximal stents have been inset into the fabric slightly to reduce radial flare. Experience to date has shown that this change results in more stable deployment, which may prevent the rare instances of “bare spring flip” observed when deploying in an extremely angulated arch.

Furthermore, longer stent grafts are particularly desirable when treating most pathology in the thoracic aorta. The great majority of thoracic aortic conditions require stent graft coverage of up to 200 mm. Although shorter stent grafts are fine for treating focal disease processes such as penetrating ulcers, transections, or saccular aneurysms; in most instances we are treating fusiform longer segments of disease. Longer endografts result in fewer modular junctions and fewer passes of large delivery systems through small diseased iliac arteries.

CONCLUSION

It is consistently observed that it is difficult to identify proximal and distal aspects of modular components once inserted. The new Valiant device has distinct “figure eight” radiopaque markers proximally and “zero” markers distally that provide enhanced visibility and result in more precise overlap at modular junctions. The Talent Thoracic and Valiant devices are compared in Table 1. Although the preliminary outcomes of the VALOR high-risk arm using the Talent Thoracic Stent Graft System are encouraging and reveal high procedural success in the setting of low operative mortality, stroke incidence, and paraplegia rates, enhancements in stent graft design are evolving. The delivery system and stent graft changes culminating in the Valiant design will allow more precise placement of endografts and should further reduce deployment-related complications.

The VALOR test arm is now in the follow-up phase, and the PMA will be filed with the FDA very soon. Medtronic is currently initiating their US clinical trial using the Valiant Stent Graft System.

Ronald D. Fairman, MD, is Chief, Division of Vascular Surgery, University of Pennsylvania Medical Center, Philadelphia. He has disclosed that he receives research funding from Medtronic. Dr. Fairman may be reached at (215) 614-0243; ron.fairman@uphs.upenn.edu.
Multicenter Results of the Talent™ Thoracic Device in All Comers

A summary of the Talent Thoracic Retrospective Registry’s procedural results and mid-term and long-term follow-up data from 457 consecutive patients undergoing emergent or elective endovascular thoracic aortic repair.

BY ROSSELLA FATTORI, MD, FOR THE TALENT THORACIC RETROSPECTIVE REGISTRY INVESTIGATORS

This article is an adapted summary of “Results of Endovascular Repair of the Thoracic Aorta With the Talent Thoracic Stent Graft: The Talent Thoracic Retrospective Registry,” which was originally published in The Journal of Thoracic and Cardiovascular Surgery in August 2006. Please see the original publication for a full review of the data from the Talent Thoracic Retrospective Registry.

In an effort to collect mid-term and long-term follow-up data for patients undergoing endovascular treatment of thoracic aortic disease, the Talent Thoracic Retrospective Registry (TTR) commenced in November 2004. Early results from previous studies of thoracic endovascular repair compared favorably with those of open surgery, but prior to the TTR, few mid-term or long-term data for thoracic endovascular repair are yet available.

The TTR enrolled 457 consecutive patients who underwent endovascular thoracic aortic repair using the Talent Thoracic Stent Graft (Medtronic, Inc., Santa Rosa, CA) at seven European referral centers between November 1996 and March 2004. Postprocedural follow-up took place over 24±19.4 months (range, 1-85.1 months).

PATIENT CHARACTERISTICS

Of the patients included in the study, 113 were emergent cases, and 334 were elective. The majority of patients were male (350 of 457), and the mean age of all patients was 59.6 years (range, 19-91 years). Patients were treated for a variety of thoracic aortic diseases, including 180 dissections, 137 atherosclerotic aneurysms, 85 posttraumatic aneurysms, 29 penetrating ulcers, 14 pseudoaneurysms, and 12 intramural hematomas.

All patients were evaluated preprocedurally using at least one tomographic imaging modality (eg, CT or MRI), in addition to angiography or transesophageal echocardiography. Follow-up imaging varied according to the protocols of the participating centers but generally included CT (85%) or MRI (21%) at 30 days, 6 months, and yearly thereafter. During follow-up evaluations, clinicians collected data pertaining to expanded or reduced aneurysm size, evidence of endoleak, aneurysm sac/false lumen thrombosis, and alteration of stent graft material.

ENDOVASCULAR REPAIR USING THE TALENT THORACIC STENT GRAFT

The majority (99.1%) of patients were treated under general anesthesia, and most cases (70%) involved the use of one Talent Stent Graft. The mean length of aorta covered by the device was 131.5 mm (range, 28-380 mm). Occlusion of the left subclavian artery (LSA) was performed in 54 patients; in 32 of these cases, the LSA was revascularized before the stent graft was placed.

PROCEDURAL AND IN-HOSPITAL RESULTS

Technical success (completion of intended stent graft deployment) was achieved in 97.8% of cases. Of the 10 cases of technical failures, seven were due to inadequate vessel diameter of the femoral or iliac artery, and three were incidences of difficult deployment. Three cases were documented as requiring immediate conversion to open surgery. Periprocedural endoleak was observed in 98 patients; 26 of these sealed spontaneously during follow-up, and 18 were resolved via adjunctive endovascular treatment that included insertion of a graft extension. There were 10 cases of primary endoleak that led to aneurysm expansion, all of which were converted to open repair. Persistent primary endoleak was seen in 44 patients (9.6%). The majority (7.7%) of endoleaks were type I, with low incidences of type II (1.5%).
and type III (0.7%). The in-hospital period was defined as within 30 days of the procedure or within the same hospitalization as the primary procedure. The average length of hospital stay was 12.8 days (range, 1-149 days).

Mortality

The in-hospital mortality rates were 7.9% of acute cases and 4% of elective; 23 total patients died in-hospital. Two of these 23 died during the procedure due to aortic rupture; both patients were emergency type B dissection cases. Patient age of 75 years or older and ASA class IV or V were shown to be independent predictors of in-hospital mortality through multivariate logistic regression analysis. Traumatic aortic injury had a statistically significantly lower risk of inhospital death than other etiologies ($P=0.03$).

Complications

Cerebral vascular accidents and vascular trauma during the procedure were the most common major adverse events to occur during the in-hospital period. Acute status and ASA class IV or V were shown to be independent predictors of in-hospital complications, whereas traumatic aortic injury was associated with a lower complications rate.

Seventeen patients suffered strokes, a complication that was significantly associated with LSA occlusion without previous revascularization. Paraplegia occurred in three patients, and paraparesis occurred in five; of these eight patients, four were degenerative aneurysm cases, and four were type B dissections. Paraplegia and paraparesis were significantly associated with the length of covered aorta exceeding 20 cm. Paraparesis was shown to have resolved completely in four out of five patients at follow-up, but spinal ischemic damage was persistent in the paraplegia cases.

FOLLOW-UP DATA

The mean clinical and imaging follow-up period was 24 ± 19.4 months (median, 19.5; range, 1-85.1 months). Longer follow-up milestones included 104 of 422 patients reaching 3 years of follow-up and 28 surpassing 5 years.

Late mortality was reported in 36 patients (8.5%). Eleven of these deaths were related to the aorta; seven were due to aortic rupture occurring between 40 days and 35 months, two were cases of extension of dissection, and there were two aortoesophageal fistulas. The seven patients who had an aortic rupture during follow-up subsequently died; 6 of these patients were initially presented with aortic dissection as their primary disease, and all seven had type I persistent primary or secondary endoleak, with aneurysm expansion at imaging follow-up.

There were secondary endoleaks (types I and III) in 44 patients (10.4%). Nineteen of these were successfully treated with an adjunctive endovascular procedure, one resolved spontaneously, and three cases were converted to open repair; the remaining 21 patients did not undergo treatment for secondary endoleak.

Device migrations of more than 5 mm were reported in seven patients, (median, 10 mm; range, 5-40 mm); type I endoleaks were present in two of these cases. There were six cases in which stent-graft segments were disconnected, leading to secondary endoleak type III in four patients. There were two reported incidences of graft material alteration and one aortoesophageal fistula at 2 years after successful treatment of an atherosclerotic aneurysm. In the latter case, there was detachment of a distal nitinol frame facing the esophageal erosion. In another case involving proximal detachment of a distal nitinol frame, there were no clinical consequences.

Data regarding changes in aneurysm dimension were collected in 287 of 422 follow-up patients. Of these, there were 165 incidences of decreased dimension, 72 increased, and there was no change in 50.

The overall Kaplan-Meier survival estimates were 90.1% at 1 year, 84.6% at 3 years, and 74.1% at 5 years. Estimates on freedom from related death were 96% at 1 year, 93.9% at 3 years, and 90.2% at 5 years. Freedom from second procedures (either open or endovascular) were 92.4%, 81.3%, and 70% at the same time intervals, respectively.

