

AAA Roundtable

Moderator Roy K. Greenberg, MD; Ronald M. Fairman, MD; and Rodney A. White, MD, discuss how clinical trials versus operator experience affect patient care, treating the low-risk patient, and paradigm-changing new devices.



Roy K. Greenberg

What are the current indications for therapy between the high-risk and low-risk anatomies, and what are the anatomic restrictions?

Dr. Greenberg: I always look at this in terms of what we have learned, how we thought about treatment options before we had the results of the EVAR 1 and 2 trials, how the EVAR trials may have changed our paradigms, which ultimately must be viewed in the context of our own concepts of appropriate treatment indications.



Ronald M. Fairman

Dr. Fairman: To be honest with you, I do not think the EVAR trial results have influenced my routine decision making as much as my own clinical experiences. When one has performed many hundreds of AAA stent graft procedures, that level of experience has more influence than anything else.



Rodney A. White

Dr. White: I agree with Ron, the EVAR studies have had little influence on my decisions aside from convincing me that we need to have high-quality US studies addressing these issues. I am always surprised at the discrepancies between some European studies and those in the US, and I am curious why this is the case. Regardless of the factors leading to these differences, we need to know the results in the US center so that use is appropriate to our environment.

Dr. Greenberg: I look at things a bit differently and categorize patients into groups. For example, I was generally concerned about putting an endograft in a low-risk patient. Following the EVAR 1 results, I would not say that I am not concerned about placing an endograft in low-risk patients if they are young, but in the classic 70- to 75-year-old patient who has an aneurysm, the results of EVAR 1 give us more confidence. I also think they gave us more pause in terms of treating a high-risk patient who may not have an unusually large aneurysm (ie, a 5.5-cm aneurysm) in which treatment was justified based on the small aneurysm trial now should be addressed more cautiously.

Dr. Fairman: Sure, I agree.

Dr. Greenberg: In that sense, I think the EVAR trial results have influenced patient care overall, or at least I hope they have. However, it is necessary to look at the high-volume centers and their results because our results in treating high-risk patients, whether the patients are similar to the EVAR 1 patients or not, is somewhat irrelevant, because it has to do with judgment as to who you are going to treat. It boils down to whether you think you are going to get the patient through the procedure and if you are going to disable them by doing it. In my opinion, if you think you are going to get them through the procedure and they are not going to be disabled from that procedure, then you should treat the aneurysm.

Dr. Fairman: That is exactly how I make my decision. In older, high-risk patients, unless I leave them after the procedure exactly as they were before the procedure, it is a bust. If I believe there's a likely chance they are going to end up in a nursing home and they are going to lose whatever independent status they have, or they are going to likely suffer a complication along the way such that they are not going to get back to the level of function where they started, I stay away from them.

Dr. White: Ron and Roy have focused on the most important factor in determining eligibility for treatment, (ie, functional outcome of the patient). We cannot expect to change the overall length of survival for this older age group of patients, but we can prevent death and disability from aneurysm rupture and recovery from conventional surgical procedures.

Dr. Greenberg: I agree completely, although we have to consider other therapies like statins and beta blockers, which takes us to the concept that if you have a high-risk patient (from the physiologic prospective) and you superimpose high-risk anatomy, such as a short proximal neck or bilateral common iliac aneurysms, or marked tortuosity, you must take that into account with respect to a higher risk of debilitating that patient.

Dr. Fairman: I think it's interesting that often you can get past one anatomic restriction, but when they become additive, such as a short or angulated neck, or tortuous small stenotic iliacs, and you start adding multiple anatomic hurdles, it becomes a set-up for failure.

Dr. Greenberg: I agree. I think there is a limitation to every device, and when we start talking about these extreme anatomic circumstances, we are probably outside the design criteria for the device and the instructions for use. Yet, it is done frequently in this country and around the world, with some, if not good success in certain circumstances. I think that the risk of renal issues and short proximal neck are probably greater, as well as compounding issues with the risk of inducing claudication and pelvic and lower-extremity perfusion when we start to embolize internal iliacs. I have seen some patients with severely disabling claudication if we occlude both internal iliacs.

