Selected short papers from

The Sixth Annual Controversies in Dialysis Access

12-13 November 2009

The Westin St. Francis
San Francisco, California
USA

Course Directors

Ingemar Davidson, MD, PhD
Professor, Department of Surgery
The University of Texas Southwestern Medical Center, Dallas, TX

Bart Dolmatch, MD
Professor, Department of Radiology
The University of Texas Southwestern Medical Center, Dallas, TX

Controversies in Dialysis Access

The Sixth Annual CiDA

THURSDAY NOVEMBER 12, 2009

Controversies in Dialysis Access - Day I

7:00 AM	Breakfast and Visit Exhibits	
Session I: AVF Maturity		Moderators: **Ingemar Davidson, MD, PhD, Marc Glickman, MD**
7:30 AM	Welcome and Introduction to Audience Polling	Speaker: **Ingemar Davidson, MD, PhD**
7:40 AM	YOU Are the Expert! Making the Right Decisions	Speaker: **Ingemar Davidson, MD, PhD**
7:50 AM	ARE You the Expert?	Speaker: **Bart Dolmatch, MD**
8:00 AM	Finding Our Way Through the Maze of Published Data	Speaker: **Scott Trerotola, MD**
8:10 AM	Pre-op Vascular Mapping: What Findings Predict AVF Maturity?	Speaker: **James Reus, MD**
8:20 AM	Translating Pre-op Vein Mapping to Fistula Maturity: The Surgeon's Role	Speaker: **Marc Glickman, MD**
8:30 AM	AVF Immaturity and the Center Effect	Speaker: **Ingemar Davidson, MD, PhD**
8:40 AM	AVF Immaturity: Impact Upon Success of the Fistula First Initiative	Speaker: **Lawrence Spergel, MD**
8:50 AM	Balloon Assisted AVF Maturation: A Primer for Non-believers	Speaker: **Gregg Miller, MD**
9:00 AM	CASE PRESENTATIONS I: AVF Immaturity	Panelists: **Marc Glickman, MD, Gregg Miller, MD**
		James Reus, MD, Lawrence Spergel, MD, Scott Trerotola, MD
		Speaker: **Selcuk Baktiroglu, MD**
9:40 AM	Refreshment Break and Visit Exhibits	
Session II: Access Creation and Maintenance		Moderators: **Bart Dolmatch, MD, Prabir Roy-Chaudhury, MD**
10:00 AM	**Controversies in AVF Prevalence (FFBI Target Goal of 66%)**	
10:00 AM	To Infinity and Beyond – More AVFs Mean Better Care	Speaker: **Lawrence Spergel, MD**
10:06 AM	Not So Fast, Buzz Light-Year – Quality Not Quantity	Speaker: **Marc Glickman, MD**
10:12 AM	Discussion With Questions and Answers	Panelists: **Marc Glickman, MD, Lawrence Spergel, MD**
10:20 AM	The Best AVF and AVG Patency Data You Never Saw: Surprising Outcomes from the Dialysis Access Consortium	Speaker: **Miguel Vazquez, MD**
10:30 AM	AVF Stenosis Angioplasty: How Does Balloon Venoplasty Work?	Speaker: **Prabir Roy-Chaudhury, MD**
10:40 AM	Recoil and Spasm in AV Access Veno-plasty: How important?	Speaker: **Sanjoy Kundu,MD**
10:50 AM	The Why and When of Cephalic Arch Stenosis	Speaker: **Surendra Shenoy, MD, PhD**
11:00 AM	**Controversies in Cephalic Arch Stenosis – What to Do?**	
11:00 AM	Surgery Is the First Step	Speaker: **Surendra Shenoy, MD, PhD**
11:06 AM	PTA+/- Stent or Covered Stent Is the First Step	Speaker: **Dheeraj Rajan, MD**
11:12 AM	Discussion With Questions and Answers	Panelists: **Dheeraj Rajan, MD, Surendra Shenoy, MD, PhD**
11:20 AM	CASE PRESENTATIONS II: AVF Stenosis	Panelists: **Marc Glickman, MD, Sanjoy Kundu, MD, Dheeraj Rajan, MD**
		Surendra Shenoy, MD, PhD, Lawrence Spergel, MD, Miguel Vazquez, MD
12:00 PM	Lunch and Visit Exhibits	
Session III: AV Grafts and Graft-Covered Stents		Moderators: **Dirk Baumann, MD, Bart Dolmatch, MD**
1:00 PM	Should Anyone Get an AVG When an AVF Is Anatomically Possible?	Speaker: **Dirk Baumann, MD**
1:10 PM	**Controversies in Forearm AVG When an Upper Arm AVF Could be Created**	
1:10 PM	Forearm Loop Graft Before an Upper Arm AVF	Speaker: **Dirk Baumann, MD**
1:16 PM	Forget the Forearm Loop Graft and Proceed to the Upper Arm AVF	Speaker: **Surendra Shenoy, MD, PhD**
1:22 PM	Discussion With Questions and Answers	Panelists: **Dirk Baumann, MD, Surendra Shenoy, MD, PhD**
1:30 PM	Covered Stents for Access intervention: What We Know and Where We're Going	Speaker: **Ziv Haskal, MD**
1:40 PM	**Controversies in the Treatment of AVG Venous Anastomotic Stenosis**	
1:40 PM	PTA Only, Unless it Fails or Ruptures	Speaker: **Gerald Beathard, MD, PhD**
1:46 PM	The Data Show That Primary Covered Stenting Is Preferred Over Simple PTA, When Possible	Speaker: **Ziv Haskal, MD**
1:52 PM	Discussion with Q&A	Panelists: **Gerald Beathard, MD, PhD, Ziv Haskal, MD**
2:00 PM	Covered Stents for AVF Stenosis	Speaker: **Bart Dolmatch, MD**
2:10 PM	Cannulation Pseudo-aneurysms: Are Covered Stents Useful?	Speaker: **Scott Trerotola, MD**
2:20 PM	CASE PRESENTATIONS III: Grafts and Graft-covered Stents for AV Access	Panelists: **Dirk Baumann, MD**
		Gerald Beathard,MD, PhD, Ziv Haskal, MD
		Surendra Shenoy, MD, PhD, Scott Trerotola, MD
		Speakers: **Murty Mantha, MD, Evan Samett, MD, Marc Webb, MD**
3:00 PM	Refreshment Break and Visit Exhibits	
Session IV: Peritoneal Dialysis		Moderators: **Ingemar Davidson, MD, PhD, Maurizio Gallieni, MD**
3:20 PM	The PD First Breakthrough Initiative – "Clinical Benefits of PD First"	Speaker: **Maurizio Gallieni, MD**
3:30 PM	PD or Hemodialysis in Children	Speaker: **Mary Brandt, MD**
3:40 PM	**Controversies in Who Is Unwilling or Unable to Use PD, the Nephrologist or the Patient?**	
3:40 PM	Nephrologists Could Do a Better Job	Speaker: **Maurizio Gallieni, MD**
3:46 PM	Patients Could Consider PD More Often	Speaker: **Miguel Vazquez, MD**
3:52 PM	Discussion With Questions and Answers	Panelists: **Maurizio Gallieni, MD, Miguel Vazquez, MD**
4:00 PM	Failure Modes of PD	Speaker: **Mary Brandt, MD**

4:10 PM	Invited Access Cases from the Floor: What Would the Experts Do?	Panelists: **Gerald Beathard, MD, PhD, Danny Chan, MD, Bart Dolmatch, MD, Gregg Miller, MD, Thierry Pourchez, MD, Dheeraj Rajan, MD, Fred Schild, MD** Speakers: **Amy Dwyer, MD, Dirk Hentschel, MD, Timmy Lee, MD**
4:40 PM	Daily Closing Remarks, Electronic Polling Sign-up for Clinics, CIDA on EVF, and Adjournment	Speakers: **Ingemar Davidson, MD, PhD, Bart Dolmatch, MD**
4:45 PM	The Westin St. Francis: An Historical Overview	
5:00 PM	Welcome Reception in Exhibit Hall	

FRIDAY NOVEMBER 13, 2009

Controversies in Dialysis Access - Day II

7:00 AM	Breakfast and Visit Exhibits	
Session V: Hand Ischemia		Moderators: **Ingemar Davidson, MD, PhD, Marc Glickman, MD**
7:30 AM	Opening Remarks and Audience Polling	Speakers: **Ingemar Davidson, MD, PhD, Marc Glickman, MD**
7:40 AM	What Causes AV-access Related Hand Ischemia?	Speaker: **Fred Schild, MD**
7:50 AM	Simplifying Non-invasive Assessment of Hand Ischemia	Speaker: **Danny Chan, MD**
8:00 AM	Undoing the Sin of Stealing. Treatment Options for Hand Ischemia	Speaker: **Ingemar Davidson, MD, PhD**
8:10 AM	Percutaneous Banding: Why, When, and How	Speaker: **Gregg Miller, MD**
8:20 AM	CASE PRESENTATIONS IV: Hand Ischemia	Panelists: **Danny Chan, MD, Gregg Miller, MD, James Reus, MD, Fred Schild, MD** Speaker: **Sidney Glazer, MD**
Session VI. Thrombosed AV Access		Moderators: **Gerald Beathard, MD, PhD, Bart Dolmatch, MD**
9:00 AM	The Clotted AVF: Are There Any Indications for Surgical Thrombectomy?	Speaker: **Surendra Shenoy, MD, PhD**
9:10 AM	Is it Ever Too Early or Too Late to Attempt AVF Declotting?	Speaker: **Scott Trerotola, MD**
9:20 AM	CASE PRESENTATIONS V: Thrombosed AV Grafts and Fistulae	Panelists: **John Ross, MD, Prabir Roy-Chaudhury, MD, Surendra Shenoy, MD, PhD, Scott Trerotola, MD**
10:00 AM	Refreshment Break and Visit Exhibits	
Session VII. Central Vein Obstruction in AV Access		Moderators: **Gerald Beathard, MD, PhD, Bart Dolmatch, MD**
10:20 AM	Symptomatic Chronic Central Vein Obstruction: PTA +/- Stenting Results	Speaker: **Sanjoy Kundu, MD**
10:30 AM	**Controversies in Subclavian Vein Angioplasty and Stenting**	
10:30 AM	Stenting Is a Good Solution That Buys Time	Speaker: **John Ross, MD**
10:36 AM	Stenting Is So Bad it Should Rarely be Done	Speaker: **Michael Allon, MD**
10:42 AM	Discussion With Questions and Answers	Panelists: M**ichael Allon, MD, John Ross, MD**
10:50 AM	Covered Stents for Central Venous Obstruction	Speaker: **Sanjoy Kundu, MD**
11:00 AM	Percutaneous Techniques for Total Central Venous Occlusion	Speaker: **Dheeraj Rajan, MD**
11:20 AM	CASE PRESENTATIONS VI: Treatment of Symptomatic Central Vein Obstruction	Panelists: **Michael Allon, MD, Sanjoy Kundu, MD, Dheeraj Rajan, MD, John Ross, MD, Surendra Shenoy, MD, PhD**
12:00 PM	Lunch and Visit Exhibits	
Session VIII: Clinics		
1:00 PM	Adoption of New Access Technology in the Dialysis Unit	Moderators: **Brian LaMendola, RN, BSN, Miguel Vazquez, MD**
1:00 PM	Duplex Exam of Arteries, Veins, and AV Access	Moderators: **Danny Chan, MD, Ingemar Davidson, MD, PhD, Muhammad Hasan, Mr., James Reus, MD**
1:00 PM	Technical Aspects of Access Intervention	Moderator: **Bart Dolmatch, MD,** Speakers: **Michael Cohen, MD, Stanley Cooper, MD, Elsie Koh, MD, Matthew Mulloy, MD**
Session IX: Catheters for Hemodialysis		Moderators: **Ingemar Davidson, MD, PhD, Michael Tal, MD**
2:00 PM	What Everybody Needs to Know About Catheter Flow Rates, Pump Settings, and Successful Dialysis	Speaker: **Maurizio Gallieni, MD**
2:10 PM	**Controversies in Hemodialysis Catheter Prevalence**	
2:10 PM	During the Fistula First Years Catheter Prevalence is Definitely Up	Speaker: **Gerald Beathard, MD, PhD**
2:16 PM	There's Been No Increase, and I Can Prove It	Speaker: **Lawrence Spergel, MD**
2:22 PM	Discussion With Questions and Answers	Panelists: **Gerald Beathard, MD, PhD, Lawrence Spergel, MD**
2:30 PM	Catheter Coatings and Locking Solutions – Are These Clinical Advances?	Speaker: **Michael Allon, MD**
2:40 PM	Data-driven Tunneled Catheter Selection: Oxymoron?	Speaker: **Michael Tal, MD**
2:50 PM	Put That Catheter Tip Where?	Speaker: **Michael Tal, MD**
3:00 PM	A Novel Vascular Access Device for Patients With Venous Obstruction	Speaker: **John Ross, MD**
3:10 PM	CASE PRESENTATIONS VII: Tips, Unusual Solutions and Complications of Central Venous Catheter Access	Panelists: **Michael Allon, MD, Gerald Beathard, MD, PhD, John Ross, MD, Lawrence Spergel, MD, FACS, Michael Tal, MD,** Speaker: **Troy Plumb**
3:50 PM	Concluding Remarks	Speakers: **Ingemar Davidson, MD, PhD, Bart Dolmatch, MD**
4:00 PM	Adjourn	

Controversies in Dialysis Access (CiDA)
The 6th Annual CiDA Meeting In San Francisco

Welcome to San Francisco, the town that shakes up its people every 50-100 years or so. This is our 6th annual CiDA, Controversies in Dialysis Access. In fact, we are back, as the CiDA meeting in 2006 was also held here, in the historic St Francis Hotel at Union Square.