DISCUSSION POINTS

The Talent Thoracic Retrospective Registry represents the largest number of patients treated with a thoracic stent graft published to date, with data from a total of 457 consecutive patients reported. Also of note is that follow-up reached up to 3 years on more than 100 patients and up to 5 years on 28. Overall, the registry showed that endovascular treatment using the Talent device provides good long-term results, including a 90.2% rate of freedom from related death at 5 years as shown by Kaplan-Meier analysis. One of the important trends observed was that traumatic ruptures were associated with a significantly lower risk of in-hospital mortality than other etiologies. Also, the rate of complications was reasonably low, and the complications were not device-specific. Covered aorta length exceeding 20 cm was the only predictor of paraplegia, and coverage of the LSA without prior revascularization was the only predictor of stroke. Migration of more than 5 mm was reported in only seven patients. These results could be indicative of the performance of Medtronic’s Valiant Thoracic Stent Graft, which was built from the Talent device platform.

Rossella Fattori, MD, is the Chief of Cardiovascular Radiology at University Hospital S. Orsola, in Bologna, Italy. She has disclosed that she is a consultant to Medtronic. Prof. Fattori may be reached at 39 051 636 4747; rossella.fattori@unibo.it.
European Experience With the Medtronic Valiant Thoracic Endograft

The data from Europe indicate a significant advance in endovascular treatment of the thoracic aorta.

BY MATT THOMPSON, MD, FRCS; STELLA IVAZ, MBBS; ROB MORGAN, FR CR; AND IAN LOFTUS, MD, FRCS

The pathology affecting the thoracic aorta is complex and adds to the challenges that must be faced with thoracic endografting. Common conditions now treated with endovascular techniques include thoracic aneurysms, acute aortic syndromes, chronic dissections, and transections. As experience with thoracic endografting grows, the case mix has become increasingly complex, with the indications for thoracic endovascular procedures expanding. It is now common to treat pathologic lesions affecting the aortic arch, to use hybrid approaches to treat thoracoabdominal aneurysms, to tackle patients with a ruptured thoracic aorta, and to attempt repair of lesions with unfavorable anatomy.

EVIDENCE BASE FOR THORACIC ENDOGRAFTING: LESSONS FROM FIRST-GENERATION ENDOGRAFTS

First-generation thoracic endografts were derived from designs originally intended for the abdominal aorta. Despite these constraints, results from early series of thoracic endovascular surgery were very encouraging, especially when compared to the results from conventional surgery. The Eurostar/United Kingdom Registry reported an elective mortality rate of 5.3% for thoracic aneurysms and 6.5% for thoracic dissections. The corresponding emergency mortalities were 28% and 12%, respectively. These figures were substantially better than those reported from prospective community-based audits of open thoracic surgery or national society figures (www.scts.org). Systematic reviews of single-center case series also demonstrated good early reports. Sayed et al analyzed series comprising 1,518 patients with 810 thoracic aneurysms, 500 type B dissections, and 106 aortic transections. The overall mortality rate was 5.5% with a 97% technical success rate.

Early data suggested that endovascular repair of the thoracic aorta was rapidly becoming the first-line therapy for thoracic aneurysms, dissections, and transections. This led to expansion of these procedures to encompass more difficult lesions and also led some to suggest that endovascular repair might be utilized for treatment of pathologies that were traditionally treated conservatively. The rapid expansion of these techniques revealed some technical limitations in endograft design because the thoracic aorta poses some significant challenges in endograft delivery, deployment, and fixation.

ENDOGRAFT DESIGN

In general, it would be true to say that endograft design and manufacture has not kept pace with clinical ambition in the thoracic aorta. This difference has often resulted in considerable technical difficulty when attempting to treat complex thoracic diseases with first-generation thoracic endografts. Common problems have included:

- the ability of relatively rigid thoracic endografts to conform to the anatomy of the aortic arch. Nonconformity of grafts may lead to a graft sitting proud in the aortic arch, with subsequent instability and graft failure. In particular, grafts that do not appose to the curvature of the arch may be prone to migration, collapse, and pseudo-coarctation
- the ability of long delivery systems to track through tortuous, calcified vessels. This is a particular problem when treating long-segment aneurysmal disease in which the curvature from the abdominal aorta to the thoracic aorta to the arch may be excessive. This situation can lead to the requirement for excessive force in attempting...
to deliver the endograft, which in turn may lead to cerebral embolization or distal microembolization (Figure 1).

- the ability of current stents to provide secure fixation and long-term graft durability. Although the short-term outcome of endovascular repair is reasonably well documented, there are fewer reports of long-term graft outcome and the number of aortic-related deaths after endovascular repair. Recent evidence has started to emerge regarding the incidence of long-term endoleak and graft migration. These studies have suggested that thoracic endovascular repair will be affected by the same types of migration, endoleak, and late rupture that affect the abdominal aorta after endograft placement.

- inaccurate deployment leading to great vessel occlusion or a proximal endoleak
- high forces of deployment resulting in inaccurate positioning or the necessity for repeated manipulation and use of brachial wires
- the same graft type being used for both thoracic aneurysms and dissections, despite the grossly different pathologies and desired outcomes. One of the most feared complications after endovascular repair is retrograde type A dissection, which may be fatal (Figure 2). There has been consistent speculation regarding the effect of various proximal fixation designs on the incidence of type A dissection, but no robust conclusions can be drawn from the data to date.

**MEDTRONIC VALIANT ENDOGRAFT**

In response to the challenges of the thoracic aorta, Medtronic (Santa Clara, CA) introduced the Valiant thoracic endograft into clinical practice in 2005. The Valiant was an evolution from the Talent thoracic endograft and contained some improved design features, which included modifications to stent design, delivery sheath, graft configuration, deployment methodology, and markers. Some of the most significant changes to the Valiant graft included:

- an eight-peak spring to provide proximal fixation. This design allows better apposition to the vessel and distributes the radial force over more apices. This design was introduced in an attempt to improve proximal fixation and also to reduce the likelihood of type A dissection (Figure 3).
- no connecting bar, which allows greater flexibility of the main endograft (Figure 4)
- increased flexibility in graft choice, with longer lengths available (up to 227 mm)
- improved graft cover design leading to less stretching, improved trackability, and lower force of deployment
- integrated handle for deployment (same platform as the Talent AAA stent graft), which provides a mechanical advantage and a lower user-sensed deployment force

The Valiant stent graft is available in lengths from 100 mm to 227 mm and in diameters from 24 mm to 46 mm. Both straight and tapered grafts are available.
EARLY CLINICAL EXPERIENCE AT ST. GEORGE’S VASCULAR INSTITUTE

The first Valiant cases were performed at St. George’s Vascular Institute, London. The Valiant graft has since been introduced into Europe, and more than 4,000 grafts have now been implanted. The St. George’s experience involves 45 patients at the time of this writing. Although it is difficult to derive any meaningful clinical data from a series of this size, a number of anecdotal observations may be made.

Initial clinical experience has confirmed the promise of the Valiant graft in the treatment of thoracic aortic pathology. The delivery system is a significant improvement on the Talent system because it allows tracking of the device through tortuous vessels and allows placement in the proximal arch without impacting on the aortic valve. The deployment has been made significantly easier with the integrated mechanical handle such that the user-experienced force is significantly reduced, and accurate deployment is possible in most situations (Figure 5). This has overcome one of the biggest disadvantages of the Talent system, which was often difficult to deploy if the graft had to be positioned through a tortuous system.

Removal of the connecting bar allows conformation to acutely angled aortic arches, and the Valiant graft appears to conform extremely well to challenging aortic arch angulation (Figure 6). In our series, we have not seen the Valiant endograft sitting proud in the arch.

Removal of the connecting bar does pose some challenges in deployment because the graft has lost some longitudinal support during the initial stages of deployment. In our experience prior to deployment of the Valiant endograft, the blood pressure should be lowered to less than 100 mm Hg systolic, and the graft positioned 1 cm to 2 cm proximal to the final desired deployment position. In order to minimize caudal displacement of the endograft, two stent lengths should be deployed to gain some apposition of the aortic wall before final positioning is achieved (Figure 6) by withdrawing the entire system to the desired position.

The Valiant endograft was designed to have two proximal configurations—an open and closed web. This was

Figure 3. Valiant stent graft. The open web design has an eight-peak proximal stent, which allows for radial force to be distributed over more apices than the Talent graft and with less flare.

Figure 4. Removal of the connecting bar has led to increased graft flexibility.

Figure 5. Patient presenting with a large proximal arch aneurysm. Treatment involved a bypass from the ascending aorta to the innominate and left common carotid artery through a median sternotomy (A), followed by placement of a Valiant endograft to exclude the aneurysm (B). Positioning was crucial in this case because the fabric of the graft had to oppose the aorta at the takeoff of the bypass.
theoretically attractive because it was assumed that the closed web configuration might be utilized in the treatment of acute aortic syndromes. This has proved possible in the descending thoracic aorta, but the closed web should not presently be utilized in the arch due to the hemodynamics forces involved.

