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SPECIAL REPORT: THE STATE OF ENDOVASCULAR ANEURYSM REPAIR IN HIGH-RISK PATIENTS

Dialysis Roundtable

A panel of interventional radiologists discusses the issues and controversies surrounding hemodialysis, and the use of catheters, fistulae, and grafts as access.

PANEL



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What is the current state of treatment of patients with kidney disease?

Dr. McLennan: Approximately 400,000 Americans have severe chronic kidney disease (CKD stage 5) requiring renal replacement therapy. That number is expected to increase to approximately 600,000 patients by 2010. Approximately 20 million patients have mild to moderate renal insufficiency, and an additional 20 million patients are at risk.

When considering this large population of patients with progressive renal insufficiency, many of whom are under the care of a primary care physician, there should be better awareness of the patient's renal deterioration, with early referral to a nephrologist. The goal for these patients is to establish a permanent vascular access, ideally an arteriovenous fistula, at an appropriate time so that it is functional when it is ultimately needed for hemodialysis. Unfortunately, primary care physicians remain unaware of their important role in this process.

With patients who have renal insufficiency/renal disease, whose kidneys are starting to fail or are at some level of failure, the medical system needs to get them into the care of nephrologists so that they can start being triaged for how they can have their renal replacement therapy done. Medically, that is a very difficult thing to do, but as the patients get worse (CKD stage 4 or 5, or diabetes stage 3), the recommendation is to start getting patients in for evaluation for fistula placement so that they are not hospitalized for extended periods during which they receive multiple IVs that ruin venous access before they are ever evaluated by a surgeon for the placement of a fistula. The goal then is to place a fistula so that it is functional and the procedure has lower morbidity and mortality for the patients who actually need renal replacement therapy.

Dr. Haskal: It is also important to keep in mind the estimated costs of treating these patients. In 2006, approximately 200,000 people are going to be dialyzed just by AV access grafts. In 2004, there were approximately 330,000 patients on hemodialysis, and it is projected that by 2010 there may be as many as 435,000, an approximate 25% increase.

What is the Fistula First Program and why is it important?

Dr. McLennan: Much of the initiative for the Fistula First program originates from DOPPS (Dialysis Outcomes and Practice Patterns Study), which is an international registry to assess a variety of patient-related factors associated with long-term dialysis treatment. DOPPS looks at demographic factors, including age, comorbid diseases,



Dr. McLennan

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access type, and morbidities and mortalities. These data show that the most important factor that relates to poor outcomes (ie, cardiovascular deaths, early morbidity and mortality, long hospital stays) is the type of vascular access. In patients who dialyze via a fistula, there is a decreased incidence of vascular access-related complications, a decreased need for hospitalization, and a lower relative risk of death, when compared to patients who dialyze via a PTFE graft or central venous catheter.

The Fistula First Program originated in 2002-2003 from the National Vascular Access Improvement Initiative (NVAII), which is also termed the Fistula First Initiative. This is a CMS quality improvement program with a goal to increase the national prevalence rate of fistulae to 40% by July 2006. We have come fairly close to that rate nationally. This achievement was accomplished by educating nephrologists as to their role as gatekeepers for directing patients to surgeons who place fistulae, and by encouraging collaboration between surgeons and nephrologists for management of vascular access-related issues. Under the guidance of this national program, some hemodialysis treatment centers achieved dramatic changes within a short period of time. There are other types of dialysis practices that fall along a spectrum of how much they have been able to implement the tenets of this program to increase the prevalence of fistulae.

The next goal, with a deadline of 2009, will be to achieve a 66% fistula prevalence rate, which is a very tall order. Achieving this goal will require increasing the percentage of patients who have fistulae placed by between 4% and 5% per year. CMS has decided that this should be the goal for nephrology quality assurance programs.

Dr. Haskal: Some of the reasons why this has been slow have been (1) a late referral of patients for getting access established, (2) a lack of recognition of factors that are detrimental to the success of a fistula (ie, repeated antecubital IVs, venapuncture, and PICC lines), (3) issues

with surgical training and preferences, (4) lower reimbursement for creation of fistulae when compared to grafts, and (5) the lack of enthusiasm among the medical industry. The sale of PTFE graft material for vascular access applications represents a significant share of that market, and the national agenda to utilize native fistula could reduce the need for this product.