What makes the CiDA meetings unique and worth participating? First, we are not affiliated with a specific ESRD, dialysis or other governing medical societies. In fact, all dialysis access interests are represented in the audience, among speaker and exhibitors. Optimal dialysis access management and success is not an isolated event in the operating room, in the angio-suite or in the nephrologist's office. It is the result of a concerted team efforts best captured by the term Continuum of Care, where patients move freely between treatment specialists without inhibiting forces. All of this must happen in the spirit of the best possible outcome, within the framework of the society in which we live and work. However, this ideal situation is still far from being a reality. Here we have much to learn from Doctors without Borders.

Second, the meeting structure is designed to engage all participants. Much discussion time has been allotted. The controversial debate sessions are aimed to expose and enlighten sharply different viewpoints. Special attention will be devoted to the perhaps most underutilized but powerful tool in determining the best access site i.e. duplex Doppler Sonography vascular mapping.

We are deeply grateful to our sponsors and exhibitors. Please spend time and visit the exhibit hall and show our sponsors your appreciation. Several new dialysis access tools and devices will be exposed here.

The opportunity to again publish the abstracts and meeting proceedings in the Journal of Vascular Access is greatly appreciated. We continue to be most impressed with this first class journal, and the on time, highly professional, clear and crisp delivery.

Finally, this meeting is unique because we are in San Francisco. Although we want you to be present at every meeting sessions, you must also not miss the opportunity to enjoy some of the sites in the most exciting city in the world. Let's shake it!

Ingemar Davidson *Bart Dolmatch*

1129-7298/236-01$25.00/0

The Journal of Vascular Access 2009; 10: 237-291

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

You are the Expert! Making the Right Decisions

Ingemar J.A. Davidson

University of Texas Southwestern Medical Center and Parkland Memorial Hospital, Dallas, TX - USA

Some people (including doctors) seem to walk on water. Clearly some pilots can land a jetliner on the Hudson River. Are these accomplished individuals just struck by good luck? Or, is there something else that makes some (professionals) more successful than others? In other words, what does it take to become a world class expert? (1) (Tab. I). There are certain professions or activities more easily recognized as having special or exceptional skills and hence referred to as "experts" (Tab. II). (1). In reference to this meeting, surgery and interventional procedures require certain skills and knowledge to perform the necessary operations. In addition, in the spirit of this meeting, interdependent mindset with seamless, inhibited flow of information between treating departments and the decision-making governing bodies will improve the effectiveness and outcome. Some personal attributes defining team players and leaders have been linked to brain cell physiology (2, 3) (Tab. III). When people work in concerted synergy as a team, quality improves and the world class experts have created a natural Center of Excellence. However, good leadership may suffer negative consequences by organizations dominated with legal-rational authority characterized by blame and shame (4). True expertise develops when professionals openly report and share mistakes where everyone can learn from them without risk of punishment (5).

TABLE I - CHARACTERISTICS OF AN EXPERT

- Be at the Right Place
- Born and be around at the Right Time (year)
- IQ of about 115
- Have resources, ie rich parents
- Be passionate about what you do
- Practice for 10.000 hours

TABLE II - EXAMPLES OF EASILY IDENTIFIED EXPERT (PROFESSIONAL) ACTIVITIES THAT FOLLOW THE TABLE I RULES

- Violin player
- Tennis player
- Opera singer
- Computer programmer
- Piloting an air plane
- Surgery (ie dialysis access)
- Interventional radiology

TABLE III - WHAT MAKES AN EFFECTIVE TEAM MEMBER OR LEADER?

- "People skills"
- Nice and firm
- Abundant personality
- Interdependent mentality
- Service above self
- Trust
- Good listener
- Going the extra mile
- Leader (not a dictator)

1129-7298/237-55$25.00/0

References

1. Caldwell M. Outliers: The Story of Success. New York: Little, Brown & Co, 2008. HCISBN 978-0-316-01792-3.
2. Goleman D. Social Intelligence: The New Science of Human Relationships. Bantam Books, 2006. IBSN-13:978-0-553-80352-5.
3. Goleman D, Boyatzis B. Social intelligence and the biology of leadership. Harvard Business Review September 2008.
4. Vaughan D. The dark side of organizations: mistake, misconduct, and disaster. Annu Rev Sociol 1999; 25: 271-305.
5. Dekker S. Just Culture, Balancing Safety and Accountability. Ashgate Publishing Company, 2007.

ARE You the Expert?

Bart Dolmatch

Department of Radiology, University of Texas Southwestern Medical Center, Dallas, TX - USA

An EXPERT is "a person with extensive knowledge or ability in a given subject". (Wiktionary, 2009). Do YOU have extensive knowledge or ability in dialysis access? Not sure? OK, maybe you don't consider yourself an expert, but certainly you're better than average, right?

If you believe that you are better than average, let's define average as the mid-level of knowledge and ability for all 2009 CiDA attendees - right here, right now. Now we'll test ourselves. In this scenario, about half of us would be better than average and half would not. Still sure you're better than average? If so, you are not alone. In fact you are joined my many more people than could possibly be above average!

This phenomenon has been called the Lake Wobegon effect (Wikipedia). This odd name traces back to a radio show called "A Prairie Home Companion", hosted by Garrison Keillor (National Public Radio). He created a fictitious town, Lake Wobegon, Minnesota, where "all the women are strong, all the men are good looking, and all the children are above average." Naturally, not ALL the women can be strong, nor can ALL the men be good looking. It would be impossible for ALL the children to be above average. Yet, the Lake Wobegon effect describes a real and pervasive human tendency to overestimate one's achievements and capabilities in relation to others.

There are two explanations for the Lake Wobegon effect. It is either due to an unfounded belief that we are better than most, or it may be due to the design of many educational tests where a vast majority of participants achieve results above the norm. Simply stated, we either have a visceral (emotional) sense of being better than average, or we design tests so that many more people do better than "average." Either way, the fundamental problem seems to be our need to feel special, better than others, and certainly better than average - and in many cases we design our test to prove what we believe.

Given our tendency to see ourselves as better than average, there are some challenging questions that we should all ask ourselves at CiDA:

- ARE you an expert in dialysis access?
- Are you better than average?
- Are you competent?
- How do you measure expertise, outcomes, and competency?

There are no easy answers, and beyond these questions of personal aptitude, it's important to mention that there's a hugely complex system for providing dialysis access care and YOUR talents are only a small component of the end result. In the broad sense of providing care, many other issues remain, including:

- Do you understand how your colleagues contribute to management of dialysis access?
- Are you working with them to improve overall outcomes?

• Are your decisions and skills considered valuable by your colleagues?

An Indian fable describes a group of blind men who are asked to describe an elephant, having never encountered one before. Each blind man touches the elephant to learn what it is like, but touches only one part, such as the side, the tusk, the ear, the trunk, or the tail. They then compare notes on what they felt, and learn they are in complete disagreement. Similarly, each of us encounters different facets of dialysis access, and the risk is that we become "expert" at what we know - but do not improve the end result because we only see a part of the process. While we must be good in our own area, that's not enough. We need a comprehensive understanding of what everyone does so that our efforts contribute to the ultimate final product of dialysis access.

Does expertise matter? I believe we all want to be at the top of our game because we are competitive people who aim for high standards of patient care. But beyond this, our outcomes may be very important in determining compensation. Ongoing healthcare coverage in Massachusetts, as well as the current push toward a new healthcare policy in the United States, will likely use clinical outcomes as an important determinant in factoring physician payment (and controlling healthcare costs). Excellence is not only the high bar of our professional ego, but may determine how much we earn.

Welcome to CiDA, the only meeting that includes everyone who works within the complex system of dialysis access. CiDA is not a society or university, and there is no particular agenda (political, social, or economic) other than a vigorous academic examination of our knowledge and aptitude. It's a place where everyone has the opportunity to participate, where the faculty is challenged by you, and where they challenge each other. Once this meeting is finished and you return to your dialysis community where the average is different, the insight you gain during your time at CiDA can make you better-than-average, if not an expert. ARE you an expert? It's not important at CiDA, but we hope you return home as one.

Finding Our Way through the Maze of Published Data

Scott Trerotola

University of Pennsylvania Medical Center Philadelphia, PA - USA

The 21st century has been dubbed "the era of evidence-based medicine" even before the latest round of discussions about using evidence basis to help reduce the costs of healthcare. Now more than ever, applying evidence basis to daily practice is essential not only to achieving optimal outcomes, but also to managing utilization of increasingly expensive technologies available to us.

Hemodialysis access management continues to lack a solid evidence basis in many areas, although the situation has improved dramatically since the publication of the original K/DOQI guidelines in 1997. Those guidelines, and the subsequent updates, serve as a research manual for this area, identifying areas of evidentiary vacuum. Many researchers have helped to fill these gaps with prospective, randomized trials which have moved our practices higher on the evidence pyramid and in some areas even allow systematic reviews to be performed.

However, in this field in particular, there are often inconsistencies in reporting, definitions and even understanding of these interventions. The situation is not helped by disparities in reporting standards from three separate societies. Further, there has been a trend throughout the history of medical research to focus on one's own area of expertise, sometimes blinded to existing evidence in other disciplines. While careful literature searches should avoid this, especially in the information age, it is remarkable how often this continues to occur. To further compound the situation, even well-meaning investigators in well-designed studies may reach conclusions that are not based on the evidence gathered, and if those unfounded conclusions are perpetuated, adverse consequences to patient care can occur.

Nowhere is this problem more evident that in prophylactic PTA of dialysis grafts. Several prospective randomized trials have now been performed purporting to address this issue (1-5), and on the basis of these trials payors are now beginning to discuss curtailing and/or eliminating reimbursement for

this very important practice. Yet, if one carefully examines the "evidence" referenced in these discussions, it does not, for the most part, directly study prophylactic PTA, rather different screening methods. This has not prevented authors from concluding that prophylactic PTA is not worth doing and that inaccurate conclusion being perpetuated. This is but one example, of course.
Thus, in hemodialysis access interventions as in other areas in medicine, practitioners must weigh the evidence they read as it emerges in light of all existing evidence in all related disciplines; they should read each publication critically using the evidence pyramid; and they should be aware of differences in standards between societies. Even more important is the need for researchers and innovators in the field to avoid "reinventing the wheel" and ensure that lessons learned in the past, even by researchers in other disciplines, are not repeatedly simply because the investigator was ignorant of existing work. Fortunately, the modern search engine should make this error increasingly infrequent, provided this basic research and clinical tool is applied consistently.

References

1. Moist LM, Churchill DM, House AA, et al. Regular monitoring of access flow compared with monitoring of venous pressure fails to improve graft survival. J Am Soc Nephrol 2003;14: 2645-53.
2. Ram SJ, Work J, Caldito GC, Eason JM, Pervez A, Paulson WD. A randomized controlled trial of blood flow and stenosis surveillance of hemodialysis grafts, Kidney Int 2003; 64: 272-80.
3. Dember LM, Holmberg EF, Kaufman JS. Randomized controlled trial of prophylactic repair of hemodialysis arteriovenous graft stenosis. Kidney Int 2004; 66: 390-8.
4. Tessitore N, Lipari G, Poli A, et al. Can blood flow surveillance and pre-emptive repair of subclinical stenosis prolong the useful life of arteriovenous fistulae? A randomized controlled study. Nephrol Dial Transplant 2004; 19: 2325-33.
5. Malik J, Slavikova M, Svobodova J, Tuka V. Regular ultrasonographic screening significantly prolongs patency of PTFE grafts. Kidney Int 2005; 67:1554-8.

Translating Pre-op Vein Mapping to Fistula Maturity: The Surgeon's Role

Marc H. Glickman

Eastern Virginia Medical School, Norfolk, VA - USA

Does a good vein, good artery automatically mean excellent results? Does a high bifurcated brachial artery portend poorer outcomes in access formation? Is there anything the surgeon can do to improve outcomes with knowledge from pre-op vein mapping? Are there any surgical techniques that can be performed that will improve fistula patency?
Valenti et al from King's College in London presented a paper demonstrating that the incidence of high brachial artery bifurcation was common, and that the maturity rate was substantially worse in those patients undergoing brachial cephalic fistulas with such anatomy compared to patients with standard bifurcation anatomy. This is an important paper demonstrating the importance of the artery in fistula maturity and development. This paper also demonstrates the importance and knowledge of the high brachial artery bifurcations in access placement.
Shenoy and et al demonstrated the importance of performing an interrupted anastomosis in fistula maturation. This paper was an analysis of patients who underwent autogenous fistula creation using non-penetrating clips and comparing outcomes to standard suture placement. They found a marked improvement in access development when compared to standard techniques. A prospective randomized study using a penetrating clip to standard suture, reported by this author also demonstrated improved outcomes and maturity of the fistula. Vein size and anatomy were similar in both groups when looking at outcomes only for the radio cephalic fistula.
Site selection of the access placement is also very important in translating vein mapping to impro-

ving fistula maturity. Maturation rates of the radio cephalic vein in multiple studies are noted to be below those of the brachial cephalic access. Marginal forearm veins often mean marginal access; and therefore, one should proceed to a brachial cephalic access to promote fistula maturation.
Altering turbulent blood flow and altering the angle of the arteriovenous fistula creation can alleviate the angle that occurs just distal to the anastomosis. Shenoy has presented a novel anastomotic angle of the vein to the artery which reduces turbulent blood flow and reduces swing segment stenosis creation. This novel approach to fistula creation can translate to improved maturation by reducing swing segment stenosis.
Finally, there are new products being developed with hopes of improving fistula patency and maturation. One product is a pancreatic elastase that induces vein dilatation and therefore the hope is to improve fistula maturation. The other product is an allogenic endothelial cell product that induces vein dilatation and remolding of the venous endothelial cells that hopes to reduce intimal scarring. Both of these concepts are intriguing and promising.