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— Dr. Greenberg

Dr. White: I think we have to be careful any time we treat a patient outside of the instructions for use of the device. We do not have data to substantiate long-term durability of any device outside of the approved guidelines, and to suggest that this is good routine practice requires further long-term studies addressing these parameters. None of the current devices do exceptionally well outside of the instructions for use, and we must carefully consider this when offering this option to patients to clearly delineate the risks of stretching the guidelines.

Dr. Fairman: It is interesting that, as you review the literature, you can definitely walk away with the impression that embolizing both internal iliac arteries is a well-tolerated intervention with, at worst, temporary disability, but that I think is very far from reality. And one needs to give serious consideration to that scenario, as Dr. Greenberg suggested. There is very serious morbidity, including fatalities, associated with taking out the pelvic circulation.

Dr. Greenberg: Another consideration is that we may simply be training our patients not to walk. Therefore,

they may have claudication, stop walking, and over time, stop complaining about claudication. We then interpret this as resolved claudication.

Dr. Fairman: Another important topic to discuss is the current indications for therapy. I would like to comment on the low-risk patient. I do not know how Drs. White and Greenberg feel, but there was a time when I looked at relatively young patients who had large aneurysms or surgical aneurysms and said, “Well, they are too young or they are too healthy to have a stent graft.” I do not use that as a criterion anymore. In those patients, I look at the anatomy. If I have someone who can benefit equally from an open repair or an endovascular procedure, meaning that they are a good-surgical-risk patient and they have good anatomy, I do not think as much about it anymore, and I recommend a stent graft for that patient. If patients have favorable anatomy for an endovascular repair, that is what I offer them regardless of their age, regardless of whether they are low risk or not.

Dr. Greenberg: It depends on the definition of “young.” I always look and ask, “Why does this young patient have an aneurysm so early?” The patients that I most worry about putting an endograft in are those who are young and healthy, who have a family history, and are getting screened. I think we are probably getting a snapshot in time, very early before that aneurysm has matured to the longitudinal extent of the disease. We need to be able to find where the aorta is healthy and not healthy, which is sometimes a challenge. In my practice, I see a lot of patients who have had previous infrarenal AAA repairs who come back with proximal neck dilatation and aneurysms.

Dr. White: I view a young patient (younger than the known 74-year-old demographic for this entity) with an AAA as higher risk for either conventional or endovascular repair. Published data support that the survival curves for younger patients with aneurysms survive at a rate similar to older patients with the same pathology, emphasizing Roy's comment that younger patients are vasculopathies who are going to die from other vascular problems, coronary, carotid, or familial aneurysms. I tell younger patients with aneurysms that they are at higher risk regardless of the procedure performed, while older patients with aneurysms and no occlusive disease do quite well with either open or endovascular repairs. The most important factor favoring endovascular repair in older patients is the reduced disability and shorter recovery time.

Dr. Fairman: I do also. I think it is important to clarify

the term “young.” We really should be saying “low-surgical-risk patient.”

Dr. Greenberg: I was talking about patients who are younger than 70 years. Frequently, these aneurysms are 4 cm or 4.5 cm, and we watch them. However, if that same patient were not treated and then imaged 10, 15, or 20 years after the initial diagnosis, I would hypothesize that the proximal neck would be much shorter. Thus, if patients are treated early, at a young age, will we later be faced with a whole series of endografts floating in aneurysms? It scares me that these younger patients might have a life expectancy of 20 years, and the devices certainly do not. Of course, it is a Catch-22 because, perhaps in 10 years or perhaps even sooner, we will have devices that will fix broken devices.

Dr. Fairman: For me, part of it relates to what my experience has been with conversions; I have had patients who have had an endograft placed, and years later it has migrated. I have also had patients who have been sent to me with migrated endografts that were placed 5 or 6 years previously. I have been able to intervene in those patients very successfully, either by removing the endograft and fixing the aneurysm, or by replacing the endograft with a graft-within-a-graft-type procedure. I usually tell patients that I do not know if this is going to last them 10 years or 20 years, but I also tell them that we will still be able to address what develops down the road. Given that, patients still seem to prefer avoiding a large operation.