There are also some patient subgroups in which fistulae do not do as well, such as older patients and diabetic patients. A certain degree of surgical interest is needed when working with these patients in order to establish successful fistulae.

Dr. McLennan: Although all of those may be contributing factors, the most common reason for an unsuccessful fistula is because many patients are older and have significant comorbid diseases. The DOPPS database has assessed comorbid conditions as a factor for fistulae success and, interestingly, reported that diabetes is not a risk factor for fistula failure.

Dr. Falk: Do you think that a fistulae prevalence rate of 66% is reasonable?

Dr. Johnson: I don't think anyone on this panel thinks 66% is reasonable.

Dr. McLennan: I don't think it is reasonable, but I don't think it matters that I don't think it is reasonable. I think that is what the government is going to ask of us, and we will do our best to reach that goal. I think it will take a dramatic shift in the way we practice to achieve that goal. It will, however, move us in the right direction.

Dr. Haskal: From the DOPPS study we know the fistula prevalence rates for different European countries. Most European countries have met or exceeded the recommended 66% prevalence rate.

Dr. McLennan: The Japanese have an 80% prevalence rate.

Dr. Haskal: We are just slow in reinventing the same well-established practices that exist in many places throughout the world.

Dr. McLennan: I am not certain that the government has thought through how to pay for the resources that will be required to implement the programs necessary to achieve that goal. That financial obligation may become the responsibility of the nephrology commu-

nity. Additional personnel will need to be hired, and local quality assurance programs will need to be implemented to monitor the outcomes of these new vascular access practices. In the future, the use of PTFE graft material for this application may need to undergo a rigorous justification process.

Patients with mild or moderate renal insufficiency must have their arm veins protected so that the surgeons will have good veins to work with. Primary care physicians must be educated about their important role in the detection and management of patients with CKD; this includes preservation of arm veins and early referral to the nephrologist.



Dr. Falk

"What we are learning from the salvage of nonmaturing fistulae is that aggressive follow-up after fistula creation and fistula intervention is mandatory . . ."

Dr. Vesely: It is a real conundrum. Everything that everyone has said thus far is true. Yet, we all know that it is not as simple as we have discussed; these continue to be confusing issues, and the scientific evidence has thus far failed to provide us with answers. A number of surgical investigators have reported high rates of success in creating fistulae, yet when other surgical practices try to repeat the same strategies, these high success rates are not reproducible.

If one looks at the regional distribution of type of vascular access, the upper New England area has always had a high prevalence of fistula (50% to 60%). For some reason, the surgeons and nephrologists in the New England area have always preferred fistulae. No one is really sure why, and until recently it has been just a novel factoid. But now, I think some investigators are beginning to investigate how and why this is the case.

It seems as though the Fistula First Program is intimidating surgeons to create more fistulae. Surgeons who perform vascular access procedures receive a quarterly report that describes how many fistulae, grafts, and catheters they have placed. I know that some of my surgical colleagues are taken aback by this "Big Brother is watching" intimidation. I believe that this quarterly report card may be forcing surgeons to attempt more

fistulae and, unfortunately, the overall success rates are not very good.

Dr. McLennan: The fact is that this is just the start of the process. The writing is on the wall with respect to pay-for-performance. Fistulae will be one of the first things that CMS looks at with respect to pay-for-performance.

There are a number of dialysis-related treatment issues regarding nephrology care that are also on the pay-for-performance scale, and it is going to hit the surgeons very early.

What is the role of the interventional radiologist in the promotion of this fistula movement? What have interventional radiologists done, and what can and are they doing?