AVF Immaturity and the Center Effect

Ingemar J.A. Davidson

University of Texas Southwestern Medical Center and Parkland Memorial Hospital, Dallas, TX - USA

Some hospitals and healthcare corporations proclaim themselves as “centers of excellence”, implying they are better than the one you work at. In many towns around the USA, doctors vote for the best colleges/friends to create the “Best Doctor list” in your city, ie picked by peers and published in the magazine to be read by the city’s affluent members.
This presentation is about the care of the end-stage renal disease (ESRD) patients, ie renal transplantation and specifically about dialysis access. This is a challenging patient population with an overall annual mortality of about 20% in the USA. The timing and choice of dialysis modality, the type and site of hemodialyis access may mean death or survival of that patient, but it will certainly impact longevity (1). A center administrative leadership style and culture (2, 3) will affect the center’s overall success. Protocols and policies in place must be followed. Preoperative duplex Doppler ultrasound evaluation is one example of such an outcome improvement policy (1, 4).
The transplant community has long recognized the outcome variability between kidney transplant center outcomes as reported annually by UNOS (United Network for Organ Sharing) (5). This phenomenon is known as the “Center Effect”, a concept generally accepted, although it is difficult to define what specific factors make a center do better or worse. Likewise, dialysis practices and outcome varies greatly around the globe as well in the USA (6). More specifically access outcome such as early arteriovenous fistula (AVF) clotting thrombosis at 6 weeks varies widely between centers from 6-20% (unpublished data) (7). Likewise, the primary patency with PTFE grafts is reported as high as 69% at 1 year (8), while others report graft function of less than 30% in recent years (9).
Although it is difficult to pinpoint the exact causes of success, it is clear that it is multi-factorial. In fact it may be the “Tipping Point” effect as described by Caldwell in his book with the same title (10). In this context, doing the right thing for the right patient at the right time in the right amount for the right reasons.. In other words, one has to do many “rights” to each and every patient by every team member to make a Center of Excellence. From daily experience most healthcare workers and hospitals are far away from this imaginary goal. A fistula failure rate for 60% to mature that is to be usable for dialysis (7) likely reflects a multitude of system factors leading to failure (2, 3).

TABLE I - FACTORS THAT MAY AFFECT OUTCOME OF DIALYSIS ACCESS IN ESRD PATIENTS

- Leadership including hospital administrative support.
- Crisis vs. planed dialysis access management style
- Access team members' skill, knowledge and experience
- Policies and protocol sophistication and adherence
- Patient selection algorithm for mode of dialysis and type of hemo-access
- Degree of interdependent thinking among team members and leadership
- Attitude and culture of the institution
- Communication skills between team members
    - Personalities
    - Character
    - Trust level
    - Honesty

References

1. Davidson I, Gallieni M, Saxena R, et al. A patient centered decision making dialysis access algorithm. J Vasc Access 2007; 8: 59-68.
2. Vaughan D. The dark side of organizations: mistake, misconduct, and disaster. Annu Rev Sociol 1999: 25; 271-305.
3. Dekker S. Just Culture, Balancing Safety and Accountability. Ashgate Publishing Company, 2007.
4. Kiseleva YA, Caylor KL, Royer,RM. Noninvasive vascular testing with the surgeon present in the planning and maintenance of arteriovenous hemodialysis access. Journal for Vascular Ultrasound 2006; 3: 141-8.
5. UNOS Center specific report 2004 Annual Report of the US Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1994-2003. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, Rockville, MD; United Network for Organ Sharing, Richmond, VA; University Renal Research and Education Association, Ann Arbor, MI.
6. Gallieni M, Saxena R, Davidson I. Dialysis access in Europe and in North America: Are we on the same path? Seminars in International Radiology 2009; 26: 87-105.
7. Dember L, Beck GJ, Allon M, at al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis- a randomized controlled trial. JAMA 2008; 299: 2164-71.
8. Davidson I, Hackerman C, Kapadia A, Minhajuddib A. Heparin bonded hemodialysis e-PTFE grafts result in 20% clot free survival benefit. J Vasc Access 2009; 10: 153-6.
9. Dixon BS, Beck GJ, Vazquez MA, at al. Effect of dipyridamole plus aspirin on hemodialysis graft patency. N Engl J Med 2009; 360: 2191-201.
10. Caldwell M. The Tipping Point: How Little Things Can Make a Big Difference. New York: Little Brown & Co, 2000; ISBN 0-316-31696-2.

AVF Immaturity: Impact upon Success of the Fistula First Initiative

Lawrence M. Spergel

Fistula First Breakthrough Initiative, Midlothian, VA - USA

Early AVF failure and AVF immaturity

The incidence of early arteriovenous fistula (AVF) failure has been reported to be as high as 30-50%, when both early thrombosis and non-maturity (within 90 days of surgery) are included (1-4). Thrombosis that occurs immediately following surgery is usually secondary to either a technical error, an error in judgment in the choice of vessels, or a period of extreme hypotension. Non-maturity signifies a patent AVF that still cannot be used for dialysis. Some do not consider an immature AVF to be an early failure until/unless salvage has proven to be unsuccessful in bringing about maturity within a 3-month period following AVF construction. Based on the A-V Fistula First Breakthrough Initiative (FFBI) (6) and KDOQI (1), an AVF that does not show evidence of maturation, ie thickened wall (arte-

rialization) and dilatation, by 4-6 weeks, or that may have signs of maturity within this time frame but does not mature adequately to permit routine event-free, 2-needle dialysis by 3 months, is considered to be a failed or non-maturing AVF, and requires investigation and intervention. Failure of an AVF to mature or provide adequate flow for dialysis can be due to a focal anatomic lesion or a generalized sclerosis of the vein, possibly representing a vein that may already have been damaged or diseased. Failure of the vein to mature can also be due to inadequate inflow due to low baseline systemic blood pressure or significant arterial occlusive disease. When an obstructing lesion is not identified, access flow measurement should be performed to rule out low flow as the cause. This is especially important because low flow is a common cause for early failure, but is often overlooked when an anatomic cause is not found, resulting in extensive delays in intervention, thrombosis, and the prolonged use of catheters with the associated complications. It is the recommendation of the FFBI (6) that all AVFs be routinely evaluated at 4 weeks to determine whether or not the AVF is maturing adequately as well as to examine for any problems. This practice is extremely important, since the success rate for salvage procedures is considerably higher if the dysfunctional AVF is still patent. KDOQI (1) and other groups also recommend such evaluation at 4-6 weeks following AVF construction. This 4-6 week time frame is based on reports and opinions that the majority, if not all, of the causes of AVF dysfunction are readily identifiable by 4 weeks, most on physical exam alone (1, 7) - and that a significant percentage of the AVFs eventual maximum flow is reached in the majority of AVFs by this time as well (1, 8). The root causes for non-maturity are numerous and can be related to the vessels utilized, the site chosen, type of AVF construction, systemic factors and surgeon experience. If there is a question regarding maturity, a duplex ultrasound (DU) can be performed. After 8 weeks, it is reported that the likelihood of an AVF reaching maturity to support dialysis can be predicted if the fistula has both a minimum diameter of 4 mm and a flow of 500 ml/min. (8). At centers which have adopted an aggressive or all-autogenous approach, a higher early failure rate can be expected (5). However, a majority of these early failures can be salvaged by either endovascular or surgical intervention, or both (1, 2), and the benefits of an AVF far outweigh any disadvantages associated with a failed AVF attempt. Further, a thorough physical examination, use of pre-operative vessel mapping by either the operating surgeon or a technologist experienced in vessel mapping for dialysis, and meticulous attention to detail at surgery - along with experience - should significantly reduce non-maturity and other causes of early AVF failure. Finally, although the rate of non-maturing AVFs has not yet been quantified, which is an FFBI goal, the rate of increase in AVF use (functional AVFs for dialysis) has steadily increased at over 3.0%/yr. over the 6 years of Fistula First, where AVFs increased from 32% to 52%. The potential negative impact of the non-maturing AVF on increasing AVF use has therefore likely been little, if any, probably because of increased awareness of the problem as well as the high salvage rate.

References

1. National Kidney Foundation-KDOQI Clinical Practice Guidelines in Vascular Access: 2006 update. Am J Kidney Dis 2006; 48 (suppl): s176-306.
2. Gray RJ, Sands JJ. Dialysis Access: A Multidisciplinary Approach. Lippincott Williams & Wilkins, 2002.
3. Schild AF, Prieto J, Glenn M, Livingstone J, Alfieri K, Raines J. Maturation and failure in a large series of arteriovenous dialysis access fistulas. Vasc Endovasc Surg 2004; 38: 449-53.
4. Dixon BS. Why don't fistulas mature? Kidney Int 2006; 70: 1413-22.
5. Patel ST, Hughes J, Mills JL Sr. Failure of arteriovenous fistula maturation: an unintended consequence of exceeding dialysis outcome quality initiative guidelines for hemodialysis access. J Vasc Surg 2003; 38: 439-45.
6. FFBI.org.
7. Asif A, Roy-Chaudhury P, Beathard GA. Early arteriovenous fistula failure: a logical proposal for when and how to intervene. Clin J Am Soc Nephrol 2006; 1: 332-9.
8. Robbin ML, Chamberlain NE, Lockhart ME, et al. Hemodialysis arteriovenous fistula maturity: US evaluation. Radiology 2002; 225: 59-64.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Aggressive Approach to Salvage Non-Maturing Arteriovenous Fistulas: A Retrospective Study with Follow-up

Gregg A. Miller[1], Naveen Goel[2], Aleksandr Khariton[1], Alexander Friedman[1], Yevgeny Savransky[3], Ilya Trusov[1], Kiran Jotwani[4], Eric Savransky[1], Dean Preddie[1], William Perry Arnold[1]

[1]American Access Care of Brooklyn, Brooklyn, NY - USA
[2]American Access Care of Florida, Plantation, FL - USA
[3]American Access Care of Bellmore, Bellmore, NY - USA
[4]American Access Care of Queens, Queens, NY - USA

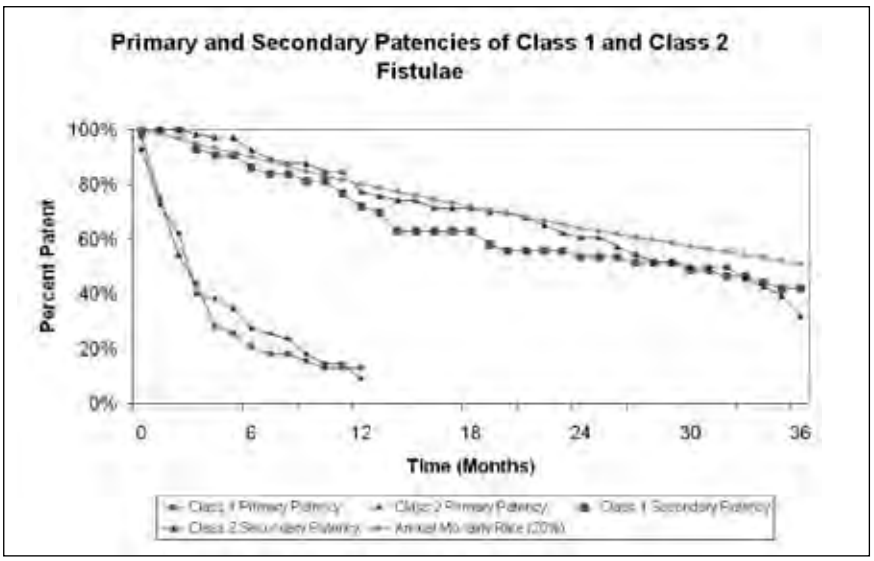
Early fistula failure has been defined as an inability to cannulate the fistula and/or support flow rates adequate for dialysis (350 mL/min) within 3 months of fistula creation (1). Up to 60% of arteriovenous fistulas (AVFs) fail to mature (2-5). Historically, endovascular techniques were unable to salvage up to 52% of non-maturing fistulas due to diffusely narrow outflow throughout the entire fistula body or inaccessibly deep position (1, 6, 7).

The K-DOQI "Rule of 6's" describes fistula characteristics associated with minimal risk of infiltration and the ability to deliver the prescribed blood flow throughout a dialysis treatment. The guideline suggests a fistula can be used when it is at least 6 mm in diameter, less than 6 mm deep, and has a blood flow greater than 600 mL/min. Based on this technical guideline, a 6 mm diameter fistula should be ready for use (8). In clinical practice, however, this same 6 mm diameter fistula, if greater than 6 mm deep, was very difficult to cannulate at dialysis and cannulation attempts frequently resulted in infiltration. This experience led us to the conclusion that fistula diameter and depth are interdependent factors and the appropriate diameter for a fistula is relative to the depth of the target vein.

We have developed an immature fistula classification and a corresponding protocol which allows for salvage of nearly all unusable small diameter and deep AVFs using aggressive staged balloon angioplasty maturation (S-BAM). A retrospective analysis of consecutive patients (n=122) with non-maturing fistulas presented to our outpatient vascular access center for percutaneous interventions to assist in maturation. The techniques used included flow rerouting, competing branch vein elimination, staged balloon angioplasty, and limited controlled extravasation.