RESULTS OF VALIANT ENDOGRAFT AT ST. GEORGE’S VASCULAR INSTITUTE

The experience at St. George’s reflects the potential of the Valiant endograft in treating thoracic pathology. The introduction of this graft has overcome many of the problems associated with first-generation endografts, which has allowed patients with more challenging pathology to be treated. Although this is an encouraging development, it makes analysis of outcomes between first- and second-generation endografts difficult. In general, newer endograft designs will be applicable to more difficult anatomic and pathologic challenges and, therefore, might be expected to have poorer outcomes. Analysis of all series must therefore be undertaken with reference to case mix.

The series at St. George’s Vascular Institute contains 45 patients. Twenty-four of these were ASA class 3 or 4. Pathologies treated included 16 thoracic aneurysms, eight thoracoabdominal aneurysms, five patients with acute aortic syndrome, and 15 patients with chronic aortic type B dissection. Etiologically, most patients had atherosclerotic pathology, but the group included four patients with Marfan syndrome and one patient with Ehlers-Danlos syndrome. The proximal sealing zone was proximal to the innominate artery in one patient, proximal to the left common carotid artery in six patients, proximal to the left subclavian artery in 20 patients, and distal to the left subclavian in 18 patients.

In view of the complexity of the patients, 18 of the 45 required surgical bypass before endovascular repair. These bypasses included one ascending to innominate bypass, eight carotid reconstructions, and eight retrograde visceral bypasses to allow treatment of thoracoabdominal aneurysms. Overall, all patients had endografts deployed successfully. There were four in-hospital deaths. The cause of mortality was cerebrovascular accident in two patients, paraplegia in one patient, and multiple organ failure in one patient with a thoracoabdominal aneurysm. Technical success was achieved in all but two patients who had significant type I proximal endoleak at the end of the procedure.

At the time of this publication, follow-up is limited. There have been two aortic-related deaths. One patient had a large ascending aortic aneurysm awaiting repair that ruptured before surgery. Another patient died of a retrograde type A dissection 6 weeks after the initial endovascular repair.

LESSONS LEARNED—ACQUISITION OF DATA

These results highlight some of the difficulties in interpreting contemporary data describing endovascular repair of the thoracic aorta. The overall combined elective and emergency mortality of the series (four of 45) is acceptable, and yet is not an obvious improvement on reports that have utilized first-generation devices. There may be several explanations for this but the most likely remains a difference in case mix. As thoracic endografts become more “fit for purpose,” the range of thoracic pathology treatable by endovascular means will expand.

Lesions will be treated by current endografts that were not amenable to first-generation devices. These will inevitably include difficult lesions that arise further around the aortic arch or impinge on the visceral vessels, tortuous lesions with difficult access, and sealing zones with greater diameters. It might be anticipated
that these challenging lesions will have poorer results than more straightforward lesions, in a similar way to the differential results of treating small and large abdominal aortic aneurysms. Given the changing indications for endovascular repair of the thoracic aorta, it is essential that sufficient clinical information be collected to allow correction of the data for confounding factors. It is therefore crucial that a body of data is reported that will allow robust subgroup analysis of lesions corrected for etiology, location, comorbidity, and degree of endovascular difficulty. Correction of results for case mix should be possible as long as there is a commitment to collection of quality data. For example, it is possible to see the changing patterns of treatment by comparison of the St. George’s experience with the Talent Thoracic Retrospective Registry. In the Talent Retrospective Registry, data were collected on 457 patients who underwent endovascular thoracic repair with the Talent graft between 1996 and 2004. In this cohort, only 54 patients (12%) had the proximal sealing zone proximal to the left subclavian artery as compared to 60% in the St. George’s series. This demonstrates the evolution in the types of lesions now amenable to endovascular therapy.

It is a point of considerable debate as to who should bear responsibility for collecting these data. Registries appear to be the most sensible way forward, but funding is difficult, and our view is that the endovascular industry must take some responsibility for data provision. Medtronic currently supports two studies in Europe that aim to provide contemporary data on the endovascular treatment of the thoracic aorta. A retrospective investigation of the performance of the Valiant thoracic endograft is being analyzed at present. This retrospective study involves cases from St. George’s and St. Mary’s, London, Bologna, Toulouse, Nieweigen, Lille, and Grenoble. Data from nearly 200 patients have been collected, which should allow presentation of outcome with correction for lesion type.

In addition, the VIRTUE registry (Valiant Thoracic Stent Graft evaluation for the treatment of descending thoracic aortic dissections) has just started in Europe. This registry will prospectively collect data from the treatment of thoracic dissections with the Valiant endograft. Data will be independently analyzed and imaging assessed by a core lab. This registry will again supply lesion-corrected data.

CONCLUSION

The Valiant endovascular graft system represents a significant advance in endovascular treatment of the thoracic aorta. This graft has allowed a significant expansion in the types of lesions suitable for endovascular therapy. In the future, collection of clinical data is essential to define the role of endovascular procedures in the thoracic aorta. Definition of subgroups with good and adverse outcomes will be important in the future of this technology.

Matt Thompson, MD, FRCS, is a Professor of Surgery, St. George’s Vascular Institute, London, United Kingdom. Professor Thompson may be reached at +44 208 725 3205; matt.thompson@stgeorges.nhs.uk.

Stella Ivaz, MBBS, is an academic F2 trainee, St. George’s Vascular Institute, London, United Kingdom.

Rob Morgan, FRCR, is a consultant interventional radiologist, St. George’s Vascular Institute, London, United Kingdom.

Ian Loftus, MD, FRCS, is a consultant vascular surgeon, St. George’s Vascular Institute, London, United Kingdom.

An Overview of Hybrid Procedures for TAAAs

Although endovascular technology is evolving rapidly, the visceral hybrid repair remains a robust and adaptable method for treating this complex disease process.

BY ANDREW M.T.L. CHOONG, MB BS, MRCS; ROBERT E. BRIGHTWELL, BM, MRCS; AND NICHOLAS J.W. CHESHIRE, MD, FRCS

Thoracoabdominal aortic aneurysms (TAAAs) are defined by the involvement of the origins of the celiac, superior mesenteric, and renal arteries. Crawford’s classification is universally accepted (Figure 1), although Safi subsequently added a fifth class of TAAAs in his version of the classification system (Figure 2).

Open repair of TAAAs has a high mortality and morbidity rate when treated with open techniques. These risks have persisted despite advances in operative techniques (including left heart bypass, spinal cord protection, hypothermic cardiopulmonary arrest, and selective visceral perfusion) and higher standards of perioperative care.

In 1991, Parodi used the first endovascular stent graft in an infrarenal abdominal aortic aneurysm. As a direct evolutionary step, by 1994, endovascular techniques had developed such that Dake was able to use an endovascular stent graft for descending thoracic aortic aneurysms. This use of endovascular stent graft for TAAAs limited to the thoracic segment showed significant early promise. However, their use for more extensive TAAAs was necessarily limited by the presence of the visceral and renal arteries in the chest and abdomen.

Hybrid repair of TAAAs refers to procedures combining both open surgical and endovascular techniques (either staged or within the context of one operative procedure). By revascularizing vital aortic side branches first, it is possible to achieve total endovascular aneurysm exclusion. We refer when the visceral and renal vessels are involved in the TAAA and require retrograde revascularization as the visceral hybrid repair.

EXPERIENCES OF HYBRID REPAIR OF TAAAs

Hybrid repair of TAAAs begin with an open abdominal procedure to first revascularize the visceral and or renal vessels, depending on their relationship to the TAAA. This is followed by aortic endovascular stent graft placement (either as part of the same procedure or intentionally delayed). These repairs are particularly attractive because they avoid the need for a thoracotomy, supraceliac aortic cross clamp, left- or full-heart bypass, and extensive tissue dissection.

In 1999, Quinones-Baldrich et al were the first to report such a combined endovascular and open surgical approach for type IV TAAAs. Previous abdominal aortic...
surgery and concomitant visceral artery aneurysms precluded an open repair. Retrograde visceral bypasses from a limb of a pre-existing bifurcated aortic tube graft were performed, followed by TAAA stent graft placement.

After the Quinones-Baldrich report, several centers worldwide have published five or fewer individual cases/small series of hybrid approaches to TAAAs.8-25 The results of these cases are encouraging considering the complicated nature of the TAAA disease process, as well as the patients’ comorbidities. Of the 30 patients in this combined series, spinal cord ischemia was rare or unreported. Other postoperative complications were greatly reduced, and intensive care stay was shorter than for open TAAA surgery. Of note, no standard operative technique was employed, and there was much variation in the endovascular stent graft used.