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Dr. Greenberg: I do not entirely disagree. Our results in conversions are certainly worse than our results in conventional open surgery, but that is a subset of patients that is difficult to stratify. I still think that the key for these patients is to pick the right patients up front.

Dr. Fairman: I agree.

Dr. White: I think we need to be careful about telling patients that they are entirely secure in the long-term

whether they have an open or endovascular repair. If patients with aneurysms (either aneurysmotic or atherosclerotic in origin) live long enough, they will have other aneurysmal and/or occlusive problems and need to be observed in some fashion for additional treatment. I think the old paradigm of telling the patient that “you are fixed and the problem is over” after aneurysm repair is wrong, and that we know recurrence is part of the underlying disease process. The most important factor is the morbidity and mortality rate of the secondary interventions—here endografts win except for the conversions that Roy has described.

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— Dr. White

Dr. Greenberg: It is important to figure out if there is a healthy aorta that you are going to put the stents into because if you are fixing stents in aneurysms, you are looking at a short-term success. The aorta always narrows as it goes distally, unless it is abnormal; therefore, if you have an area below the renals that is bigger than an area above the renals, you are putting the stents in abnormal tissue. It is not that you cannot do that, you just have to recognize that you are doing that and that you are looking at short-term success.

Dr. Fairman: During the last 10 years, I have become more willing to turn down a case for endovascular repair than I was 5 or 6 years ago. Picking the right patients up front is the most important thing.

Dr. Greenberg: Agreed.

What are the imaging modalities available for aneurysm sizing, and what are the preferences?

Dr. Greenberg: There really is not a standard or a straightforward infrarenal aneurysm for which it is difficult to design a device. No matter the hospital, appropriate imaging facilities exist, in terms of a spiral CT scanner and an imaging workstation, or the ability to just interpret the spiral CT data in an axial format to size an appropriate device of any manufacturer. Pitfalls include angula-

tion and looking at a short axis diameter versus a major or minor axis diameter, looking at calcification versus contrast, and judging the amount of occlusive disease.

Dr. Fairman: I agree.

Dr. White: I agree, yet the standard imaging in many institutions and even core lab facilities is based on axial imaging. Use of high-resolution centerline imaging is the only technique that will eliminate selection and sizing errors and enable better understanding of device function and failure modes over time.

Dr. Greenberg: The criteria for sizing are a good, high-resolution, spiral CT scan and, in any case with complicated anatomy, any angulation of moderate nature should be looked at on a centerline-of-flow display and sized in that method.

Dr. Fairman: Early on, when I was looking at only the axial films, I tended to err not in terms of diameters, but in terms of length assessment. I found that I was putting in more modular devices (more pieces) to complete the case than I do now. For the last several years, we have focused on reconstructions that enable us to do centerline measurements and it is very rare that we ever need an extension any more, just because we're so much more accurate in assessing the lengths.

Dr. Greenberg: That is my observation as well. In the early days, we were looking at a Vanguard device (no longer on the market) and choosing between a 135 and a 160. Now, we have many more choices.

What new devices are on the horizon that will change the established paradigms, and what future graft studies will be conducted?

Dr. Fairman: There are a number of new devices and clinical trials that we should be aware of. The Anaconda (Vascutek Ltd., a Terumo company, Renfrewshire, Scotland) trial is ongoing in phase 1, and the Lombard device (Lombard Medical Technologies, Oxford, England) trial is just getting underway in the US. This device is purported to have the potential to treat very angulated aortic necks. There is the Aptus trial, which is a stapling technology that achieves proximal fixation with screws. It is a novel concept and hopefully will prevent device migration down the road.

Dr. Greenberg: There are iterative improvements in the commercially available devices, such as the larger neck diameters. I would look at it and lump the new developments into the problems that we have, or the

problems that we may have, with the current devices—perhaps there is always an easier way to do a procedure, perhaps there is an even less invasive way to do a procedure, and perhaps we can reduce the French size and worry less about iliac issues, even though the devices are pretty streamlined now. There is also the issue of durability. I think it will be very hard for any device to show benefit over another device with respect to something like migration because there is such a low incidence.