Otherwise unusable fistulas underwent successful maturation procedures in 118/122 patients. Fistulas were divided into two classes according to initial vessel size: Class 1 (6.0-8.0 mm diameter, >6 mm deep) and class 2 (2.0-5.0 mm diameter) fistulas were evaluated for differences in technical procedures and clinically successful fistula maturation. Class 1 and class 2 fistulas were evaluated for mean number of procedures to maturation (1.6 and 2.6, respectively), and time to maturation (5 and 7 weeks, respectively). Follow-up for 109 of the initial 118 patients was achieved (mean=24 months, range=0.25-60 months). Class 1 and class 2 fistulas had primary patencies of 47% and 49% at 3 months; and secondary patencies of 72% and 77% at 12 months, respectively. Primary and secondary patencies (Mann-Whitney test, p=0.44 and p=0.38, respectively) of class 1 and class 2 fistulas did not differ significantly, and secondary patencies were comparable to other fistula salvage studies.

A fistula classification system, combined with aggressive angioplasty in accordance with our techniques, allows the interventionalist to quickly, safely and effectively mature a non-functioning fistula. S-BAM has allowed us to decrease maturation time and promote clinical success in both small-diameter and deep (>6 mm) AVFs. Despite differences in initial vein diameter, nearly all AVFs can undergo staged dilation to establish a functional fistula. As such, our protocol yields high rates of immediate success and long-term patency.



References

1. Beathard GA, Arnold P, Jackson J, Litchfield T. Aggressive treatment of early fistula failure. Kidney Int 2003; 64: 1487-94.
2. Tordoir JH, Rooyens P, Dammers R, et al. Prospective evaluation of failure modes in autogenous radiocephalic wrist access for haemodialysis. Nephrol Dial Transplant 2003; 18: 378-83.
3. Clark TW, Cohen RA, Kwak A, et al. Salvage of nonmaturing native fistulas by using angioplasty. Radiology 2007; 242: 286-92.
4. Schild AF, Prieto J, Glenn M, et al. Maturation and failure rates in a large series of arteriovenous dialysis access fistulas. Vasc Endovascular Surg 2004; 38: 449-53.
5. Dember LM, Beck GJ, Allon M, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. JAMA 2008; 299: 2164-71.
6. Peynircioglu B, McLennan G, Handkins B, et al. Percutaneous interventions for non-maturing arteriovenous fistulae (abstract). J Vasc Interv Radiol 2004; 15: s215.
7. Samaha A, Strayer, K, Moussa, A. Salvaging fistulas with early failure: outcome in 178 patients. Presented at the American Society of Nephrology Renal Week 2005; November 10, 2005; Philadelphia, PA.
8. National Kidney Foundation. Kidney disease outcomes quality initiative clinical practice guidelines for vascular access: 2006 updates - treatment of fistula complications. Am J Kidney Dis 2006; 48: s234-42.

To Infinity and Beyond - More AVFs Mean Better Care

Lawrence M. Spergel

Fistula First Breakthrough Initiative, Midlothian, VA - USA

It has been well established that the autogenous arteriovenous fistula (AVF) is superior to other access types in all categories: patency, complications, interventions needed, mortality and costs. Further, the need for an AVF initiative in the USA was well established in 2003, when AVFs in use were only 32%, compared with rates in the 60-90% range in other developed countries - where access-related events, interventions and costs were far lower than in the USA. “Fistula First” is a moniker for the Fistula First Breakthrough Initiative (FFBI), whose objective is that all patients should be evaluated and considered for an AVF first, utilizing best practices, including vessel mapping. The AVF goal set by the FFBI Work

Group was 66%, which is conservative based on the experience in other developed countries as well as many centers in the USA. An increasing number of centers throughout the USA have already achieved this goal, and higher, proving that the 66% target is feasible and reasonable. These centers report a reduction in catheter use as well as morbidity and costs and missed dialysis treatments, as a result of their high AVF rates. Further, there are currently centers which consistently have AVF rates of greater than 90%, with the lowest CVC prevalence. This 66% target also takes into account the many patients who are not going to be considered suitable candidates for an AVF. The intent of the FFBI is to increase the prevalence of *functioning* AVFs and not AVFs that are patent but not usable for dialysis. If the intent were just to achieve higher and higher AVF rates, regardless of need for functionality and reduced morbidity and costs, the target would have been set much higher than 66%. Certainly, as the envelope is pushed by doing more complex AVFs, including transpositions, and as young surgeons go through a lengthy learning curve, to develop the necessary skills and judgment necessary for success, there will be a higher early failure and non-maturation rate. Only time and experience and the necessary studies will identify the outcomes and suitability of various procedures and what criteria, mapping and others, should be used to better evaluate the suitability of a potential AVF candidate.

Not so fast, Quality not Quantity

Marc H. Glickman

Eastern Virginia Medical School, Norfolk, VA - USA

As we are all aware, autogenous fistulas have been recommended to be placed in all patients. Outcomes have been shown in numerous articles to be superior in arteriovenous fistulas (AVF) than AV grafts (AVG) in patency and complications. However, does that mean that every patient, regardless, of age, race and gender should receive an AVF rather than an AVG or tunnel dialysis catheter? Does an 85-year-old female, going on dialysis for the first time behave the same way as a 32-year-old male with renal failure secondary to diabetes? Do African-American females (AAF) behave the same way as Caucasian females in regards to their access patency and access performance? KDOQI guidelines would intimate that everyone should be treated the same and offered the same autogenous fistula therapy.

It is well established that AVF creation can be performed in the majority of patients, however, the percentages of these accesses going on to be useful has fallen short of our European counterparts. There are demographic reasons, one being a higher incidence of diabetes in the American populations as compared to their European counterparts and second being a generalized higher BMI in the American population as compared to the European population. High failure rates and poor maturation has plagued American dialysis patients over the past decade, while the exact cause for the discrepancy between US and European literature has remained elusive. With that being said, the answer is multifactorial at best. We have been able to analyze the outcomes of patients undergoing AVF vs. AVG as their first-time permanent access surgery and determine if there are any demographic factors that lead to worse outcomes in AVF maturation. If this is the case, then perhaps the KDOQI guidelines need to be modified to account for demographic changes in criteria for autogenous access placement.

We performed a study with the approval of the Eastern Virginia Medical School Institutional Review Board, reviewing all patients who underwent AV access surgery between 1 January 2005 and 31 December 2005. Patients who had previous access surgery were excluded from the analysis, as the focus of this study was for only the "first access" in patients. Presence of a temporary or tunneled dialysis catheter was recorded, but not used to exclude patients.

A functional AVF was defined as a fistula being cannulated for at least one successful hemodialysis treatment, and a patent AVF was defined as having a palpable thrill or a bruit on auscultation. An AVF was considered abandoned if it required a major revision, including creation of a new anastomosis or placement of a jump graft, required ligation, or if a new access was required. An AVF requiring a

patch angioplasty revision was not considered abandoned. Post-operative interventions were categorized as open or percutaneous, and included balloon angioplasty, mechanical thrombectomy, stent deployment, vein branch ligation or embolization, and patch angioplasty with either an autologous or prosthetic patch. The primary endpoints included AVF abandonment, renal transplantation, death or the time measurement of patency. The standards recommended were used to define patency for this patient population.

All calculations were performed using Microsoft Excel and the Excel plug-in XLstat. Categorical data was compared using chi squared analysis, nominal data was compared using the students t-test, and $p<0.05$ was considered statistically significant. Kaplan-Meier survival curves were used to determine patency of the access and patient survival with log rank testing used to compare differences among curves.

Demographics: During the period 1 January to 31 December 2005, 239 patients underwent first-time AV access procedures. There were 168 (70.3%) AVFs and 71 (29.7%) AVGs. Sixty-two percent of the AVFs were placed in male patients and 70.2% of the AVGs were in female patients ($p<0.0001$). Both groups were similar with respect to pre-operative clinical variables. Tunneled dialysis catheters were used in 77% of the patients in the peri-procedural period for the initiation of hemodialysis. Of the 168 AVFs, 48 patients (29%) were 70 years of age or greater and we defined this as elderly.

Outcomes: The AVF group had 33 primary failures (19.6%) and the AVG group had three primary failures (8%) ($p=0.02$). Primary and primary assisted patency were 23% and 54% for AVF vs. 18% and 35% for AVG ($p=0.01$ and $p<0.0001$). The secondary patency was 56% for AVF and 60% for AVG, which was not significantly different. The AVF group had an average intervention rate of 0.91 (interventions/year), whereas the AVG group had yearly intervention rate of 1.53 ($p<0.001$). In subgroup analysis, it was noticed that in AAF patients primary failure was significantly higher (36 vs. 16.7%, $p=0.013$) than the remaining AVF cohort, primary patency rates were significantly worse (9 vs. 27%, $p=0.002$), and more interventions were required in these patients. AAF patients with AVG had similar patency rates as the non-AAF patients.

At the end of the data collection, 23 (48%) of the elderly patients were deceased as compared to 24 (20%) of the non-elderly patients. When survival was viewed with Kaplan-Meier survival curves, the 18-month survival was 50% for the elderly vs. 75% for the non-elderly patients ($p=0.004$). Of the 23 deceased elderly patients, the average time to death was 13.1 months. Only eight (35%) had their AVF accessed and only one of the eight had a radio cephalic fistula.

When fistula patency was examined, there was a substantial decrease in primary assisted and secondary patency of the elderly vs. non-elderly. The primary assisted patency was 39% and 69% at 12 months; elderly vs. non-elderly, respectively ($p=0.0002$). The secondary patency was similar at 38% and 68% ($p=0.004$).

Vascular access management as a component of the K/DOQI guidelines has changed drastically over the past decade. Since the guidelines inception in 1997, the creation and utilization of AVF for chronic access has increased. However, access surgeons have failed to attain the goal set to have two-thirds of dialysis patients dialyzing via an AVF by 2009. Despite the steady progress towards these goals, there has yet to be a demonstrable decrease in the mortality and morbidity in this difficult patient population. While these guidelines have forced access surgeons to re-evaluate the methods used to create hemodialysis access, the question remains does it apply to all patient populations?

It was found that 70% of patients had an autologous fistula created as their first time chronic dialysis method and the ratio of RCAVF to BCAVF created is consistent with the ratio reported in the literature. The reason for the lower number of RCAVF is related to vein size on pre-operative vein mapping and this may be a result of the number of female patients undergoing first time AVF access. No patients in this cohort underwent basilic vein transposition (BVT) as a first attempt at chronic AV access. While BVT remains in each of the surgeon's armamentarium, it is rarely performed as a first attempt at AV access in our practice. It is usually reserved as the next step after failed RCAVF or BCAVF.

Primary failures in AVF creation are reported to be 40%. Three factors were associated with increased primary failure in their study: female gender, RCAVF, and age greater than or equal to 65. Our data suggests that an additional factor may influence successful access creation specifically race. The af-

fect of race on the success of other vascular procedures, particularly infrainguinal revascularization, has been well studied and being of African-American race has been associated with worse outcomes. While some of these differences may be attributed to more advanced or diffuse disease, when controlled for these variables the disparity between ethnicities still holds true. These factors, especially the combination of African-American race and female gender leads to poor results in autologous fistula creation. It appears in this patient population that the AVG may be the preferred primary access of choice due to the poor outcomes of autogenous fistulas in these patients.

In our review of the elderly patient, these patients were also found to have a much reduced overall survival when compared to the younger cohort of patients undergoing dialysis. Primary assisted patency and secondary patency in this elderly group was 30% less at 12 months. These poor outcomes lead us to believe that this patient population also needs to be treated differently than a younger patient undergoing dialysis. A patient 70 years and older, undergoing dialysis for the first time has a statistically higher 1 year mortality and fistula failure rate than the general patient population.

It is well established that autologous fistula creation can be performed across all patient populations. However, the question remains should it be the first-line treatment in all patient subgroups. This data suggests that AAF patients have a limited benefit secondary to their increased primary failures and decrease in primary patency. The elderly patient population also has a higher failure rate as well and we need to reassess our approach to this patient population. Access surgeons and nephrologists should carefully weigh up all access options when dialysis is initiated and what method of chronic access is best for these patients. It is difficult to recommend that fistulas should be first choice for all patients and as more data to corroborate these findings becomes available the K/DOQI guidelines should be revisited.

The Best AVF and AVG Patency Data You Never Saw: Surprising Outcomes from the Dialysis Access Consortium

Miguel A. Vazquez

UT Southwestern Medical Center, Dallas, TX - USA

The Dialysis Access Consortium (DAC) was established by the National Institutes of Health/National Institutes of Diabetes, Digestive and Kidney Diseases to improve outcomes on vascular access for hemodialysis. The DAC recently completed two large multicenter clinical trials on vascular access: the DAC Fistula Study and DAC Graft Study.

The DAC Fistula Trial was a multicenter trial comparing the effects of the antiplatelet agent clopidogrel with placebo on early fistula failure (1). The primary outcome of the study was fistula thrombosis 6 weeks after fistula creation. The secondary outcome of the study was fistula suitability for dialysis, ascertained at 4 months after fistula creation or during the first month of dialysis (for those patients not on dialysis yet by the fourth month after fistula creation). The DAC Fistula Trial included 877 patients, and study enrollment was terminated after interim data analysis showed that clopidogrel reduced the risk of fistula thrombosis by 37% (relative risk 0.63: 95% confidence interval, 0.46-0.97 for clopidogrel). Unfortunately, clopidogrel had no beneficial effect on the more clinically meaningful secondary outcome of fistula suitability for dialysis (relative risk 1.05; 95% confidence interval, 0.94-1.7 for clopidogrel vs. placebo). The findings of the DAC Fistula Study suggest that failure of fistula maturation is now the main obstacle to successful fistula use (1-3).

The DAC Graft Trial was a multicenter randomized trial comparing the effects of extended-release dipyridamole plus aspirin (ERD-ASA) with placebo on dialysis graft stenosis and thrombosis (4). The primary outcome of the study was loss of primary unassisted patency (patency without thrombosis or requirement for interventions) of grafts. Secondary outcomes were cumulative graft failure and death.