More recently, Resch et al have reported their series of 13 staged hybrid repairs of TAAAs.26 All patients underwent retrograde visceral bypasses (11 iliovisceral and two infrarenal aortovisceral) as a first procedure before completion with endovascular stent graft placement. They report a 30-day mortality of 23% (three of 13) for all
patients. The mean follow-up in the 10 surviving patients was 23 months (range, 1-45 months), during which time two additional deaths were related to the hybrid repair. Two patients had paraplegia, and two additional patients had transient parapetic events.

**ST. MARY’S VISCERAL HYBRID REPAIR**

**Technique**

The patient is placed in the supine position under general and epidural anesthesia, with routine cerebrospinal fluid drainage. We routinely use cell-salvage techniques (with rapid infusers available) and invasive monitoring with arterial and central venous lines, urethral catheterization, and transesophageal echocardiography.

A midline laparotomy allows for adequate exposure of the abdominal aorta, the origin of each renal artery, the celiac axis, and the superior mesenteric artery (SMA) (Figure 3). The inflow site for visceral bypass graft placement is determined by previous abdominal aortic surgery and distal extent of aneurysmal disease. Where a previous infrarenal repair has been undertaken, the bypass grafts are anastomosed in an end-to-side fashion to the existing graft. If an infrarenal repair is necessary (either aneurysmal disease is present or the repair will facilitate a distal landing zone for the subsequent stent grafting), this is completed first. The bypass grafts are then sutured to this infrarenal graft in an end-to-side manner. If the infrarenal aorta is normal, an arteriotomy is performed, and the bypass grafts are anastomosed in an end-to-side fashion to the native aorta. If the aneurysmal disease extends to the bifurcation, one external iliac artery provides the inflow sites.

Most often, two inverted (14-mm X 7-mm or 16-mm X 8-mm) Dacron grafts function as the conduits. The renal arteries are sequentially anastomosed in an end-to-side fashion. The two remaining graft limbs are routed along the base of the small bowel mesentery to the celiac axis and SMA in an end-to-side fashion. If Doppler signals are satisfactory in the bypass grafts (with the origins of the native vessel clamped), they are subsequently suture-ligated to prevent retrograde flow into the aneurysm sac (termed type II endoleak).

After successful visceral and renal bypass, a suitable access site is chosen for endovascular stent deployment (usually a dedicated conduit attached to the common iliac artery or the abdominal aorta). An angiography catheter is introduced on the contralateral side, and the stents are deployed in a sequential fashion from the left subclavian artery through the thoracic aorta to the landing zone. Completion angiography after adjunctive procedures (extension cuff, giant Palmaz stent [Cordis Corporation, a Johnson & Johnson company, Miami, FL], balloon moulding) then confirms exclusion of the aneurysm.

We prefer this technique for Crawford type I, II, and III TAAAs, whereas an open approach with medial visceral rotation is used for Crawford type IV aneurysms.

---

**TABLE 1. RESULTS FROM THE REGIONAL VASCULAR UNIT, ST. MARY’S HOSPITAL, LONDON**

<table>
<thead>
<tr>
<th>Description</th>
<th>Count/Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>47 patients</td>
</tr>
<tr>
<td>Age (median)</td>
<td>71, range 37-81</td>
</tr>
<tr>
<td>Sex: male, female</td>
<td>23, 24</td>
</tr>
<tr>
<td>Mean ASA grade</td>
<td>3</td>
</tr>
<tr>
<td>27 elective, 15 urgent, 5 emergency</td>
<td></td>
</tr>
<tr>
<td>Crawford type I (5), type II (21), type III (16), type IV (1), and complex (4)</td>
<td></td>
</tr>
<tr>
<td>43 (91%) had a completed procedure</td>
<td></td>
</tr>
<tr>
<td>The median ischemic time (range)</td>
<td>15 min (13-27 min)</td>
</tr>
<tr>
<td>2 cases paraplegia (%) within 30 days</td>
<td>4%</td>
</tr>
<tr>
<td>Elective 30-day mortality</td>
<td>13%</td>
</tr>
<tr>
<td>Endoleak: type I (9), type II (6), type III (1)</td>
<td></td>
</tr>
<tr>
<td>Hospital stay (median, range)</td>
<td>28 days, 7-120 days</td>
</tr>
<tr>
<td>At 13-month median follow-up, 94% of visceral grafts were patent</td>
<td></td>
</tr>
</tbody>
</table>

---

**TABLE 2. ADVANTAGES**

The authors perceive several advantages of this approach over standard, open techniques:

- No thoracotomy
  - Potentially fewer pulmonary complications
  - Fewer cardiac arrhythmias
  - Less pain
- Reduced hypothermia with subsequent reductions in:
  - Coagulopathy
  - Cardiovascular instability
- Reduced rate of spinal cord ischemia
- Reduced duration of mesenteric and visceral ischemia with reduction in:
  - Acidosis and associated problems
  - Gut bacteria translocation/sepsis
  - Renal failure/use of renal replacement therapy
- Less blood loss/reduced transfusion requirement
- Reduced hospital stay
  - Intensive Therapy Unit
  - Absolute
- More patients previously excluded by comorbidity can be treated
THE FUTURE OF HYBRID REPAIR

Visceral hybrid repair of TAAAs may be a bridging measure until branched endovascular stent graft technology matures to the point of established use.

Endovascular repair of juxtarenal and suprarenal abdominal aortic aneurysms with preservation of visceral perfusion by fenestrated or branched endovascular stent graft has been shown to be feasible, and, using similar technology, several investigators have described total endovascular repair of complex thoracic aortic disease. Until recently, Chuter et al were the only investigators to report total endovascular repair of a TAAA with preservation of all four visceral vessels in a single patient. Anderson et al reported a series of four patients treated in which 12 of 13 target vessels were revascularized, with no endoleaks. Three of the patients required further procedures to correct bleeding from access vessels, and one patient died from multiorgan dysfunction syndrome after such a procedure. Computed tomography at 12 months confirmed antegrade perfusion in all 10 target vessels.

Further improvement of, and access to, such devices, and correct patient selection (in light of the EVAR 2 trial results) will see a reduction in the numbers of visceral hybrid procedures being performed for TAAA. In the meantime, and in cases unsuitable for fenestrated/branched EVSG, the visceral hybrid repair remains a robust and an adaptable method of treating this complex and life-threatening disease process.
The European randomized trials have provided level-1 evidence to show that endovascular aneurysm repair (EVAR) is more effective in preventing aneurysm-related death than conventional open surgery.1,2 Patients who are too sick to be considered for open surgery do not appear to gain any significant survival advantage from EVAR over noninterventional management.3 And, lingering uncertainty about the durability of EVAR in the long term probably tips the balance in favor of open surgery for the few low-risk patients who present with abdominal aortic aneurysms (AAAs) at a young age (<60 years). With these two exceptions, endovascular repair can now be regarded as the treatment of choice for patients with AAAs, subject to anatomical suitability.

Because current constraints upon the wider application of EVAR are principally anatomic in nature, current drivers for the evolution of the associated technology focus on overcoming the obstacles imposed by unfavorable anatomy. However, the relatively high cost of EVAR continues to impede its uptake in many parts of the world, and this is another issue that needs to be addressed in the interests of patients. Financial expenditure on the endograft itself is more than offset by shorter hospital stay and elimination of the need for postoperative intensive care. It is the relatively high rate of secondary intervention after EVAR that accounts for its higher cost over time. Therefore, the need to reduce the requirement for secondary intervention is another important driver for further technical development.

OVERCOMING ANATOMIC CONSTRAINTS TO EVAR

Issues Relating to the Neck of the Aneurysm

Unfavorable anatomy relating to the neck of the aneurysm is the most common reason for patients being rejected for EVAR. Short or absent infrarenal neck, large aortic diameters, and excessive angulation at this level are the main problems. There is potential for all of these issues to be addressed effectively by further advances in endograft technology.

In the last few years, considerable progress has been made in overcoming the technical problems posed by juxtarenal aneurysms where the neck is either too short for a secure seal or where there is no neck at all. Cook Medical (Bloomington, IN) now offers fenestrated and branched devices based upon the Zenith Endograft platform that are designed specifically to address these issues (Figure 1). Access to this technology was originally restricted to a small number of centers that contributed to its development and the initial clinical assessments. But, in 2006, Cook celebrated implantation of the 1,000th fenestrated endograft worldwide and announced that these products were now available to any center with appropriate resources and technical skills to deal with the added complexities associated with their use.

Although the clinical results reported with fenestrated endografts have generally been excellent, at least in the short to medium term,4-8 there is a significant incidence of target vessel loss, amounting to approximately 5% after 2 to 3 years. Early occlusion is likely to be a consequence of technical factors encountered during the course of the procedure, such as “shuttering” of the vessel orifice due to malpositioning of the endograft. There is little room for error when deploying these devices, and although a partially “shuttered” vessel may sometimes be recovered by placement of a stent, this is not always possible.