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I also lump the new device developments into devices that are pushing the envelope beyond an infrarenal repair, such as the fenestrated devices, the branch devices, and the branch devices for the internal iliacs, which allow us to treat patients who otherwise were not candidates for endovascular grafts. Those devices are already commercially available in Europe and Australia, and they are in trials in the US. They will, to a much greater extent than many people think, likely open the door for more patients to be endovascular candidates.

Dr. Fairman: And, it also takes so long to happen.

Dr. Greenberg: New AAA devices will have a particular challenge in that they will have to show some benefits over currently available commercial devices; that is a hard thing to do unless you have a new idea. Maybe the Aptus device (Aptus Endosystems, Inc., Sunnyvale, CA) and the 14-F sheath fit that category, although the TriVascular device (Boston Scientific Corporation, Natick, MA) was in a 14-F sheath and there were issues with that—not to draw parallels, but just to point out that attempts have been made before.

Dr. White: The new devices can be viewed in two categories: those that improve delivery of current devices, and those that will extend the applicability to patients outside the instructions for use for current devices. Current devices all function equally well when used according to the instructions for use, which are all the same for approved devices. The challenge is to design

studies that address problems with current devices and to address the factors already mentioned that lie outside of current instructions for use.

Dr. Fairman: I agree. In terms of the fenestrated phase 1 trial that we participated in, we are anxiously waiting to find out where we go next. There is a different challenge with new devices that are starting in phase 1 trials, and even pivotal trials for AAA disease. To ethically enter patients into phase 1 trials for AAA disease is much more difficult now, at least in my experience, than it has ever been. How do you have a discussion with patients and encourage them to sign up for a phase 1 trial unless you are utterly confident that the device brings something new or better to the table than a Zenith device (Cook Incorporated, Bloomington, IN), or an AneuRx device (Medtronic, Inc., Santa Rosa, CA), or an Excluder device (Gore & Associates, Flagstaff, AZ)? It is not always easy to justify putting a patient in a phase 1 trial for a new device when you know that there is something that is a known quantity out there.

Dr. White: The best patient for a phase 1 study is obviously one who does not fit current instructions for use. An example is a proximal neck greater than a 60° angle that can be entered into an aorto-uni-iliac trial for a device that accommodates more severe angles.

Dr. Greenberg: I agree wholeheartedly, and it is a similar problem for the current thoracic trials. Patient recruitment in this context of good devices that are commercially available becomes very difficult. It is the opposite of what we had when we were doing the Zenith study and the Gore trial.

Dr. Fairman: It used to be very easy to enroll patients in trials when they had no other options except open surgery, but now they have a number of commercial options. We have seen this also on the carotid stenting side; there are a host of carotid stent trials that are on the horizon, and really it comes down to the same sort of issue—when you have FDA-approved devices available, it becomes more difficult to enter a patient into a clinical trial.

What are some current issues concerning follow-up paradigms?

Dr. Greenberg: It is interesting how some of the studies that have been published have looked at cost analysis of endovascular versus open repair, which, in my mind, is very flawed because we have not developed an appropriate follow-up paradigm for these devices. For example, the FDA studies for the devices in the US gen-

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erally involve a CT scan within 30 days, at 6 months, and at 1 year, and then annually for a minimum of 5 years. After that, it is almost as if to say “well, they’re 5 years out, so we do not really care about them.” That just does not make sense. What we have evolved into at our institution is a CT scan within 30 days after a procedure for a conventional AAA repair. If there is no endoleak and the graft looks to be in good condition and everything looks okay in terms of the device and the meeting device, we scan them again at 1 year. If the aneurysm is decreasing in size, and it is not an exceptionally large aneurysm, the next year, we may obtain an ultrasound and a four-view KUB and then scan them again the second year.

Our concerns about these devices now center on the long term (ie, what happens after 5 years) instead of the short term (ie, what happens before 5 years). I think these protocols and the follow-up paradigms have to change, and the same concern exists with the open surgery patients—after open surgery, we want these patients to be imaged and followed because after a period of time, they are likely to develop, or potentially likely to develop, proximal neck and aneurysms in remote sites.

I think when we look at our current follow-up paradigms and the cost analyses, we have to view them in the context that these were costs of studies and the studies have not been re-evaluated to determine if we really need to do follow-up on these patients, and what follow-up is actually required.