Six hundred and forty-nine patients were enrolled in the study. The incidence of primary unassisted patency at 1 year was 23% (95% confidence interval, 18-28) in the placebo group and 28% (95% confidence interval, 23-34) in the dipyridamole-aspirin group, for an absolute difference of 5 percent points. Administration of dipyridamole-aspirin prolonged primary unassisted graft patency from 4.3 months (95% confidence interval, 3.6-5.4) to 5.8 months (95% confidence interval, 4.3-7.1). The median duration of cumulative graft patency was 22 months and similar for both groups. There were no differences in the incidence of cumulative graft failure, death, or the composite of these two measures between patients treated with dipyridamole-aspirin or those receiving placebo (4, 5).
The DAC fistula and graft studies have been the two largest trials published in the field of vascular access. The results of the DAC Fistula Trial revealed that in the recent era of aggressive fistula placement, maturation failure has become the main obstacle for successful fistula use. Arteriovenous grafts are now mainly placed in risk patients who have vascular disease or failure of prior vascular access. The DAC Graft Trial showed that the requirement for interventions and the incidence of graft failures is exceedingly high in this high risk population (4, 5).

References

1. Dember LM, Beck GJ, Allon M, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. JAMA 2008; 299: 2164-71.
2. Tonelli M. Randomized trials in hemodialysis patients: time to step up to the plate. JAMA 2008; 299: 2205-7.
3. Vazquez MA. Vascular access for dialysis: recent lessons and new insights. Curr Opin Nephrol Hypertens 2009; 18: 116-21.
4. Dixon BS, Beck GJ, Vazquez MA et al. Effect of dipyridamole plus aspirin on hemodialysis graft patency. N Engl J Med 2009; 360: 2191-201.
5. Lok CE. Antiplatelet therapy and vascular-access patency. N Engl J Med 2009; 2240-2.

Venous Angioplasty; How does it Work (or not Work)!!

Prabir Roy-Chaudhury

Cincinnati Dialysis Access Program, Cincinnati, OH - USA

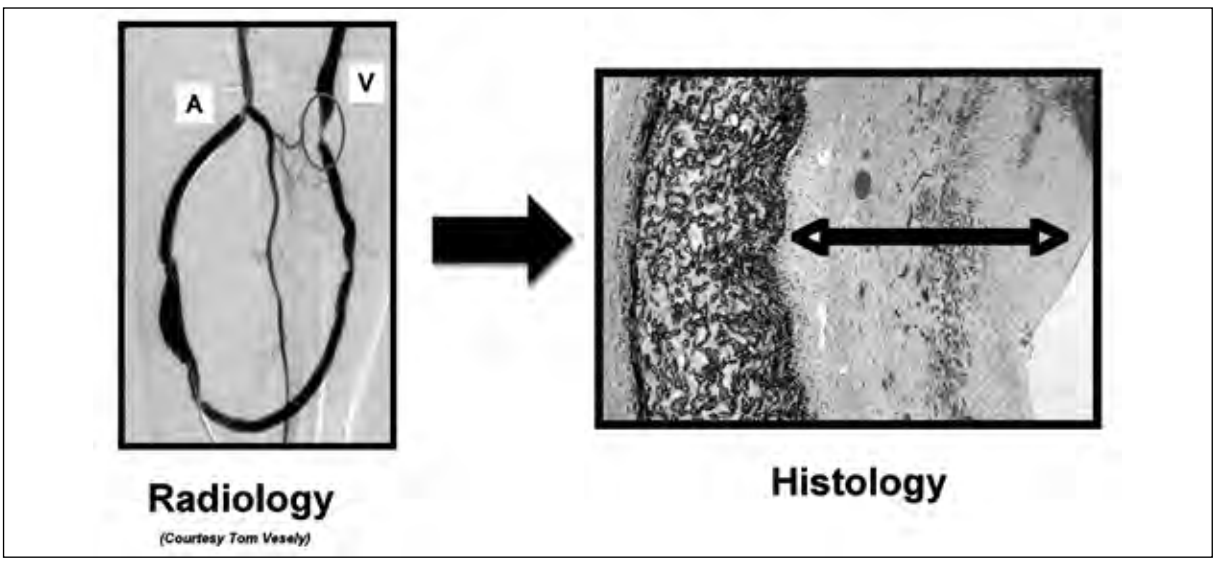
Venous angioplasty has been the mainstay of endovascular therapy for dialysis access dysfunction for over two decades. Despite the long duration of use, the results of venous angioplasty in the setting of dialysis access stenosis have been "dismal". A compilation of numerous data sets suggests that venous angioplasty of a non-thrombosed dialysis access graft has a post-intervention primary patency of 50% at 6 months, while the corresponding figures for a thrombosed PTFE graft are 40% at 3 months (1)! More recent data on balloon angioplasty in the setting of arteriovenous fistulae (AVF) suggest a post-intervention primary patency of 50% at 12 months (2) (although cumulative patency data for both AVF and grafts are greater than 80% at 1 year). At a radiological level this poor post-intervention primary patency is due to a tight venous stenosis (2-4), and at a histological level, it is characterized by an aggressive neointimal hyperplasia (5, 6) (Fig. 1). In marked contrast the 2-year post-intervention primary patency following balloon angioplasty in the setting of peripheral vascular disease, even for the worst case scenario of infra-popliteal lesions is 42% (7).
While angioplasty by definition causes direct injury to the vessel wall (8) which then results in an aggressive re-stenosis (balloon angioplasty, for example, is the classic experimental model for the creation of neointimal hyperplasia), this does not explain why the results of balloon angioplasty in dialysis access stenosis are so poor. Potential reasons for this poor survival include a number of factors that are specific only to the use of balloon angioplasty in the setting of dialysis access stenosis. These include (a) an aggressive *venous* response to injury as compared to the more common *arterial* injury,

(b) the role of compliance mismatch (between artery and vein or graft and vein), (c) the impact of continuing hemodynamic stress (non-laminar flow and turbulence) at the graft-vein or arteriovenous anastomosis, (d) the impact of uremia and the resultant increase in oxidative stress and endothelial dysfunction which could predispose to a more aggressive stenosis post-angioplasty (e) pre-existing neointimal hyperplasia and medial hypertrophy, and (f) the repeated use of high-pressure balloons to achieve an adequate result (9, 10).

Despite the extremely poor results of balloon angioplasty in the setting of venous stenosis, the only available intervention that has improved upon the results of venous angioplasty in the setting of a randomized controlled clinical trial, has been the PTFE covered stent; which when deployed at the site of balloon angioplasty improved primary patency of the treated area from 29% to 51% at a mandated 6-month angiogram (11). There are, however, a number of potential therapies that might be available in the future, including drug coated balloons (12), drug eluting stents (13, 14) and perivascular drug delivery systems using either an endovascular or percutaneous approach (15).

Finally, it remains unclear as to whether surgery or angioplasty should be the primary intervention in specific settings of dialysis access stenosis (16-20). In addition, there is also no fixed consensus as to when to abandon angioplasty in favor of surgery, in the setting of repeat stenotic lesions at the same site.

In summary, although venous angioplasty has been the workhorse for dialysis access stenosis for over two decades, it remains a relatively ineffective intervention in terms of post-intervention primary patency. There is no question, however, that repeated angioplasties can result in excellent long-term cumulative patency with access blood flows that allow good quality hemodialysis. Recent advances in our understanding of the pathobiology of dialysis access stenosis as also in the availability of novel drug delivery systems suggests that combinations of balloon angioplasty with local anti-stenotic therapies may soon be introduced into routine clinical practice. In addition, we desperately need well designed clinical trials that focus on the logistical aspects of dialysis access stenosis ("when are too many angioplasties really too many" and more controversially on the issue of "angioplasty versus surgery").



References

1. DOQI. Vascular Access Guidelines. Am J Kidney Dis 2006; 48: s177-247.
2. Asif A, Lenz O, Merrill D, et al. Percutaneous management of perianastomotic stenosis in arteriovenous fistulae: results of a prospective study. Kidney Int 2006; 69: 1904-9.
3. Beathard GA, Arnold P, Jackson J, Litchfield T. Aggressive treatment of early fistula failure. Kidney Int 2003; 64: 1487-94.
4. Valji K, Bookstein JJ, Roberts AC, Davis GB. Pharmacomechanical thrombolysis and angioplasty in the management of clotted hemodialysis grafts: early and late clinical results. Radiology 1991; 178: 243-7.
5. Roy-Chaudhury P, Kelly BS, Miller MA, et al. Venous neointimal hyperplasia in polytetrafluoroethylene dialysis grafts. Kidney Int 2001; 59: 2325-34.
6. Roy-Chaudhury P, Wang Y, Krishnamoorthy M, et al. Cellular phenotypes in human stenotic lesions from haemodialysis vascular access. Nephrol Dial Transplant 2009; 24: 2786-91. Epub 2009 Apr 17.
7. Brown KT, Moore ED, Getrajdman GI, Saddekni S. Infrapopliteal angioplasty: long-term follow-up. J Vasc Interv Radiol 1993 4: 139-44.
8. Dotter CT, Judkins MP. Transluminal recanalization in occlusive disease of the leg arteries. GP 1968; 37: 98-106.
9. Roy-Chaudhury P, Kelly BS, Melhem M, et al. Vascular access in hemodialysis: issues, management, and emerging concepts. Cardiol Clin 2005; 23: 249-73.
10. Roy-Chaudhury P, Sukhatme VP, Cheung AK. Hemodialysis vascular access dysfunction: a cellular and molecular viewpoint. J Am Soc Nephrol 2006; 17: 1112-27.
11. Haskal ZJ. Results of the U.S. multicenter randomized trial of the Bard ePTFE encapsulated dialysis access stent graft. In: Society of Interventional Radiology Annual Meeting. New Orleans; 2005.
12. Unverdorben M, Vallbracht C, Cremers B, et al. Paclitaxel-coated balloon catheter versus paclitaxel-coated stent for the treatment of coronary in-stent restenosis. Circulation 2009; 119: 2986-94.
13. Morice MC, Serruys PW, Sousa JE, et al. A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. N Engl J Med 2002; 346: 1773-80.
14. Stone GW, Ellis SG, Cox DA, et al. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. N Engl J Med 2004; 350: 221-31.
15. Roy-Chaudhury P, for The Mercator Study Investigators. Perivascular dexamethasone for PTFE graft stenosis: the HAPPI (Hemodialysis Access Patency Extension with Percutaneous Transluminal Infusion of Dexamethasone) study. J Am Soc Nephrol 2007; 18: 468A.
16. Beathard GA, Marston WA. Endovascular management of thrombosed dialysis access grafts. Am J Kidney Dis 1998; 32: 172-5.
17. Marston WA, Beathard GA. Surgical management of thrombosed dialysis access grafts. Am J Kidney Dis 1998; 32: 168-71.
18. Marston WA, Criado E, Jaques PF, Mauro MA, Burnham SJ, Keagy BA. Prospective randomized comparison of surgical versus endovascular management of thrombosed dialysis access grafts. J Vasc Surg 1997; 26: 373-80; discussion 380-1.
19. Tessitore N, Mansueto G, Lipari G, et al. Endovascular versus surgical preemptive repair of forearm arteriovenous fistula juxta-anastomotic stenosis: analysis of data collected prospectively from 1999 to 2004. Clin J Am Soc Nephrol 2006; 1: 448-54.
20. Lipari G, Tessitore N, Poli A, et al. Outcomes of surgical revision of stenosed and thrombosed forearm arteriovenous fistulae for haemodialysis. Nephrol Dial Transplant 2007; 22: 2605-12.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Recoil and Spasm in AV Access Venoplasty: How Important?

Sanjoy Kundu

Scarborough General Hospital, Scarborough, Ontario - Canada

Maintenance of long-term vascular access in hemodialysis patients is of critical importance. Arm edema, poor access flow, and elevated dialysis venous pressures occur due to access thrombosis or venous stenosis. Percutaneous transluminal angioplasty (PTA) has been advocated as a primary treatment for symptomatic central and peripheral venous stenosis associated with hemodialysis fistulae and grafts (1-3).

The mechanisms of venous angioplasty in arteriovenous (AV) access have not been well studied to date. One study noted plaque dissection and vessel stretch as proposed mechanisms for angioplasty on the basis of intravascular ultrasound (4). This study also noted elastic recoil in 50% of patients. There was a predominance of elastic recoil in central venous lesions when compared to peripheral venous lesions. Elastic recoil was noted in 64% of central venous stenoses immediately post-PTA. They concluded successful angioplasty was based on vessel stretch and dissection. These are similar to mechanisms that have been validated with histologic studies of coronary artery balloon angioplasty (5).

Outside of the above study, elastic recoil in AV access venous angioplasty has not been mentioned or studied in the hemodialysis literature based on a comprehensive literature search. Elastic recoil is a well documented entity in the percutaneous transluminal coronary angioplasty (PTCA) literature as a cause of post-PTCA re-stenosis, in addition to thrombogenesis at sites of intimal injury and vascular medial smooth muscle cell proliferation (6).

We are currently in the process of accruing patients for a study; examining elastic recoil and spasm, using endovascular thermodilution based flow measurements in correlation with digital subtraction angiography in hemodialysis patients post-angioplasty for venous outflow stenoses. Preliminary results suggest that both spasm and elastic recoil occur in a small number of patients post-venous angioplasty, and further study will be required.