Dr. McLennan: While the power of referral is in the hands of the nephrologists, they can choose not to refer patients to surgeons who put in grafts. In environments where an interventional radiologist is actively involved in the care of dialysis patients, the interventionist becomes a liaison between surgery and nephrology and can help maintain a dialogue between nephrology and surgery. Because we see patients with complications related to their access, it is in our interest to see the best access placed in each patient. Furthermore, it is in our interest to be involved in the monitoring of access. For example, in our institution, we have found that having radiologists involved in the monitoring and/or assisting of monitoring access results in a dramatic decrease in the number of clotted access, as well as an actual increase in the number of accesses that are identified as beginning to fail. This benefits us in our scheduling and results in fistulae that need angioplasty alone rather than thrombectomy before angioplasty.

Dr. Vesely: As previously mentioned, one of the most important roles for the interventional radiologist is preservation of peripheral veins. We are involved in so many different aspects of vascular access. We should be cognizant of deteriorating renal function in patients who are sent to us for any type of central venous access. We need to avoid using the subclavian vein and peripheral veins and be knowledgeable of alternative access sites.

Dr. Johnson: If I can just put a finer point on something that Dr. Vesely said, we check our patients' creatinine, and any patient with a creatinine level >3 will not get a PICC, ever. We also routinely do not place PICCs in renal transplant patients. Instead, we place a tunneled infusion catheter centrally.

Dr. Haskal: To emphasize that point, interventional radiology is often like a positive externality—an entity, like the power company, that a hospital society expects to always be there, without being aware how significantly its presence affects their daily lives. We have changed so many dialysis practices, that few recall that these changes came from specifically intended programs. For example, we have all changed respective catheter management in our hospital and access centers by abjuring the use of subclavian accesses, establishing evidence-based line exchange policies, and providing exotic access (eg, translumbar, etc).

Are fistulae becoming grafts and vice versa?

Dr. Falk: Ideally, fistulae have a lower morbidity associated with their creation, the best long-term patency rates, fewest interventions, improved performance over time, and lower complication rates compared to grafts. With the current emphasis on increasing fistula prevalence, our practice as interventionists has changed. We are now involved with improving the maturation of fistulae that fail to mature, and also enhancing the long-term patency of mature fistulae.

What we are learning from the salvage of nonmaturing fistulae is that aggressive follow-up after fistula creation and fistula intervention is mandatory; dilations can be anywhere in the access circuit (from the inflow artery, to the anastomosis and through the venous outflow), vein ligation and/or coil embolization is necessary to obliterate side branches, and occasionally a thrombectomy is necessary. Most importantly, multiple procedures are needed to assist in fistula maturation.

As we become more involved in the management of dysfunctional fistulae, we are performing repeated interventions on fistulae. In fact, fistulae that are younger than 1 year need more reintervention than older fistulae and have lower patency rates. We are performing an increasing number of interventions and reinterventions on fistulae to increase fistulae prevalence; with this come newer concerns. Are the numbers of interventions in fistulae equivalent to the number of interventions performed in grafts? Are multiple repeated angioplasty procedures, which are not considered acceptable for grafts, acceptable for fistulae?

Are grafts so bad? Technological advances have improved our ability to treat graft stenoses and maintain graft patency. We have stents (bare, covered, drug-eluting), balloons (high-pressure, ultrahigh pressure, cutting), and cryoplasty. Vascular access surveillance programs are more effective for grafts than fistulae. One- and 2-year patencies of fistulae and grafts are equivalent in the current literature. The mean age of grafts is increasing, and it

is no longer uncommon to see a functioning graft that is 4 to 5 years old with a large pseudoaneurysm, resembling a fistula.

Dr. Haskal: Dr. Falk published a paper that studied single-operator experience looking at the types of intervention in fistulae in which 76% forced maturation in fistulae with two procedures.¹

Dr. Falk: It was approximately 73% to 74%.

Dr. Haskal: That is a very interesting high success rate.

Dr. Falk: All patients had screening prior to fistula creation and then follow-up 1 week after placement, with continued follow-up every 4 weeks until fistula maturation. We were very aggressive, with interventions starting 6 weeks after fistula creation if the fistula was not maturing. With this aggressive management, our maturation rate was not better than historical controls.