Dr. Fairman: Dr. Greenberg and I have both written papers looking at how stent grafts behave over time after they have been placed. As one becomes increasingly familiar with a particular device, one knows how it generally should behave in terms of follow-up. For example, with a Zenith graft, I have a good idea of what I expect to see the sac do during the first year. However, we have evolved similarly to what Dr. Greenberg described; we need to obtain a 30-day CT scan and then, if things look fine on that CT, we tend to back off until about a year. I become more concerned the longer we go out; if things look good at a year, I might do the same thing at 2 or 3

years (ie, just get an ultrasound and a plain film). When we get to 5 or 6 years, I am interested in looking at other parts of the aorta.

Dr. White: Dr Fairman and Greenberg make relevant comments regarding surveillance, and in some regard, I think they emphasize the need to improve long-term longitudinal studies of device performance in both endovascular and conventional open procedures. We know the function over a short- and midrange result (5 years or so), but we do not have good long-term imaging data on many of the procedures we perform. The ability to do so is a recent benefit of improved imaging modalities with noninvasive CT and MR technologies, and will improve our understanding of device performance as we collect long-term observational data.

What treatment options result from these findings?

Dr. Fairman: I do not treat type II endoleaks unless the aneurysm sac is growing, which occurs in a small number of patients. There was a time when we would study all of our endoleaks with arteriography because we just wanted to make sure we knew what kind of endoleaks they were. I think we are far more comfortable now identifying the source of endoleaks on CT.

Dr. Greenberg: I vacillate because if I am going to change my follow-up paradigm based on the presence of a leak, sometimes I convince myself, in the absence of shrinkage, to treat the leaks. I like to say that we have reversed the natural history of the disease. And, if the aneurysm is stable, I can fall into that, "Well, I do not really know," mentality. It depends on the leaks, so I certainly will not intervene before a year on a type II endoleak unless there is sac growth. However, a year later, I may intervene because the consequences of an intervention are so minor. It is an outpatient procedure; we do it via a transarterial approach, although others do it through a translumbar approach, and our success rate is very high in terms of glue embolization of these leaks and not causing sequelae.

Dr. Fairman: If one has a patient with a large 8-cm AAA, and 1 year following endografting the patient still has an 8-cm AAA with a type II endoleak, I struggle with sitting on the endoleak. I would treat that endoleak because I am not sure I have protected him from aneurysm rupture if I leave him alone.

Dr. White: I reserve intervention for those who enlarge, based on volume determinations and lengths of proximal and distal fixation zones determined by 3D

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center-line images. I would also intervene on a patient with a leak if the volume is stable but there is enlargement in the area of the leak and a decrease in other area so that the overall volume is stable.

Dr. Greenberg: Yes, I agree. And certainly, I treat type I and type III leaks whenever possible.

Dr. Fairman: Absolutely.

Dr. White: We all agree on this.

Dr. Greenberg: I am always concerned when I see publications that state type I endoleaks are okay, or type III endoleaks are okay. I mean, they might be, but you are gambling.

Dr. White: It is more than a gamble, it is Russian roulette. One must have good reason to observe type I and III leaks, such as when the risk of intervention is prohibitively high. ■

Roy K. Greenberg, MD, is Director of Endovascular Research, The Cleveland Clinic Foundation, Cleveland, Ohio. He has disclosed that he receives research support from Boston Scientific, Cook, Cordis Endovascular, Terumo-Vascutek, and Gore. He is a consultant for Boston Scientific and Cook, and has intellectual property licensed to Cook. Dr. Greenberg may be reached at (216) 445-5306; greenbr@ccf.org.

Ronald M. Fairman, MD, is Chief, Division of Vascular Surgery, University of Pennsylvania Medical Center, Philadelphia. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Fairman may be reached at (215) 614-0243; ron.fairman@uphs.upenn.edu.

Rodney A. White, MD, is Professor of Surgery, UCLA School of Medicine, and is Chief of Vascular Surgery and Associate Chairman of the Department of Surgery at Harbor-UCLA Medical Center, Torrance, California. He has disclosed that he is a consultant and advisor for Endologix, Endomed, Medtronic, and Gore. Dr. White may be reached at rawhite@ucla.edu.