References

1. Schwab SJ, Saeed M, Sussman SK, McCann RL, Stickel DL. Transluminal angioplasty of venous stenosis in PTFE vascular access graft. Kidney Int 1987; 32: 395-8.
2. Glanz S, Gordon DH, Butt KM, Hong J, Lipkowitz GS. The role of percutaneous angioplasty in the management of chronic hemodialysis fistulas. Ann Surg 1987; 206: 777-81.
3. Beathard GA. Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. Kidney Int 1992; 2: 1390-7.
4. Davidson CJ, Newman GE, Sheikh KH, Kisslo K, Stack RS, Schwab SJ. Mechanisms of angioplasty in hemodialysis fistula stenoses evaluated by intravascular ultrasound. Kidney Int 1991; 40: 91-5.
5. Block PC. Mechanism of transluminal angioplasty. Am J Cardiol 1984; 53: 69C-71C.
6. Califf RM Fortin DF, Frid DJ et al. Restenosis after coronary angioplasty; an overview. J Am Coll Cardiol 1991; 17: 2B-13B.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Cephalic Arch Stenosis - Why? When?

Surendra Shenoy

Washington University School of Medicine, Barnes Jewish Hospital, St. Louis, MO - USA

Cephalic vein is the most commonly used vein as the needle access segment (conduit) for an arteriovenous fistula (AVF). Forearm and upper arm cephalic vein based AVF account for majority of the AVF. While inflow stenosis such as juxta anastomotic stenosis (JAS) accounts for most of the AVF failure in the forearm, outflow vein stenosis mainly cephalic arch stenosis (CAS) is a common cause of fistula dysfunction in upper arm cephalic vein based fistulae. Though the overall incidence of symptomatic CAS is low, one study reported an incidence of up to 40% for patients with brachiocephalic fistula. The exact reason for the development of CAS is uncertain. A combination of rapid increase in the blood flow in a unique anatomic site is a possible cause for this problem.

The cephalic arch is the term used for the segment of the cephalic vein from the delto-pectoral groove to the site of drainage in the axillary vein. This is the area where the cephalic vein which is a superficial vein (the vein that runs in the subcutaneous tissue above the deep fascia), takes a gentle arch to transition into a deep vein (a vein that runs deep to the deep fascia). As it undergoes this transition, it passes through an opening (defect) in the clavipectoral fascia (a fascial sheath that runs between the pectoralis minor muscle and the subclavius muscle). The other structures that accompany the vein in this defect include the throaco-acromian artery, the lateral and medial pectoral nerves and some lymphatics. Several unnamed venous tributaries that accompany the braches of thoraco-acromian artery join the cephalic vein in this area resulting in a few flow directing valves. Thus the angulation, presence of valves, crossing of other structures and traversing through a fascial defect makes the cephalic arch region anatomically unique.

With the creation of an AVF the flow in the out vein increases 20-40 folds. A baseline flow of 20-100 ml/min increases to a flow of 600-1500 ml/min. The majority of this increase happens immediately after access creation. In the setting of an upper arm (brachiocephalic) fistula, the cephalic vein which often does not have any branches in the upper arm becomes the sole conduit for this increased flow.

Laminar blood flow, producing the least shear stress on the vessel wall, is observed in the arteries under normal flow conditions. Vessels with high flow generally do not show laminar flow pattern. Flow pattern in a thin walled vein with inconsistent luminal diameter resulting from the presence of intermittent valves (such as the outflow cephalic vein of an AVF) is usually non laminar. The degree of turbulence varies in different areas of the vessel i.e. there is more turbulence in areas of valves (intraluminal flow obstruction). Turbulent flow and resulting vessel wall stress is a stimulant for smooth muscle hypertrophy.

A combination of unique anatomy and acute increase in the flow resulting from arteriovenous anastomosis makes the cephalic arch region most vulnerable to develop stenosis. A defect in tough fascia may prevent vein distension thereby causing extrinsic compression resulting in hemodynamic instability and development of smooth muscle hypertrophy resulting in stenosis. Similarly the crossing of an artery or nerve and their respective branches can produce a bow stringing effect on the dilating vein, once again causing an extrinsic compression.

Under normal circumstances the valves direct blood flow in the venous system (low flow system). They are present in tributaries close to entry points into the main vein, or in the main vein just beyond the entry point of a tributary. With the creation of AVF the valves in both these situations can become the nidus for stenosis development. With an increase in flow and intraluminal pressure, a competent valve in the tributary could promote stagnation of blood resulting in a thrombus or even thrombosis of the small tributary. The resultant inflammatory response could create a wall motion abnormality precipitating turbulence which could result in development of stenosis. Sclerosed tributaries could result in tenting of the main vein as the fibrotic vessel scar contracts over a period of time and results in flow alteration.

With the acute dilation of the vein, valves within the main vein often loose their property to opeflaccidly in the direction of the flow. This could result in a stretched out valve producing a flow obstruc-

tion → turbulence → shear stress → wall inflammation → development of stenosis → narrowing of lumen → increased intraluminal pressure → smooth muscle hypertrophy → further decrease in intraluminal diameter and perpetuation of the stenotic segment.
Thus a combination of high flow in the unique anatomic situation of cephalic arch places this area a higher risk of developing stenotic problems. The risk tends to be higher with brachiocephalic fistula where the upper arm cephalic vein becomes the sole outflow as opposed to forearm AVF.

References

1. Rajan DK, Clark TWI, Patel NK, Stavropoulos WS, Simons ME. Prevalence and treatment of cephalic arch stenosis in dysfunctional autogenous hemodialysis fistulas. J Vasc Interv Radiol 2003; 14: 567-73.
2. Turmel-Rodrigues L, Pengloan J, Baudin S, et al. Treatment of stenosis and thrombosis in haemodialysis fistulas and grafts by interventional radiology. Nephrol Dial Transplant 2000; 15: 2029-36.
3. Shenoy S. Cephalic arch stenosis – Different anatomy needs different therapy. J Vasc Access 2006; 7: 171-2.
4. Ascher E, Gade P, Hingorani A, et al. Changes in the practice of angioaccess surgery: impact of dialysis outcome and quality initiative recommendations. J Vasc Surg 2000; 31: 84-92.
5. Kian K, Asif A. Cephalic arch stenosis. Seminars in Dial 2008; 21:78-82.
6. Jaberi A, Schwartz D, Martecorena r et. al. Risk factors for the development of cephalic arch stenosis. J Vasc Access 2007; 8: 287-95.

Cephalic Arch Stenosis – Surgery is the First Step

Surendra Shenoy

Washington University School of Medicine, Barnes Jewish Hospital, St. Louis, MO - USA

The goal of managing a failing vascular access is to maintain viability using the least number of interventions and ensure successful dialysis for the longest period of time. Several surgical and interventional procedures (performed under radiologic image guidance) are currently available for this purpose. These interventions can be used in sequence following a treatment algorithm to maximize outcomes. However, treatment algorithms are often difficult to apply in many ambiguous clinical situations. Cephalic arch stenosis (CAS) is one.
Image guided interventions available for managing access outflow stenosis includes balloon angioplasty and stents. Balloon angioplasties act by producing a controlled rupture of a stenotic vessel wall. Increased scarring resulting during the healing process eventually make the treated area less resilient and more fibrotic resulting in eventual failure of this modality. Further, the response to injury is different in individual patients and the response to angioplasty tends to be variable. The response to angioplasty where a valve cicatrix (point stenosis) is ruptured is different from the response to dilation of a scarred, thickened vein wall or dilation of an extrinsic compression caused by an artery or a nerve crossing the vein. Unfortunately, radiologic imaging can only detect the luminal caliber, but not the cause of the stenosis or the amount of vessel wall thickening. Wall stents could be effective in situations where narrowing is due to extrinsic compression. Unfortunately they cannot keep the wall disease from progressing into the lumen. Stent grafts on the other hand have an advantage as they can effectively (mechanically) keep the wall disease from progressing into the lumen. However, they are subjected to new ingrowth of intimal hyperlpastic tissue that can result in stent stenosis. Many stent grafts (like the arteriovenous (AV) grafts) precipitate progressive outflow and inflow stenosis (the mechanism of this is ill understood). Unfortunately the development of outflow stenosis secondary to the treatment of CAS means central vein obstruction, which is worse. Finally, stents preclude surgery as an option to treat the stenosis.
Surgical intervention for the management of access stenosis includes surgical venoplasty or bypass

(1). Venoplasty provides a net increase in the luminal diameter. While autologous veins are ideal for venoplasty, it is often difficult to find a good source for this. Other materials used include prosthetic or biologic graft materials. Both are prone to the development of intimal hyperplastic changes. Further, the venoplasty leaves the area with part of the vessel wall with scar tissue. Scar tissue can contract and precipitate restenosis. Since no good autologous material is easily available, surgically replacing the scarred segment of the vein amounts to the use of synthetic grafts. Once again, this leads to a risk of outflow stenosis and central venous obstruction. In addition, replacement of the vein segment is surgically more challenging in this area. The other surgical option available to manage a failed cephalic arch is relocation of access outflow. In this procedure the cephalic vein is transposed medially and anastomosed to the brachial or axillary vein. Once again, this does place the outflow vein at risk for stenosis. Stenosis of the axillary vein reduces future options for access in the ipsilateral distal extremity. Treatment algorithms for stenosis management should come up with the best strategy to maximize longevity of the access with least possible interventions after consideration of all these issues in a clinical setting.

CAS has several peculiarities (2). This is a lesion that is usually seen in a mature AV access. It is often diagnosed during the work up of inadequate dialysis detected during dialysis adequacy monitoring. Clinical presentation includes increased pulsatility in the access suggesting outflow stenosis. Due to the chronicity of the lesion, many patients also develop aneurismal dilations of the needle stick segment. Occasionally, the lesion may go undetected until there is significant flow reduction and thrombosis of the AV fistula (AVF). In addition to chronicity, the other peculiarity of the problem is the location of the stenosis. CAS occurs near the cephalic vein and axillary vein junction; a location not very familiar anatomically to surgeons. It is more common in patients with higher fistula flows (3).

Angioplasty should be considered the first modality for the management of symptomatic CAS. However, due to the chronicity of presentation, angioplasty is often not very successful. Surgical revision (venoplasty), when available, provides an option to increase the longevity of the access and should be considered next (4). While surgically repaired segments can still be stented the reverse is not true. Placing a stent after failed angioplasty in the cephalic arch eliminates surgical venoplasty as an option. There is emerging data supporting beneficial effects of surgical intervention. Angioplasty tends to have longer term benefits when performed on stenoses that develop after surgical revision (5). Surgical management leaves stent grafts an option which could be used to further prolong access viability when angioplasties fail in the surgically repaired segment.

A treatment algorithm starting with angioplasty followed by surgical repair provides the best option to prolong access patency, leaving stent graft and surgical outflow diversion available as future options to further prolong the access patency. Follow-up data that support better results will strengthen the merits of this approach.

References

1. Ankit B, Shenoy S. Assessment and intervention for AV fistula maturation. In: Vascular Access: Principles and Practice. 5th edn. Wilson SE, ed. Philadelphia: Lippincott Williams & Wilkins, 2009; pp 234-42.
2. Rajan DK, Clark TWI, Patel NK, Stavropoulos WS, Simons ME. Prevalence and treatment of cephalic arch stenosis in dysfunctional autogenous hemodialysis fistulas. J Vasc Interv Radiol 2003; 14: 567-73.
3. Jaberi A, Schwartz D, Martecorena R, et al. Risk factors for the development of cephalic arch stenosis. J Vasc Access 2007; 8: 287-95.
4. Shenoy S. Cephalic arch stenosis: surgery as first line of management. J Vasc Access 2007; 8: 149-51.
5. Kian K, Unger SW, Mishler R, Schon D, Lenz O, Asif A. Role of surgical intervention for cephalic arch stenosis in "fistula first" era. Semin Dial 2007; 21: 93-6.
6. Shemesh D, Goldin I, Ibrahim Z, et al. Angioplasty with stent graft versus bare stent for recurrent cephalic arch stenosis in autologous arteriovenous access for hemodialysis: a prospective randomized clinical trial. J Vasc Surg 2008; 48: 1524-31.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Cephalic Arch Stenosis: PTA+/- Stent or Covered Stent is the First Step

Dheeraj Rajan

University of Toronto, Toronto - Canada

With increased incidence of hemodialysis fistulas within the US dialysis population, the problems pertaining to fistulas are becoming more prevalent. Unique lesions including cephalic arch stenosis (CAS) most commonly presenting in patients with brachiocephalic fistulas is particularly troubling. The gold standard of balloon angioplasty has a relatively poor primary patency and CAS is also more prone to rupture than other vein segments and often requires higher inflation pressures to obtain technical success (1).

The etiology of CAS is unclear with hypotheses including high flow, high pressure, shear stress due to angulation, shear stress due to fixation of the cephalic vein in the terminal arch due to surrounding deltopectoral fascial planes and fascial planes limiting dilation of the vein segment during maturation and during angioplasty.

However, primary patency after angioplasty is at 6 months is 42% (1), which compares to 51-75% at 6 months for other locations within dialysis fistulas (2, 3). Assisted primary and secondary patencies with repeat angioplasty are acceptable with up to 75% secondary patency at 12 months (1). In addition, other technologies have been introduced including stents and stent grafts. In a single randomized prospective study, 6-month primary patency between stents and stent grafts was 39 vs. 82%. Stent patency was equivalent to historical percutaneous transluminal angioplasty (PTA) outcomes (4).

Surgical interventions for the cephalic arch specifically include surgical turndown of the cephalic vein either to the basilic or the axillary veins, patch-plasty and division of fascial planes. Although these are viable options, short-, medium- and long-term patency of these procedures has not been studied. In a single study, surgical transposition of the cephalic vein to the axillary/basilic vein resulted in a primary patency rate of angioplasty before the surgical revision of 8% at 6 months, and following surgical revision of 69% at 6 months. However, it should be noted, the authors' PTA patency was markedly lower than what is observed in other studies (1-3), and surgical revision by SIR definition is creating a new access (5). Furthermore, secondary patency was not properly assessed as there was insufficient follow-up (6).