Late loss of target vessels has other causes, which need to be addressed. Any migration of the endograft, no matter
A DECADE OF ENDOVASCULAR AORTIC ANEURYSM REPAIR

Figure 2. Surveillance plain abdominal radiograph after fenestrated graft repair showing a crushed right renal stent at the level of the fenestration. The stent in the left renal artery shows no sign of compression.

Figure 3. A covered balloon-expandable Jomed stent (Abbott Vascular, Santa Clara, CA) engaged in a nitinol ring, which is the point of seal and also the pivot point for movement with the cardiac cycle and respiration.

how slight has potential to compress a stent within a fenestration. Examples of crushed and even fractured stents have been reported (Figure 2). The physical properties of the stents themselves are also highly relevant to this problem. They need to be resistant to crushing and fracture, but at the same time, they are required to accommodate constant movement of the target vessel relative to the stent graft, with each cardiac cycle and with respiration. It should be remembered that stents associated with fenestrated endografts have different functions than those for which they were designed. Not only are they subjected to unique stresses at the interface with the stent graft, but often the branch vessels into which they are deployed may be relatively healthy. “Normal” arteries could react in a different way than diseased vessels; for example, they may have greater or lesser potential to develop reactive intimal hyperplasia. There is a clear need to develop stents with appropriate properties to perform well in this specific situation.

When there is no infrarenal neck, or if the aortic anatomy prevents apposition between the fabric of the stent graft and the vessel wall, a branch is required to bridge the gap. Deployment of a covered stent that seals against a nitinol ring at the margin of the fenestration is one approach to this problem that has been applied very successfully in the short to medium term (Figure 3). However, there are concerns about the durability of a seal that depends upon a stent engaging with a narrow ring, especially as the stent tends to pivot at this point with movement of the target vessel as noted previously. A better solution, when there is space, is to employ endografts with cuffs rather than fenestrations. Not only does this solution provide for a more secure seal, but cuffs do not need to be positioned as precisely as fenestrations. Furthermore, considerable flexibility of design is possible with cuffs that are upward or downward pointing and external or internal to the lumen of the stent graft. Because the location of cuffs within the stent graft is not as critical, there is a possibility that generic “off-the-shelf” designs might be possible in the future, with mitigation of some of the considerable costs and delays that are associated with customized fenestrated endografts.

Another potential approach to short or absent infrarenal necks is in situ fenestration. The concept here is that a standard off-the-shelf stent graft is fenestrated and stented after deployment. This solution provides for a more secure seal, but cuffs do not need to be positioned as precisely as fenestrations. Furthermore, considerable flexibility of design is possible with cuffs that are upward or downward pointing and external or internal to the lumen of the stent graft. Because the location of cuffs within the stent graft is not as critical, there is a possibility that generic “off-the-shelf” designs might be possible in the future, with mitigation of some of the considerable costs and delays that are associated with customized fenestrated endografts.

There are concerns about the potential for a fenestration created in situ to impact adversely upon the strength of the fabric of the endograft locally. One possible solution to this might be a flared stent deployed so that the flare overlaps and is in contact with the area of potentially weakened fabric on the luminal aspect of the fenestration. If solutions to these various technical problems can be found, in situ fenestration will offer significant advantages over preformed customized fenestrated endografts in terms of cost and ready availability. It could also become a valuable bail-out option in the event of inadvertent overstenting of critical aortic side branches.

Stent graft designs that are based upon rows of Gianturco Z (Cook Medical) or similar stents do not conform well to tortuosity or angulation at the neck of the aneurysm, and the instructions for use prepared by most manufacturers define an upper limit of angulation beyond which they do not recommend their product is used. The risk is that the seal will be compromised at this point, resulting in primary type 1 endoleak. Two endografts of similar design both incorporating spring-like spiral stents have been developed partially in response to the challenge.
of neck angulation (Anaconda [Vascutek, Ltd., Renfrewshire, Scotland], and Aorfix [Lombard Medical Technologies, Oxford, England]) and are currently undergoing clinical evaluation in Europe.

**ISSUES RELATING TO THE ILIAC ARTERIES**

Adverse anatomy in respect to the iliac arteries can also thwart application of the endovascular treatment option for AAAs, although less frequently than issues related to the neck.

Narrow external iliac arteries, either constitutional (usually in women) or as a result of stenotic arterial disease can be overcome in nearly every instance by relatively minor adjuvant surgery or angioplasty. Clearly, smaller-diameter introducer sheaths are highly desirable. But, the main driver for the development of ever smaller introducer systems is the goal of percutaneous AAA repair as standard treatment.

Other problems relating to iliac artery anatomy are short common iliac arteries and aneurysmal disease. The former are reported to be a common finding in Asian populations and may be partially responsible for the relatively low uptake of EVAR to date in some parts of the world. Rarely should short common iliac arteries be a contraindication to EVAR, but additional care in planning and the performance of the procedure will be required, and commercial companies may need to give extra thought to the range of sizes of devices, especially those intended for Asian markets.

It is not good practice to exclude both internal iliac arteries during the course of EVAR. Occasionally, it may be unavoidable, in which case severe buttock claudication is likely to result. More severe complications such as gut ischemia are possible but rare. Iliac branched devices provide a means of avoiding this situation in the presence of bilateral common iliac artery aneurysms or when one internal iliac artery is already occluded. This is only possible when the anatomy of the iliac bifurcation is favorable (Figure 4).

Figure 4. Iliac bifurcation device for treatment of common iliac aneurysms (A). A bridging stent is needed to connect the iliac branched device with the hypogastric artery (B). Completion angiography shows patency of the right hypogastric after exclusion of the aortic and common iliac aneurysms. Coil embolization of the left hypogastric has been performed (C). Adjunctive stenting of the left iliac limb with a Wallstent has been performed because of kinking of the endograft in a tortuous common iliac.

REDUCING THE NEED FOR SECONDARY INTERVENTION

In the UK EVAR 1 trial, secondary intervention after EVAR was undertaken in 20% of the patients after 4 years.1 The figure for open repair was 6%, and this difference accounted for much of the excess cost of EVAR during this period. As a consequence, in parts of Europe and in other parts of the world, some health care systems are refusing to fund EVAR on grounds of relative cost inefficiency. Analysis of the reasons for secondary intervention10 shows that most are device-related. Therefore, there is an urgent need for technical modification of existing devices to address this issue.

Fortunately, the majority of secondary interventions are relatively minor, most being either transfemoral endovascular procedures or extra-anatomic bypass surgeries. Although they did add to the overall cost, in the UK EVAR 1 trial, they were not associated with any adverse impact upon mortality or other outcome measure except cost.1 By far, the most common indication for secondary intervention today is compromised iliac artery patency.10 Iliac artery tortuosity is a major risk factor for endograft limb occlusion. This is most likely to occur in association with devices that are less able to conform to the tortuous anatomy. The Zenith device manufactured by Cook is a notable example. A relatively rigid device will often convert iliac tortuosity into acute angulation with obstruction to blood flow. Selection of the most conformable device from the range of choices available is obviously advisable. Some clinicians have combined limbs produced by one manufacturer with a body produced by another to gain the best of both worlds.

An alternative option is to deploy a Wallstent (Boston Scientific Corporation, Natick, MA) within the limb extending into the iliac artery beyond it to smooth out any angulation.11 Whichever strategy is chosen, it is impor-
A decade of endovascular aortic aneurysm repair

Richard McWilliams, FRCS, FRCR, is a Consultant Radiologist, Royal Liverpool University Hospital, England. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Harris may be reached at findplh@hotmail.com.

Peter Harris, MD, FRCS, is a Professor of Vascular Surgery, University of Liverpool, and a Consultant Vascular Surgeon, Royal Liverpool University Hospital, England. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

EVAR Treatment of Ruptured AAAs and TAAs

Should endovascular repair be the standard of care for treating ruptured AAAs and thoracic aortic emergencies?

BY MANISH MEHTA, MD, MPH; JOHN B. TAGGERT, MD; ANDREAS SPIRIG, MD; YARON STERNBACH, MD; R. CLEMENT DARLING III, MD; KATHLEEN J. OZSVATH, MD; SEAN P. RODDY, MD; PAUL B. KREIENBERG, MD; PHILIP S.K. PATY, MD; BENJAMIN B. CHANG, MD; AND DHIRAJ M. SHAH, MD

Emergent endovascular aneurysm repair (EVAR) for treating abdominal and thoracic aortic emergencies is gaining acceptance based on several reports of marked reduction in morbidity and mortality rates when compared to open surgical repair under similar circumstances. Although most tertiary medical centers have progressively transitioned to EVAR as a primary therapy for aortic emergencies, there has been a slow acceptance to adopt these techniques in most hospitals throughout the US. There are several fundamental reasons for this slowness: (1) unavailability of preoperative CT scans under emergent circumstances, (2) unavailability of trained and dedicated operating room and ancillary staff equipped to perform emergent EVAR at all times, and (3) unavailability of “off-the-shelf” abdominal and thoracic stent grafts.