Dr. Haskal: That sets a benchmark to strive for. This kind of fistula intervention is not standard in the US, neither by operator determination to make the dedicated effort, nor follow up to verify their success and modify procedures. It also emphasizes the opportunities for better initial fistula creation and maturation technologies. Finally, it asks whether we are really prepared, as a community of practitioners and recipients of reimbursement, to do this type of in-depth procedures for dialysis patients. This may become essential if we want to reach 66% functioning fistulae goals.

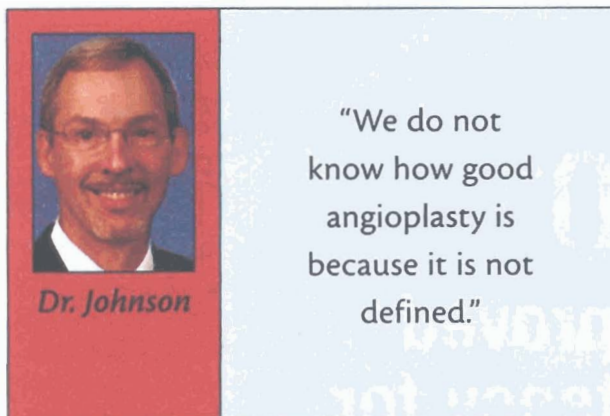
Dr. McLennan: The other part of Dr. Falk's argument is that we do not know if going to 66%, when we have to work so hard to get there, is going to yield an access that is going to be better.

Dr. Falk: Better in terms of patency rates, long-term outcomes, and overall cost.

Dr. McLennan: When you look at what the Europeans and the Japanese have been able to do, the actual patient outcomes (ie, death, morbidity, mortality, and hospitalization) are clearly related to whether they have a fistula. I understand that the fistulae that you work really hard on, in that short time period when you really need to do multiple interventions, may not last as long as a graft may have lasted in an individual patient. But, if you look at the overall population of patients, if you can get more fistulae placed, I believe that we will see, based on the DOPPS data, a better overall health

outcome for those patients (ie, less morbidity and mortality).

Dr. Haskal: There are many questions to be asked about fistulae that are being asked about grafts. For example, there are a fair number of randomized trials that have looked at the value of prophylactic, or screening-driven, interventions in grafts to both prolong graft life, and, separately, uninterrupted graft function—two very different endpoints. Quality-of-access life and quality of patient-life are mixed within this data, or ignored. The answers are cloudy for grafts and downright murky or absent for fistulae. Do interventions actually result in lower morbidity, lesser costs, reduced complications, and better quality of life for patients? It is a ripe area to tackle.



Dr. Johnson

"We do not know how good angioplasty is because it is not defined."

Dr. McLennan: I don't think we know the answer to that about the early interventions.

Dr. Vesely: I agree. The data from recently published studies are suggesting that early intervention can improve fistula maturation. The trouble is that aggressive intervention leads to an increased number of procedures, and therefore, increased costs. But fewer procedures and lower costs have always been two significant benefits of native fistulae. If we start performing more procedures, and thereby generate more costs, we may soon find that fistulae are not much better than PTFE grafts.

Dr. Falk: Another point that needs to be addressed is the duration of catheter use in patients awaiting maturation of a fistula.

Dr. McLennan: Well, certainly, that is an unfortunate consequence of nonmaturing fistulae. While waiting the 2- to 3-month maturation period (potentially 4 to 6 months), the patient is dependent upon a tunneled hemodialysis catheter. An advantageous aspect of PTFE

grafts is that the maturation period is short (3 to 4 weeks), and the initial success rate is high. This translates into a short duration of catheter dependence.

Dr. Falk: Remember, the data that the 2000 KDOQI guidelines and Fistula First were based on may be considered antiquated (references from 1977-1994). I think we are entering a new field in which we do not have enough good solid data to really back up the direction in which we are going.

Dr. Johnson: That is true, but DOPPS is not as antiquated.

Dr. Vesely: DOPPS is primarily European data.

Dr. Johnson: But they have done so well with it.



Dr. Haskal

“New technologies may be groundbreaking and may improve outcomes, but we should be able to interrogate them in a rigorous fashion.”