In addition, surgical interventions are associated with higher costs, greater use of resources with no published survival benefit over angioplasty. Concurrent lesions in the access circuit and comorbidities of the patients themselves may restrict the useful lifespan of the access, thereby resulting in the inefficient use of surgical resources. These may be more efficiently applied to the creation of new accesses rather than maintenance of access unless the patient looses all options. Balloon vs. patch angioplasty in dialysis grafts has been examined with authors finding balloon angioplasty to be more practical or no improved patency with surgery (7-9).

Compared to surgical intervention, cephalic arch PTA is a more efficient treatment and more accessible for patients. Secondary patency is likely no different and initial results suggest that stent grafts have better patency than surgical intervention (82 vs. 69%).

References

1. Rajan DK, Clark TW, Patel NK, Stavropoulos SW, Simons ME. Prevalence and treatment of cephalic arch stenosis in dysfunctional autogenous hemodialysis fistulas. J Vasc Interv Radiol 2003; 14: 567-73.
2. Turmel-Rodrigues L, Pengloan J, Baudin S, et al. Treatment of stenosis and thrombosis in haemodialysis fistulas and grafts by interventional radiology. Nephrol Dial Transplant 2000; 15: 2029-36.
3. Rajan DK, Bunston S, Misra S, Pinto R, Lok CE. Dysfunctional autogenous hemodialysis fistulas: outcomes after angioplasty--are there clinical predictors of patency? Radiology 2004; 232: 508-15.
4. Shemesh D, Goldin I, Zaghal I, Berlowitz D, Raveh D, Olsha O. Angioplasty with stent graft versus

bare stent for recurrent cephalic arch stenosis in autogenous arteriovenous access for hemodialysis: a prospective randomized clinical trial. J Vasc Surg 2008; 48: 1524-31.
5. Gray RJ, Sacks D, Martin LG, Trerotola SO. Reporting standards for percutaneous interventions in dialysis access. Technology Assessment Committee. J Vasc Intervent Radiol 1999; 10: 1405-15.
6. Kian K, Unger SW, Mishler R, Schon D, Lenz O, Asif A. Role of surgical intervention for cephalic arch stenosis in the "fistula first" era. Semin Dial 2008; 21: 93-6.
7. Bitar G, Yang S, Badosa F. Balloon versus patch angioplasty as an adjuvant treatment to surgical thrombectomy of hemodialysis grafts. Am J Surg 1997; 174: 140-2.
8. McCutcheon B, Weatherford D, Maxwell G, Hamann MS, Stiles A. A preliminary investigation of balloon angioplasty versus surgical treatment of thrombosed dialysis access grafts. Am Surg 2003; 69: 663-7; discussion 668.
9. Lemson MS, Tordoir JH, van Det RJ, et al. Effects of a venous cuff at the venous anastomosis of polytetrafluoroethylene grafts for hemodialysis vascular access. J Vasc Surg 2000; 32: 1155-63.

Should AV Grafts be used when AV Fistulas are Anatomically Possible?

Dirk Baumann

Peninsula Surgical Specialists Medical Group, Mills Peninsula Medical Center, Burlingame, CA - USA

Generally, arteriovenous fistulas (AVF) are the preferred primary access for hemodialysis (HD), offering several advantages over arteriovenous non-autogenous grafts (AVG) and tunneled central venous catheters. Overall, AVFs are associated with fewer revisions, lower costs for maintenance, fewer complications, and lower mortality than AVGs and catheters. However, recent reports emphasize that up to 50-60% of fistulas fail to mature sufficiently to provide adequate HD access (1-3) and that nearly 90% require additional intervention (3). Therefore, AVGs may be superior alternatives to AVFs and especially catheters in some situations.

Forearm AVG's have several advantages over the construction of upper arm AVFs in patients with poor quality forearm vasculature. Forearm loop AVGs have been shown to have improved primary, assisted primary and secondary patency over radial cephalic AVFs in patients with compromised forearm vessels (radial artery 1-2 mm and/or cephalic vein <1.6 mm) (4). In patients with an inadequate radial artery but ample cephalic vein, brachial artery to distal forearm cephalic vein AVGs have similar patency to transposed forearm brachial artery to cephalic vein loop AVFs. Yet, these AVGs allow for dialysis access avoiding a catheter during fistula maturation. Finally, while patency rates of forearm loop AVGs may not be as good as upper arm AVFs (5), they allow for maturation of the upper arm veins without the need for a catheter. If done distal to the antecubital fossa, the outflow veins can be later converted to AVFs. Therefore, there are several situations that forearm AVGs should be considered prior to upper arm AVF construction.

In patients with multiple factors associated with fistula failure, an AVG may also be an acceptable alternative to an AVF. Patients, who are female, are older, have diabetes or have small veins, have poorer overall outcomes from AVFs, with lower maturation rates and higher failure rates. AVGs offer acceptable alternatives in these patients to avoid long-term catheters required for fistula maturation and revision. Poor clinical condition may dictate AVG placement rather than a more complicated transposition AVF. Patients with obese arms, loose tissue or coagulopathies are often better candidates for AVGs than AVFs. Finally, lower extremity AVGs to the larger femoral vein have satisfactory patency rates, while the saphenous vein AVF tends to have lower patency than arm AVFs. It is important to consider the risks of catheter placement and usage, timing of the need for dialysis initiation, and factors involved in fistula maturation in order to offer optimal access selection. AVGs offer a preferential option either prior to or instead of AVFs in select circumstances.

References

1. Miller PE, Tolwani A, Luscy CP, et al. Predictors of adequacy of arteriovenous fistulas in hemodialysis patients. Kidney Int 1999; 56: 275-80.
2. Dember L, Beck G, Allon M, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis. JAMA 2008; 299: 2164-71.
3. Biuckians A, Scott EC, Meier GH, Panneton JM, Glickman MH. The natural history of autologous fistulas as first-time dialysis access in the KDOQI era. J Vasc Surg 2008; 47: 415-21.
4. Rooijens PP, Burgmans JP, Yo TI, et al. Autogenous radial-cephalic or prosthetic brachial-antecubital forearm loop AVF in patients with compromised vessels? A randomized, multicenter study of the patency of primary hemodialysis access. J Vasc Surg 2005; 42: 481-7.
5. Keuter XHA, De Smet AAEA, Kessels AGH, van der Sande FM, Welton RJTJ, Tordoir JHM. A randomized multicenter study of the outcome of brachial-basilic arteriovenous fistula and prosthetic brachial-antecubital forearm loop as vascular access for hemodialysis. J Vasc Surg 2008; 47: 395-401.

Forget the Forearm Loop Graft and Proceed to the Upper Arm AVF

Surendra Shenoy

Washington University School of Medicine, Barnes Jewish Hospital, St. Louis, MO - USA

There is significant controversy regarding the most appropriate access for patients who are not candidates for or have failed forearm arteriovenous fistula (AVF) (1, 2). Observing the policy "distal sites first" many believe that a forearm AV loop graft (AVG) should be the next choice for access. On the other hand, one could argue that creating an upper arm basilic vein transposition fistula (BVTF) that provides all the benefits of AVF should be considered the next access.

The goal of access planning is to provide the longest lasting access that is likely to require the least intervention, capable of providing flows necessary for adequate dialysis. A well functioning AVF enjoys the privilege of "ideal access". However, the maturation rates of AVF are highly variable. Any failed attempt at AVF creation usually results in loss of access sites and often outflow veins. Therefore, it is important to plan an AVF sequence to preserve as many sites as possible and to provide the access that has the best chance of long-lasting success for the patient.

The principles of vein conservation to avoid loss of future access sites include the following (1) use of distal veins first (2), use of superficial veins prior to using deep veins, and (3) use of peripheral deep veins prior to the central deep veins. Site selection should also take into consideration the probability of AVF maturation (based on site and quality of vessels) and other available options in case of access failure. Other factors to consider include (1) estimated access life of the end-stage renal disease (ESRD) patient (anticipated number of years patient is likely live on dialysis), and (2) time of surgical referral (pre-dialysis or on dialysis with a catheter).

Keeping in line with these principles, one could easily make an argument to use forearm veins for an AVG placement prior to using the option of BVTF, a fistula that uses the deep vein in the upper arm as the outflow for the fistula.

Patency data on BVTF suggest a reasonably good maturation and primary patency using a two-stage procedure (50-65%) (3). Recent reports of experiences with AVG have been less optimum (22-34% 1-year primary patency) (4). Secondary patency in the short term (1 year) is somewhat similar between the BVTF and AVG. However, AVG requires a higher number of interventions to achieve this. This data supports the argument for considering transposed basilic vein as the first option in a patient with failed or absent forearm options for an AVF.

Outflow or "swing point" stenosis is the most common cause for BVTF failure. The concern for losing future access options by using BVTF (deep vein fistula) as the first procedure is quite legitimate. However, this could be avoided with the use of pre-operative ultrasound (US) vein mapping

to select patients with suitable anatomy (in whom loss of basilic vein in the upper arm joins the axillary vein) and not jeopardize the forearm access options. With the improved results and use of two-stage procedures, one could also consider basilic transposition as the first option in a few patients under special circumstances. This could include patients with limited dialysis life expectancy, who have many other sites available for AVG placement in the event of basilic transposition failure on one side.

Upper arm access also includes the option of using the upper arm cephalic vein (5). The upper arm cephalic vein is quite often overlooked as it tends to be masked by the subcutaneous fat. Use of US vein mapping easily identifies this vein. This could provide an upper arm primary access option in 40-45% of patients. With the use of US and maturation criteria a larger proportion of these patients require a two-stage cephalic vein transposition procedure. Cephalic vein being a superficial vein does not risk other access options in the event of access failure.

Therefore, with the use of US vein mapping, the majority of access patients who do not have or have failed forearm AVF options would be suitable candidates for an upper arm AVF. The role for placement of a forearm AVG is at best limited to a minority of ESRD patients.

References

1. Fitzgerald JT, Schanzer A, McVicar JP, Chin AI, Perez RV, Troppmann C. Upper arm arteriovenous fistula versus forearm looped arteriovenous graft for hemodialysis access- a comparative analysis. Ann Vasc Surg 2005; 19: 843-50.
2. Torina PJ, Westheimer EF, Schanzer HR. Brachial vein transposition arteriovenous fistula: is it an acceptable option for chronic dialysis vascular access? J Vasc Access 2008; 9: 39-44.
3. Keuter XHA, DeSmet AAEA, Kessels AGH, et al. A randomized multicenter study of the outcome of the brachiobasilic arteriovenous fistula and prosthetic brachial antecubital forearm loop as vascular access for hemodialysis. J Vasc Surg 2008; 47: 398-401.
4. Dixon B, Beck GJ, Vazquez MA, et al. Effect of dipyridamole plus aspirin on hemodialysis graft survival. N Eng J Med 2009; 360: 2191-201.
5. Woo K, Farber A, Doros G, Killeen K, Kohanzadeh S. Evaluation of the efficacy of the transposed upper arm arteriovenous fistula: A single institutional review of 190 basilic and cephalic vein transposition procedures. J Vasc Surg 2007; 46: 94-101.
6. Wellen J, Shenoy S. Assessment and intervention for AV fistula maturation. In: Vascular Access: Principles and Practice. 5th edn. Wilson SE, ed. Philadelphia: Lippincott Williams & Wilkins, 2009; pp 234-42.

Covered Stents for Access Intervention: What We Know and Where We're Going

Ziv J. Haskal

Radiology and Surgery, Vascular and Interventional Radiology, University of Maryland School of Medicine, Maryland - USA

The problem of venous anastomotic stenoses plagues the majority of arteriovenous access grafts (AVG). Until recently, first-line recommended therapy was repeated balloon angioplasty. When recurrence became too frequent, surgical revision was recommended. The strategies were based upon best available practice, a natural desire to minimize invasiveness of therapies, morbidities, and reduce any interruption of hemodialysis through the primary (non-catheter) based access. At the time of its original preparation, the DOQI guidelines proposed access patency standards that were based upon available retrospective studies describing angioplasty outcomes. Since then, prospective studies have demonstrated AVG patency after balloon angioplasty to be far less than those earlier studies (eg 20%,

24% at 6 months). These findings are not surprising when the limitations of earlier retrospective studies are examined, including reporting and referral biases, lack of consistent or, arguably relevant, definitions of patency, etc.

Balloon angioplasty is a potent tool; however, it is increasingly recognized to be prone to early recoil, sometimes prior to discharge from the interventional laboratory. This fact alone can explain the initial benefit attributed to bare metal stents - the improved initial technical and anatomic outcome by virtue of the control of elastic recoil. This early effect is obviated by the later, reliable, marked trans-stent intimal hyperplasia that is provoked by the stent.

Use of an ePTFE stent graft in this setting addresses both issues: initial recoil and later intrastent stenosis by providing an endovascular equivalent to a redo of the venous anastomoses - without an incision, dissection, or interruption of dialysis. Further, it provides a unique advantage over surgery - the creation of an end-to-end anastomosis. The Flair pivotal study appears to support this experimental premise - that improved laminar flow would reduce next stage edge stenoses with less turbulent flow. At present, it is the only therapeutic approach to show significant improvement over balloon angioplasty for venous anastomosis stenoses, statistically significant to 210 days after implant. Anecdotal cases have demonstrated uninterrupted graft function more than 2 years after Flair implantation.