In our transition from elective to emergent abdominal and thoracic aortic aneurysms (AAA, TAA) with endovascular techniques, we recognized that our initial inability to coordinate a seamless transition of patients with aortic emergencies from the emergency room to the operating room, availability of endovascular trained staff, and availability of adequate equipment were the limiting factors. To facilitate EVAR of ruptured AAAs and TAAs, we developed a multidisciplinary approach that included vascular surgeons, emergency room staff, operating room staff, radiology technicians, and the availability of a variety of equipment needed for endovascular repair, including abdominal and thoracic stent grafts.

Initially, five patients with a symptomatic and not ruptured AAA that was considered suitable for EVAR underwent simulation of patients presenting to the emergency room with a ruptured AAA; the emergency room physician resuscitated the patient and alerted the on-call vascular surgery team (vascular surgeon, vascular resident/fellow, and the operating room), emergently performed an abdominal CT scan, and transported the patient to the operating room. The vascular surgeon informed the operating room staff to prepare for EVAR and open surgical repair in the operating room equipped with interventional capabilities. The operating room setup was rehearsed with the operating room staff, the radiology technician, and the anesthesiologists who were knowledgeable of the sequence of steps involved. Once a synchrony of disciplines was established, patients with ruptured AAAs as well as thoracic

Figure 1. Protocol chart for endovascular treatment of aortic emergencies.
aortic emergencies were primarily treated endovascularly. In our experience, the two most important factors that facilitated improvements in our ability to deliver endovascular care to patients with ruptured AAAs were (1) increased ruptured AAA awareness among the emergency room staff that facilitated early diagnosis and treatment, and (2) the ability of the anesthesiologists and the operating room staff to become comfortable with the synchrony of events and the setup requirements for emergent EVAR.5

**THE ALBANY VASCULAR INSTITUTE EXPERIENCE**

Since 2002, after establishing a strategic protocol for treating aortic emergencies, which included operating room staff who are adequately trained for emergent endovascular procedures, and the availability of a variety of stent grafts, we prospectively evaluated outcomes of endovascular treatment of abdominal and thoracic emergencies. All procedures were performed in the operating room under general anesthesia; in treatment of a ruptured AAA, access was obtained via bilateral femoral artery cutdown; in treatment of thoracic aortic emergencies, access was obtained via either femoral artery cutdown, iliac artery conduit, or common carotid artery cutdown and antegrade placement of a thoracic stent graft. The stent grafts used included the AneuRx (Medtronic, Inc., Santa Rosa, CA), Excluder/TAG (Gore & Associates, Flagstaff, AZ), and Zenith (Cook Medical, Bloomington, IN), and they were chosen at the discretion of the surgeon based primarily on the anatomic limitations of the patient’s thoracic and aortoiliac morphology.

**PROCEDURE**

Patients routinely underwent bilateral femoral artery cutdown, unless available CT scan suggested the need for iliac conduit or common carotid artery cutdown for access. Access was initially obtained with a floppy guidewire that was subsequently exchanged for a stiff wire. For a ruptured AAA, a 12-F sheath was placed in the ipsilateral femoral artery, and a 33-mm or 40-mm-compliant Equalizer occlusion balloon catheter (Boston Scientific Corporation, Natick, MA) was advanced over the stiff wire up to the supraceliac aorta under fluoroscopic guidance and was only inflated in cases of hemodynamic instability. Subsequently, access was achieved from the contralateral femoral cutdown, and an arteriogram was obtained to better define the aortoiliac morphology. For TAA emergencies, a preoperative CT scan was always obtained and was used to determine the site of access. Patients routinely underwent only one cutdown, either for direct femoral artery cannulation, common iliac artery conduit, or direct common carotid artery cannulation. A second access was achieved percutaneously (femoral or brachial), and a 5-F sheath was used for flush catheters. In patients who underwent left subclavian artery coverage, the need for carotid subclavian bypass was determined by the presence of dominant left vertebral artery or previous coronary revascularization using the left internal mammary artery. We generally accepted an aortic neck length of >5 mm for ruptured AAAs and 1 cm when treating thoracic aortic emergencies. Our general belief is that the overall morbidity and mortality rates of elective conversions to open surgical repair after emergent EVAR are usually better than emergent open surgical repair of aortic emergencies. In extreme circumstances, thoracic aortic debranching to create an adequate proximal stent graft fixation site should be considered. In our experience, inability to gain access from the femoral arteries was never a limiting factor. In patients with hemodynamic instability or anatomic limitations that precluded expeditious exclusion of the ruptured AAA, modular bifurcated stent grafts were converted to aorto-uni-iliac (AUI) devices by deploying aortic cuffs (AneuRx, Excluder,

<table>
<thead>
<tr>
<th></th>
<th>Ruptured AAA</th>
<th>TAA Emergency</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>54</td>
<td>44</td>
</tr>
<tr>
<td>Patient hemodynamically stable</td>
<td>41 (76%)</td>
<td>39 (92%)</td>
</tr>
<tr>
<td>Patient hemodynamically unstable</td>
<td>13 (24%)</td>
<td>5 (8%)</td>
</tr>
<tr>
<td>Preoperative CT available</td>
<td>44 (81%)</td>
<td>44 (100%)</td>
</tr>
<tr>
<td>Need for aortic occlusion balloon</td>
<td>8 (15%)</td>
<td>–</td>
</tr>
<tr>
<td>Stent graft conversion to AUI device</td>
<td>7 (13%)</td>
<td>–</td>
</tr>
<tr>
<td>Mean operative time, min (range)</td>
<td>80 (35-125 min)</td>
<td>55 (30-150 min)</td>
</tr>
<tr>
<td>Mean blood loss (range)</td>
<td>450 mL (150-1,100 mL)</td>
<td>245 mL (50-600 mL)</td>
</tr>
</tbody>
</table>
or Zenith AUI converter) across the stent graft flow-divider. The contralateral iliac artery was interrupted by open ligation, endoluminal occlusion, or placement of a covered stent from the internal iliac artery into the external iliac artery, and femoral-femoral bypass was performed. Although earlier in our experience heparin was systematically administered to all patients, we found an increased activated partial thromboplastin time (aPTT) to be a significant risk factor for development of abdominal compartment syndrome (ACS) in these patients. In patients with ruptured AAAs, postoperative care should include vigilant evaluation for the development of ACS; risk factors include the need for aortic occlusion balloon, increased requirements for blood transfusion (usually >2 to 3 units PRBC), elevated aPTT, and significant abdominal distention.

ENDOVASCULAR REPAIR OF RUPTURED AAAs

The overall mortality of endovascular ruptured AAA repair in our experience was 17% and was significantly higher for patients with ACS (63%) when compared to those without ACS (11%). Unavailability of preoperative CT scan was not a limiting factor, 19% of patients with suspected ruptured AAA did not have a preoperative CT, and all of them underwent successful EVAR. In our total experience of attempting 56 EVAR procedures for ruptured AAAs, we were technically successful in 54 patients (96%); both patients that were converted to open surgical repair after endovascular attempts. One patient with chronic renal insufficiency and a juxta-renal AAA rupture underwent successful EVAR with coverage of both renal arteries. Ten patients (18%) developed ACS within 36 hours of EVAR and required a midline decompression laparotomy. The mortality rate in patients with ACS was significantly higher (six of 10; 60%) when compared to patients without ACS (five of 44; 11%) (Tables 1 and 2).

ENDOVASCULAR REPAIR OF THORACIC AORTIC EMERGENCIES

Of the 44 patients who presented with thoracic aortic emergencies, we were technically successful in 41 patients (93%). In patients with ruptured AAAs, postoperative care should include vigilance for the development of ACS; risk factors include the need for aortic occlusion balloon, increased requirements for blood transfusion (usually >2 to 3 units PRBC), elevated aPTT, and significant abdominal distention.