Dr. Vesely: Yes, but it remains inexplicable as to why the US cannot do as well. Comparative trials have evaluated medical-related factors, such as diabetes and hypertension, but have failed to provide a good explanation as to why surgeons in Europe are more successful at creating fistulae when compared with our surgical colleagues in the US.

Dr. Johnson: Plausible explanation or the correct explanation? It is not in the best interest of the companies that make grafts to push doctors to create fistulae. And, doctors do not get paid as much to create a fistula as to create a graft.

Dr. Vesely: Both of those factors are true, but there are many surgeons who are really trying to do a good job. And yet, they still cannot achieve a 66% fistula prevalence rate.

Dr. McLennan: They also may not be getting the patients as early as the Europeans.

Dr. Vesely: With the increasing incidence and prevalence of fistulae, there is going to be a manpower problem. Many interventionists do not have the interest, skills, and/or time to work on fistulae. Fistula-related procedures often require more skill and more time. In general, interventional radiologists do not seem to have much interest in doing vascular access procedures. As the level of difficulty increases with fistulae, interventionists are going to have even less interest.

Dr. Johnson: I agree.

Dr. Haskal: I think this is very finicky work. I think we have learned from the dialysis graft PTA literature that to simply say that you have done an angioplasty is to grossly misunderstand what you have actually accomplished (or thought you accomplished) for a patient. It is an order of magnitude more complicated in a fistula; it is harder to do, it is harder to gauge results, it is more finicky, and you really have to want to do it.

Dr. Vesely: I would also add that fistula-related problems are more difficult to diagnose. Deciphering the anatomy of a fistula can be difficult for the novice and even the intermediate level practitioner.

Dr. Haskal: Every fistula procedure that I perform starts with a diagnostic ultrasound. That is not the same for an AV access graft, but it is the case for every fistula that we touch.

Dr. Falk: Another important point to remember is that interventional nephrologists are doing this work, too. Many of the new outpatient access centers are run and staffed by nephrologists.

What does the literature reveal about prolonging the patency of hemodialysis access?

Dr. Haskal: There is interesting literature that shows that we know far less about the poorer-than-realized efficacy of balloon angioplasty in grafts than previously thought.

To set the stage for this audience, it is worth noting the state of literature. The original KDOQI graft intervention guidelines were built upon consensus opinion based on largely retrospective, single-center studies without clearly defined criteria for procedural and clinical endpoints, descriptions of the anatomic sites of intervention, controls, etc. They set optimistic (but not rigorously supported) patency goals. Outcomes have begun to fall as prospective controlled trials with defined reporting standards have emerged. The biases in the data actually allow

one to conclude that screening-driven intervention is both fruitful and fruitless.

Dr. Johnson: We do not know how good angioplasty is because it is not defined. Certainly, all angioplasty is not alike. The result of placing a balloon and expanding it within a fistula and a graft is dependent on whether you achieve an optimal angioplasty, which is frequently not appreciated, understood, or even sought. That would take us to the return of a pulseless thrill of a graft, or termination of flow afterward.

Dr. Vesely: I am a circuit guy and a strong believer that you have to consider the whole circuit. If any one part of the circuit is bad, the whole circuit is going to go down. The trouble is that grafts and fistulae have multifactorial problems associated with them. It is not that often that we get just the solitary ideal lesion. Often, there will be some rough intergraft stenoses from needle sticks, there will be classic venous anastomotic stenosis, but yet there will be hypertrophied valve in the outflow, or another stenosis in the outflow. On average, there are 1.5 to 1.7 stenoses per procedure. Just because one angioplasty works, when you have to do another, you have to make sure both are good.