### TABLE 2. ENDOVASCULAR REPAIR OF RUPTURED AAA: INDICATIONS AND OUTCOMES

<table>
<thead>
<tr>
<th>Endovascular Repair of Ruptured AAA</th>
<th>54 Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary success of EVAR</td>
<td>51 (94%)</td>
</tr>
<tr>
<td>Patient hemodynamically unstable</td>
<td>13 (24%)</td>
</tr>
<tr>
<td>Preoperative CT</td>
<td>43 (80%)</td>
</tr>
<tr>
<td>Need for aortic occlusion balloon</td>
<td>10 (18%)</td>
</tr>
<tr>
<td>Stent graft conversion to AUI device</td>
<td>9 (16%)</td>
</tr>
<tr>
<td>Blood loss (mean)</td>
<td>455 mL</td>
</tr>
<tr>
<td>Blood transfusion (mean)</td>
<td>3.1 units</td>
</tr>
<tr>
<td>Operative time (mean)</td>
<td>76 min</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Respiratory failure (tracheostomy)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Renal failure (dialysis)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Abdominal compartment syndrome (ACS)</td>
<td>10 (18%)</td>
</tr>
<tr>
<td>Mortality with ACS</td>
<td>6/10 (60%)</td>
</tr>
<tr>
<td>Mortality without ACS</td>
<td>5/44 (11%)</td>
</tr>
</tbody>
</table>

### TABLE 3. ENDOVASCULAR REPAIR OF THORACIC AORTIC EMERGENCIES; INDICATIONS AND OUTCOMES

<table>
<thead>
<tr>
<th>Endovascular Repair of Thoracic Aortic Emergencies</th>
<th>44 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruptured/symptomatic TAA</td>
<td>24 (55%)</td>
</tr>
<tr>
<td>Thoracic aortic pseudoaneurysms</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Symptomatic thoracic penetrating ulcers</td>
<td>6 (14%)</td>
</tr>
<tr>
<td>Traumatic thoracic aortic transactions</td>
<td>10 (23%)</td>
</tr>
<tr>
<td>Mean time from symptom onset to operating room</td>
<td>22 h</td>
</tr>
<tr>
<td>Previous AAA repair</td>
<td>7 (16%)</td>
</tr>
<tr>
<td>Presence of AAA</td>
<td>6 (14%)</td>
</tr>
<tr>
<td>Primary success of EVTR</td>
<td>41 (93%)</td>
</tr>
<tr>
<td>Access: Femoral Iliac</td>
<td>33 (75%)</td>
</tr>
<tr>
<td>Carotid</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>Subclavian artery covered with stent graft</td>
<td>10 (23%)</td>
</tr>
<tr>
<td>Carotid-subclavian bypass</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Blood loss (mean)</td>
<td>360 mL</td>
</tr>
<tr>
<td>Blood transfusion (mean)</td>
<td>2.2 units</td>
</tr>
<tr>
<td>Operative time (mean)</td>
<td>82 min</td>
</tr>
<tr>
<td>Iliac artery rupture</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Respiratory failure (tracheostomy)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Renal failure (dialysis)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Mortality (30 day)</td>
<td>8 (18%)</td>
</tr>
</tbody>
</table>
SHOULD EVAR BE THE STANDARD OF CARE FOR TREATING ABDOMINAL AND THORACIC AORTIC EMERGENCIES?

Although there have been significant improvements in the perioperative intensive care of patients undergoing open surgical repair with ruptured AAAs and other thoracic aortic emergencies, the overall mortality rate of these procedures remains notably high, ranging from 32% to 80%. This has forced vascular surgeons to evaluate other means, particularly endovascular, for treating these life-threatening conditions. Early reports from a few select centers indicate that EVAR of aortic emergencies decreases the morbidity and mortality rates when compared to open surgical repair and offers great promise. Regardless, there remains ambiguity as to the wide acceptance of an endovascular approach for treating ruptured abdominal and thoracic aortas. During the past 5 years, we have learned significantly from our experience of approximately 100 emergent endovascular abdominal and thoracic aortic repairs:

1. A standardized multidisciplinary protocol-based approach is extremely valuable in optimizing results.
2. Preoperative CT scans are not necessarily needed for treating a ruptured AAA; 80% of patients presenting with a ruptured AAA have aortoiliac morphology that is amenable for EVAR, as long as one is willing to accept a less-stringent inclusion criteria. We evaluated 50 consecutive available CT scans of patients with ruptured AAAs and noted that by accepting aortic neck length of 1 cm and an aortic neck diameter of 30 mm with the currently available off-the-shelf stent grafts, ≤80% of patients would qualify for EVAR. In instances when aortoiliac morphology is not suited for EVAR (such as with juxtarenal AAA), the aortic occlusion balloon can be used as a temporary aortic clamp if needed during open surgical conversion.
3. One should be comfortable evaluating CT scans and identifying patients who would be possible candidates for EVAR, particularly when assessing treatment options for thoracic aortic pathology.
4. A complete inventory of stent grafts is not necessary; rather, a limited inventory of catheters, wires, sheaths, and stent grafts can be sufficient. It is more important to become facile with the use of adjunctive procedures such as placement of aortic occlusion balloons, Palmaz stents, and conversion of bifurcated stent grafts to AUI devices.
5. Become familiar with recognizing new complications of EVAR, including development of ACS, which leads to a significantly higher mortality rate. Risk factors for development of ACS include the need for an aortic occlusion balloon, emergent conversion of bifurcated stent grafts to AUI devices, and elevated aPTT at completion of the procedure.
6. Currently, there is no single objective test for recognition of ACS, and this diagnosis is based on clinical findings of sustained hypotension, significant abdominal distention, elevated pulmonary pressures, elevated bladder pressures, and intra-abdominal end-organ dysfunction resulting from hypoperfusion. We need to find better objective measures of detecting ACS because delay in diagnosis is associated with significantly increased mortality.
7. Become familiar with extra-anatomic carotid and subclavian revascularizations, including carotid-carotid, carotid-subclavian bypasses, and other thoracic arch debranching procedures as necessary, and the use of spinal drainage.
8. We routinely implement intrathecal pressure measurements with spinal fluid drainage systems in patients who require significant coverage of the thoracic aorta, particularly in cases of hypotension, with previous infrarenal aortic repair (endovascular or open), or when both hypogastric arteries are occluded. The spinal drains can be placed either before or after the procedure.

CONCLUSION

The answer to the question, “Should EVAR be the standard of care for treating ruptured AAAs and thoracic aortic emergencies?” is “Yes.” However, the proficiency level of individual surgeons and interventionists will most likely determine the treatment strategies in management of these life-threatening aortic emergencies. When patients
with ruptured AAAs and TAAs have ideal anatomy for endovascular repair and are hemodynamically stable, these procedures can usually be done without much difficulty. However, under true emergent conditions, when patients are hemodynamically unstable and not necessarily ideal candidates for endovascular repair, these procedures can be quite challenging and require expertise of advanced endovascular operators. Depending on the level of one’s capabilities, there are clearly times when patients might be better served with open surgical repair. Treatment strategies should always be individualized and depend on the physician’s expertise and patient presentation. There is no question that EVAR for treatment of abdominal and thoracic aortic emergencies has an immediate survival benefit; we think a standardized protocol that includes a multidisciplinary approach is vital to a successful endovascular program for treating these life-threatening emergencies.

Manish Mehta, MD, MPH, is from The Institute for Vascular Health and Disease, The Vascular Group, PLLC, Albany, New York. Dr. Mehta may be reached at (518) 262-5640; mehtam@albanyvascular.com.

Dr. Mehta’s coauthors are from The Institute for Vascular Health and Disease, The Vascular Group, PLLC, Albany, New York.

Impact of Recent Trial Data

An analysis of the current data on open versus endovascular repair, the trials from which they are derived, and how these data can influence everyday practices.

BY GREGORIO A. SICARD, MD

The current debate among vascular specialists regarding the benefits of endovascular aneurysm repair (EVAR) versus open surgical repair has been fueled by recent data from the EVAR-1, EVAR-2, DREAM, and the US-IDE trials. The conflicting results and conclusions of these trials have left some specialists perplexed regarding the proper selection of therapies for both high-risk and normal-risk patients, but a careful look at these data when analyzed together may help to illustrate how they should influence the everyday practice of aneurysm repair.

EVAR IN NORMAL-RISK PATIENTS

As the data accumulate, the superiority of EVAR over open repair in normal-risk patients is clear and undeniable. The DREAM and EVAR-1 trials randomized patients fit for surgery to either EVAR or open repair. Investigators from the DREAM trial reported a 30-day operative mortality rate of 4.6% for open repair versus a rate of 1.2% for EVAR.1 The combined rate of operative mortality and severe complications at 30 days was 9.8% for open repair and 4.7% for EVAR. At 2 years, the cumulative survival rates from the DREAM trial were 89.6% for open repair versus 89.7% for endovascular repair; the cumulative rates of aneurysm-related death were 5.7% and 2.1% for open and endovascular repair, respectively.

The EVAR-1 investigators showed a 4% aneurysm-related death rate in the EVAR group at 4 years after randomization compared to a 7% rate for open repair.2 All-cause mortality was similar in the two groups at approximately 28% for normal-risk patients. However, the rates of postoperative complications within 4 years of randomization were reported to be 41% in the EVAR group and 9% in open repair patients. It should be noted that many such complications do not result in a need for reintervention, but if they do, the reinterventions can be performed endoluminally. Overall, the data from these two trials strongly support the use of EVAR in normal-risk patients.

HIGH-RISK OUTCOMES

Two analyses of “high-risk” patients have been conducted. The first was the EVAR-2 trial,3 which was designed to evaluate the endovascular treatment of patients deemed unfit for open repair. Patients were randomized to receive either EVAR or surveillance (no intervention). The second analysis was performed by the SVS Outcomes Committee using US IDE registry data.4 This analysis was prompted by the results and conclusions of EVAR-2.

In 2005, Roger Greenhalgh, MD, first presented the results of the EVAR-2 study, which were subsequently published in the Lancet.3 The results of this study showed no significant difference between the EVAR group and the no-intervention group for all-cause mortality. The 30-day operative mortality rate for EVAR was 9%, and the no-intervention group had a rupture rate of nine per 100-person year. The overall 4-year mortality rate was 64%, and there was no difference in aneurysm-related mortality between the two groups.

The 9% perioperative mortality rate recorded in EVAR-2 surprised the SVS Outcomes Committee, which believed that the US results were much lower than this. The Committee decided to compare the results from the high-risk patients in the US IDE trials to those of EVAR-2. To do this, the Committee extracted all of the enrollment criteria used for the EVAR-2 trial and went back to the approximately 3,000 patients who were in the Lifeline registry of the IDE trials and looked at the number of patients who met the criteria used by the EVAR-2 investigators. The Committee was surprised to discover that 565 patients met the high-risk criteria, which was far more patients than were enrolled in EVAR-2.

Although the IDE registries were not part of randomized trials, this dataset was considered to be strong because it had undergone the very extensive auditing that occurs with the FDA evaluations of any device. The Outcomes Committee decided to compare endovascular aneurysm repair to the open surgical controls that met...
the same high-risk criteria. Not surprisingly, there were fewer open cases that met the same high-risk criteria. In order to properly compare these two datasets, the investigators used the available criteria in terms of age; size of the aneurysm; cardiac disease, including coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, and renal malfunction; renal abnormalities; and renal dysfunction, and tried to match the patients on as many data points as were available in the two studies.

When the EVAR-2 and IDE data were evaluated, there was a significant difference in 30-day mortality rates: 2.9% in the IDE registry compared to 9% in EVAR-2. In addition, when looking closely at the published EVAR-2 data, it became clear that a significant number of patients in the treatment arm died before treatment. Nine of the 20 deaths that occurred in the treatment arm were aneurysm-related and occurred before the patients were treated, but after randomization. The mean waiting period for the treatment arm was 57 days. In addition, of the 172 patients in the surveillance arm of the trial, 47 crossed over to the endovascular aneurysm repair arm. The 4-year survival rate for the IDE group was 56% (based on all-cause mortality, not just aneurysm-related mortality), whereas in EVAR-2, the 4-year survival rate was 36%.

Analysis Flaws in EVAR-2

As noted previously, there was an extensive waiting period in the endovascular treatment arm of the EVAR-2 study. It has been explained that some of these patients were in such bad medical condition that they needed immediate medical attention to get the patient in better shape prior to endovascular treatment. The Outcomes Committee concluded that EVAR-2’s set-up and method of data analysis (using a small number of patients with a significant number of deaths prior to treatment in the endovascular repair arm and a significant number of patients crossing over from the surveillance arm) created a negative result for endovascular repair.

Another point of debate is that the inclusion criteria for this trial employed a “pragmatism rule” in which internists, cardiologists, radiologists, or surgeons were required to make a determination of whether the patient was unfit for surgery. The lack of objectivity inherent in using this “pragmatism rule” is verified by the fact that a significant number of patients (47) from the surveillance arm crossed over to the EVAR treatment arm, and in this group, the mortality rate was only 2%. For this reason, the high-risk patient population that was included likely lacks uniformity, because no standard, objective criteria were used in making this determination.

There is no adequate means of explaining the large difference in both aneurysm-related and all-cause mortality between the EVAR-2 and US-IDE data unless every patient who lived and died were to be analyzed. One explanation that the EVAR-2 trial investigators have raised is that they were dealing with sicker patients.

Another possible explanation is that the actual medical care of these patients was different. Perhaps the patients in the EVAR-2 trial did not have the same access to their doctors as those in the US do. The only way to give credibility to any particular explanation for the differences in results between the IDE trial and the EVAR-2 trial is to analyze the raw data for both groups.

New Data Favor EVAR in High-Risk Patients

More data are showing that high-risk patients do well with EVAR compared to open surgery. Bush et al compared EVAR in high-risk patients to open repair using the VA National Surgical and Quality Improvement Program and confirmed that the results were much better with EVAR than open repair. Their large dataset of 788 EVAR patients and 1,580 open repair patients showed that the 30-day mortality rate was 3.4% for EVAR versus 5.2% for open repair. These data demonstrate that EVAR is the treatment of choice for high-risk patients.

IS EVAR OR OPEN REPAIR RIGHT FOR YOUR PRACTICE?

Quality of Life

Quality of life is increasingly being evaluated in aneurysm repair studies. It is very important to assess quality-of-life issues; if you provide lifesaving treatment to a patient, but afterwards, he has no meaningful life, then you have to question whether the procedure had any real benefit. Studies have shown that, especially in the elderly patients, quality-of-life scores are low in the postoperative period after open repair. Quality-of-life studies of EVAR patients show that quality of life after 6 months or more is not much different.

Long-term surveillance and follow-up are two possible downsides to endoluminal repair, with patients required to visit the office frequently for evaluation. However, this will likely change as we gather more information, develop better devices, and conduct more subgroup evaluations of patients who may not require such close follow-up.

As shown in the EVAR-1 study, EVAR patients are clearly more likely to require interventions in the long term; however, most of these interventions can be addressed in an endoluminal fashion, and many do not require reintervention at all. There are areas of controversy in which unneeded interventions are performed in EVAR patients (eg, patients with type II endoleaks). We now know that
reintervention should only be contemplated for type II endoleaks when there is a persistent endoleak and the aneurysm grows. In most of these cases, the treatment is endoluminal and does not result in an open conversion. I have always been a proponent of endoluminal aneurysm repair, and I believe that I can offer EVAR to a good-risk elderly patient, and know that I am recommending a therapy that is safe, even though it requires close follow-up. Open repair remains relatively safe, effective, and durable, so I do continue to offer both options. However, open repair involves higher morbidity and mortality rates, a longer hospital stay, and a longer time to return to normal activity compared to EVAR. When patients understand this comparison, few choose open surgery.

In younger patients, aged between 50 and 60 years, I make a much stronger case for open repair because these patients will probably have a longer survival period, and we do not yet know how an endograft will behave in 25 years. I make a stronger case for open surgery in those patients, but even in those circumstances, fewer people accept open surgery now.

LOOKING TOWARD THE FUTURE

For the EVAR devices currently in use, we will benefit from 10-year data showing long-term outcomes. These results may or may not impact our decision-making and patient selection, as well as whether one device is selected over another. Having said that, the technology evolves as device behavior is better recognized and understood. Continued surveillance of current devices will illustrate the specific ways in which individual stent grafts have appealing characteristics in particular patient anatomies. As we move forward and look at long-term data, we will likely have less need to conduct extensive follow-up imaging on these patients.

Gregorio A. Sicard, MD, is Professor of Surgery, Chief of General and Vascular Surgery, Washington University School of Medicine, St. Louis, Missouri. Dr. Sicard may be reached at (314) 362-7841; sicardg@wudosis.wustl.edu.

When facing a small abdominal aortic aneurysm (AAA), the question is . . .

Is it appropriate to treat?

Traditionally, physicians have delayed treatment of aneurysms until they reach a diameter of 5 to 5.5 cm. This is due to a lack of data to support the treatment of smaller aneurysms with endovascular repair.

The PIVOTAL study (Positive Impact of endoVascular Options for Treating Aneurysms earLy) was designed to evaluate whether early endovascular repair might demonstrate benefits over periodic surveillance or “watchful waiting” for the management of smaller aneurysms.

The PIVOTAL study, a multicenter, prospective, randomized trial, is planned to include nearly 1700 patients at 70 clinical centers nationwide, and involve more than 70 top endovascular surgeons. It is designed to compare endovascular repair with an on-label FDA-approved device of small AAAs—4.0 to 5.0 cm in diameter that meet certain inclusion criteria—vs surveillance, with respect to rupture or AAA-related death over a 3 year follow-up period.

Although smaller aneurysms have a low risk of rupturing, this risk increases as the aneurysm enlarges over time. The PIVOTAL study will determine if earlier endovascular intervention of less anatomically challenging small AAAs may improve long-term outcomes.

Patients are still being accepted as participants in the PIVOTAL trial. Physicians are encouraged to enroll or refer patients. All patients enrolled will be monitored with multiple follow-up visits, including an endpoint analysis at 3 years, and continued follow-up through 5 years post-study entry.

With the PIVOTAL trial, physicians can help play a part in determining the most appropriate course of treatment for small AAAs. By enrolling or referring small AAA patients, physicians can also help their hospital reinforce its position as a leader on the cutting-edge of technology that provides the latest treatment for patients.