Dr. Haskal: Part of the problem with the literature is the question of whether are we using methods of detection that are uniform, comparable, and ultimately useful. Why should binary restenosis or physical examination (as an outcome variable indicating graft function) stand equal to sophisticated intragraft flow measurements? I think we now know that dialysis angioplasty is not performed homogeneously well (ie, that all contributory lesions are treated to maximal achievable diameter, that flow is sufficiently restored, etc.). We know that recoil is frequent and frequently occurs outside of the operating time frame. Also, we are not always seeking all proper objectives—is it purely about access life (to abandonment), is it time to thrombosis, is it cost, is it the possibly reduced morbidity of having fewer access thromboses, interim catheter dialyses (and blood stream infections), and how are these balanced against the efforts of repeated interventions on patent but failing accesses? What we still have, is a lot of underappreciated noise in the literature.

What does it actually mean? Does it mean that angioplasty is good or bad? I think it is good, I think that data in some studies suggesting that graft life may not be prolonged by intervention cannot be used to negate screening. The question is inextricably linked to the success of angioplasty, and well-done angioplasty. What it

does mean is that we do not necessarily know, but it is better than not doing it. It is important to dilate well, it is important to use appropriate criteria (ie, pressures and flow), it is important to assess recoil, and it is important to be prepared to use secondary tools such as higher inflation pressures and PTFE stent grafts. Newer devices may improve balloon angioplasty results, or may at least highlight the inadequacies of balloon techniques.



Dr. Vesely

"I am a circuit guy and a strong believer that you have to consider the whole circuit."

Dr. McLennan: The Bard dialysis stent graft trial and the cutting balloon trial have prospectively studied their respective novel devices. The results of the cutting balloon trial showed little difference from angioplasty. Neither the Bard nor the cutting balloon trials had very good control arms. There are no such data for cryoplasty, nor for any of the atherectomy devices.

Dr. Haskal: One message that we can clearly send is that new technologies may be groundbreaking and may improve outcomes, but we should be able to interrogate them in a rigorous fashion. There is a tremendous opportunity for people to do research in this area. We see these patients regularly, we have tremendous follow-up, and we ought to be able to improve this literature by doing these kinds of prospective, controlled population studies. This literature needs to be created for all of these technologies. Single-arm studies, case reports, or retrospective single series can no longer suffice, and certainly not in the dialysis area.

Dr. McLennan: There are too many data to be mined. *The fact is, it would be possible to gather 20 to 30 private practice practitioners to work together to do a trial on just about any new technology, but the ones who are selling that technology need to be willing to pay for that study. That seems to be one of the stumbling blocks in getting these types of studies up and running.*

Dr. Vesely: Our nephrology colleagues have created the Dialysis Access Consortium (DAC) to conduct a NIH-sponsored, long-term, multicenter clinical trial to determine the use of different drugs for prevention or inhibition of neointimal hyperplasia in patients with grafts and fistulae. A substantial amount of data is being collected, some of which pertains to number and type of vascular access-related interventions that are performed on the patients who are receiving these drugs. The same team of investigators is developing a prospective, observational clinical trial to evaluate the maturation of native fistulae. Hopefully, the results of this clinical trial will provide us with information that will increase our fistula success rate.

Everyone accepts that surgically created access, whether a fistula or a graft, is superior to catheter access, but obviously many patients require such catheters. Are there any take-home points regarding catheters that should be made?

- Avoid subclavian catheters.
- Try to go jugular, preferably right jugular. Need high flow, but the flow should be matched to the patient. You do not necessarily need a 14.5-F catheter in a child. Place tunneled catheters to avoid the worst possible complications (ie, infection).
- There are two possible tip configurations, step tip or split tip, that might have an impact on whether the provision of dialysis is more adequate. Both have advantages. Match the tip to the patient's needs.
- Image guidance is critical (ultrasound and fluoroscopic).
- The goal should be to reduce the number of catheters as much as possible. Regarding catheter placement, the message to the patient should not be that this is the final access and that this access is better than anything else. Catheters really are a stopgap. One thing that has improved catheter care over the past 5 years has been the realization that guidewire exchange is successful, particularly for the infected catheter. Five years ago, infected catheters were being pulled, and we were putting in a new catheter at a new site. These days, under the appropriate circumstances, guidewire exchange reutilization of the same site is very beneficial. You can salvage the majority (80%-85%) of catheters, and it all leads to preservation of the central veins. ■