This endovascular strategy opens the arena to numerous investigational and potentially beneficial uses of stent grafts. Designs suitable to these specific applications may be driven by their proof of concept and clinical need. Examples include exclusion of graft pseudoaneurysms, native vein outflow stenoses remote from the access, cephalic arch and central vein stenoses, and conversion of failing intra-fistula segments to directly puncturable graft segments (eg graft-ula or fistu-graft).

PTA Only, Unless it Fails or Ruptures

Gerald A. Beathard

Lifeline Vascular Access, Vernon Hills, IL - USA

Currently, there are three recognized indications for the placement of a stent in association with the management of dialysis vascular access dysfunction - (1) acute angioplasty failure, (2) rapid recurrence of a treated lesion and (3) vessel rupture not controlled by more conservative means. Recently, there has been an increasing tendency to use stents for expanded indications even to the extent of placing a stent following a routine successful angioplasty. This is based upon results that have been presented from the as of yet unpublished Flair stent study.

Before one should adopt a new treatment methodology or approach there are several questions that should be asked. The first of these is - "Is the treatment actually effective?". If one reviews the literature on vascular stents used in association with the treatment of venous stenosis affecting dialysis access grafts, certain problems become immediately apparent. There are very few randomized controlled trials with stents. The ones that have been done have been rather small series (1-3) done using stainless steel stents and have shown no benefit.

More recently, nitinol and covered stents have replaced the use of the stainless steel devices. Although a number of studies have been reported (4-8), no randomized control studies have been published. Based upon these various studies, the primary patency of stents in this disease model is - 53-85% at 3 months and 23-72% at 6 months for stainless steel stents, 69-72% at 3 months and 23-60% at 6 months for nitinol stents, and 50-93% at 3 months and 23-87% at 6 months for stent grafts. Basically, these three stent types do not differ based upon these reports at these time periods. The Flair stent study (unpublished at the time of this writing) is said to have shown a primary patency of 82% and 51% at 2 and 6 months for the study group (n=97) and 77% and 23% at these time periods for the control group (n=93). These values overlap with what has been reported for the other types of stents.

The second question that should be addressed is - "are stent results significantly better than those

for angioplasty alone?". Angioplasty results in the treatment of venous stenosis related to dialysis access grafts have been the subject of a number of reports (9-14). If one uses all of these studies and calculates a weighted average for reported primary patency a value of 85%, 78%, 64% is seen at 2, 3 and 6 months respectively for a total of 2311 cases. These values fall within the range for primary patency reported for stents including the Flair study group. They are considerably better than the Flair control group.

It is important to note when comparing the values for percutaneous transluminal angioplasty (PTA) alone with the values reported from the Flair study that the end point used for determining primary patency was different. The Flair study used bimodal restenosis as an end point, while all of the other studies (PTA alone and PTA followed by stenting) used clinical indicators. Does this mean that the Flair study is valid and the other studies are not? This conclusion cannot be accepted as valid. The dialysis access is important only as it functions as a conduit for dialysis blood. Clinical indicators relate to this function. Morphological indicators, although undoubtedly more accurate, relate only indirectly.

The third question relates to cost of a new therapy and the cost benefit ration. In this regard, based upon the RVUs attached to the stent code and providing treatment in a free-standing facility, it costs over $4K to increase the primary patency at 6 months for an individual patient by 27%. It can also be said that it costs almost $9K for each patient that achieves a 6-month primary patency, based upon a cost of over $4K and a 50% primary patency at 6 months. And all of this is based upon morphology rather than function.

One cannot by any reasonable argument make a plausible case for the routine placement of a stent following uncomplicated angioplasty. Without a valid medical indication for stenting based upon the accepted criteria of (1) acute angioplasty failure, (2) rapid recurrence of a treated lesion, and (3) vessel rupture not controlled by more conservative means, the stent should stay in its box.

References

1. Beathard GA. Gianturco self-expanding stent in the treatment of stenosis in dialysis access grafts. Kidney Int 1993; 43: 872-7.
2. Quinn SF, Schuman ES, Demlow TA, et al. Percutaneous transluminal angioplasty versus endovascular stent placement in the treatment of venous stenoses in patients undergoing hemodialysis: intermediate results. J Vasc Interv Radiol 1995; 6: 851-5.
3. Hoffer EK, Sultan S, Herskowitz MM, Daniels ID, Sclafani SJ. Prospective randomized trial of a metallic intravascular stent in hemodialysis graft maintenance. J Vasc Interv Radiol 1997; 8: 965-73.
4. Sapoval MR, Turmel-Rodrigues LA, Raynaud AC, Bourquelot P, Rodrigue H, Gaux JC. Cragg covered stents in hemodialysis access: initial and midterm results. J Vasc Interv Radiol 1996; 7: 335-42.
5. Farber A, Barbey MM, Grunert JH, Gmelin E. Access-related venous stenoses and occlusions: treatment with percutaneous transluminal angioplasty and Dacron-covered stents. Cardiovasc Intervent Radiol 1999; 22: 214-8.
6. Quinn SF, Kim J, Sheley RC. Transluminally placed endovascular grafts for venous lesions in patients on hemodialysis. Cardiovasc Intervent Radiol 2003; 26: 365-9.
7. Naoum JJ, Irwin C, Hunter GC. The use of covered nitinol stents to salvage dialysis grafts after multiple failures. Vasc Endovascular Surg 2006; 40: 275-9.
8. Vesely TM, Amin MZ, Pilgram T. Use of stents and stent grafts to salvage angioplasty failures in patients with hemodialysis grafts. Semin Dial 2008; 21: 100-4.
9. Saeed M, Newman GE, McCann RL, Sussman SK, Braun SD, Dunnick NR. Stenoses in dialysis fistulas: treatment with percutaneous angioplasty. Radiology 1987; 164: 693-7.
10. Beathard GA. Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. Kidney Int 1992; 42: 1390-7.
11. Beathard GA. Angioplasty for arteriovenous grafts and fistulae. Semin Nephrol 2002; 22: 202-10.
12. Mori Y, Horikawa K, Sato K, Mimuro N, Toriyama T, Kawahara H. Stenotic lesions in vascular access: treatment with transluminal angioplasty using high-pressure balloons. Intern Med 1994; 33: 284-7.
13. Kanterman RY, Vesely TM, Pilgram TK, Guy BW, Windus DW, Picus D. Dialysis access grafts: ana-

tomic location of venous stenosis and results of angioplasty. Radiology 1995; 195: 135-9.
14. Longwitz D, Pham TH, Heckemann RG, Hecking E. Angioplasty in the stenosed hemodialysis shunt: experiences with 100 patients and 166 interventions. Rofo 1998; 169: 68-76.

The Data Show that Primary Covered Stenting is Preferred over Simple PTA, When Possible

Ziv J. Haskal

Radiology and Surgery, Vascular and Interventional Radiology, University of Maryland School of Medicine, Maryland - USA

The estimated cost of maintaining hemodialysis access in the USA is $62,000 per patient per year. Between 16 and 25% of hospital admissions among US end-stage renal disease patients are related to vascular access-related complications. The associated costs have been estimated at close to $1 billion/yr.
Increasing prospective evidence has demonstrated that the patencies and durability of balloon angioplasty of graft related stenosis were overly optimistic, based largely upon single center retrospective reports, devoid of prospective patency definitions and subject to reporting and referral biases. In contrast, data has shown that comparative use of covered stents can significantly prolong access treatment area and access circuit patency over simple percutaneous transluminal angioplasty by prevention of recurrent intimal hyperplasia, reduction of downstream proliferation, and control of early elastic recoil.
The dialysis access patient is not an annuity, nor an ATM. Interventions should be determined, whenever possible, by the highest level of evidence and best options for the patient.

Covered Stents for Native Arteriovenous Fistula Stenosis

Bart L. Dolmatch[1], John J. Duch[2], Bryant Boren[3], Sam Chao[1], Rajankumar Patel[3], Sherry Sturdivant[3], Ingemar J.A. Davidson[1]

[1]University of Texas Southwestern Medical Center and Parkland Memorial Hospital, Dallas, TX - USA
[2]Lincoln Nephrology and Hypertension, Lincoln, NE - USA
[3]University of Texas Southwestern Medical Center, Dallas, TX - USA

The benefit of a covered stent for improving patency after angioplasty of arteriovenous graft (AVG) venous anastomotic stenosis has been demonstrated for the Flair device (Bard Peripheral Vascular, Tempe, AZ) through a clinical trial that was multicenter, randomized, and prospective (1). However, in the USA, the past decade has seen an increase in the prevalence of arteriovenous fistulae (AVF's), which are now approximately twice as prevalent as AVGs. So far, there is no compelling data of any sort to suggest that covered stents are effective for treating stenoses in AVF's. Gupta et al's recent report of the Fluency covered stent used to salvage five AVF's (2) with 80% 9-month primary patency, while provocative, represents only the earliest experience.
To address the question of covered stents in AVF's, we obtained IRB approval for a retrospective review of technical outcome and 6-month patency data for patients who underwent placement of the Fluency covered stents in their native AVF's. Fluency devices were implanted in 2004 and 2005 at two medical centers and the combined data was analyzed. During this time we identified 106 patients who were treated with a Fluency covered stent, of which 40 patients had a stenotic AVF where the Fluency was placed in a peripheral venous segment of the circuit related to poor angioplasty outcome.
Primary circuit patency (PCP) and cumulative circuit patency (CCP) were determined from dialysis

center records, procedure reports, and clinic notes. Sub-analyses were based upon covered stent diameter and configuration of upper arm AVF.
Results: 40 patients (40 AVF's) were treated with a total of 52 Fluency covered stents. Indications for Fluency placement included residual post-percutaneous transluminal angioplasty (PTA) stenosis (n=28, 70%), extravasation (with associated stenosis in most cases; n=11, 28%), and recurrent stenosis within 3 months (n=5, 13%). The only procedural complication related to Fluency placement was one contrast-related rash. No covered stent infections were found during the 2-year period of review.
Overall, 6-month PCP and CCP were 58% and 72%, respectively.
We looked at patency based upon Fluency diameter. Most patients were treated with either a 10 mm Fluency (14 patients), or an 8 mm Fluency (19 patients). No one received a 9 mm diameter Fluency, six were treated with a 7 mm Fluency, and only one patient received a 6 mm device. In our sub-analysis based upon diameter, patients were divided into two groups; 10 mm (14 patients) vs. 6-8 mm (26 patients). While the different PCP's for these two groups did not reach a significant difference of $p \leq 0.05$ at the 95% confidence level, there was a trend toward better 6-month PCP for the larger diameter group; 79% for the 10 mm diameter group compared with 42% for the 6-8 mm diameter group (p=0.07).
We also looked at PCP based upon the type of upper arm AVF. There were five AVF's that were neither brachiocephalic or brachiobasilic and these were excluded from analysis. Of the remaining 35 AVF's, there were 18 brachiocephalic AVF's and 17 brachiobasilic AVF's. There was a 6-month PCP of 59% for brachiocephalic AVF's and 57% for brachiocephalic AVF's (p=0.58; NS).
In summary, our series of 40 AVF's with stenosis where PTA did not yield an acceptable result (residual stenosis, early recurrent stenosis, or rupture) who were treated with the Fluency covered stent had excellent 6-month PCP and CCP with no device-related complications. There was a trend toward better patency of the 10 mm diameter implants, but no patency difference for brachiocephalic vs. brachiobasilic AVF's. While single center retrospective analysis is never a surrogate for prospective, randomized clinical trials, our results indicate a role for the Fluency covered stent salvage of unacceptable PTA result in AVF's.

References

1. Haskal ZJ, Schuman E, Meitling S, et al. Results of the U.S. multicenter randomized trial of the Bard ePTFE encapsulated dialysis access stent graft (abstract). Presented at the 30th Annual Meeting of the Society of Interventional Radiology; 31 March to 5 April 2005; New Orleans, LA. J Vasc Interv Radiol 2005.
2. Gupta M, Rajan DK, Tan KT, Sniderman KW, Simons ME. Use of expanded polytetrafluoroethylene–covered nitinol stents for the salvage of dysfunctional autogenous hemodialysis fistulas. J Vasc Interv Radiol 2008; 19: 950-4.

Cannulation Pseudoaneurysms: Are Covered Stents Useful?

Scott Trerotola

University of Pennsylvania Medical Center, Philadelphia, PA - USA

In order to answer the question of the utility of covered stents in access pseudoaneurysms, a series of definitions are in order. First, a pseudoaneurysm is a defect in the wall of a vessel while an aneurysm involves all components of the vessel wall. Thus, both aneurysms and pseudoaneurysms occur in hemodialysis access, the latter only in fistulae and the former in both grafts and fistulae. The question at hand addresses only pseudoaneurysms, so utility of these devices in aneurysms (actually a far more difficult question) will not be discussed further.
Unlike native vessels, pseudoaneurysms in grafts can be further divided into narrow neck lesions typi-

cal of those seen in the arterial system after femoral catheterization, for example, and what I prefer to call graft degeneration, where due to repeated puncture in the same general location (usually exacerbated by failure to rotate needle sites), the graft dilates to a point where there is only skin overlying the flowing blood and little or no remaining graft material. To my knowledge, this lesion does not occur in fistulae.

Narrow neck pseudoaneurysms nearly always occur in high pressure settings, such as outflow stenosis, and develop suddenly or over a very short period of time (days). The adjacent access is always pulsatile, indicating an outflow lesion. Treating the cause of the lesion (ie, percutaneous transluminal angioplasty (PTA) of the outflow stenosis) is almost always successful in treating the pseudoaneurysm as well. Thus, covered stents have little or no role in treating access pseudoaneurysms.

Graft degeneration, which according to strict definition is a pseudoaneurysm, has a very broad base and develops over a much longer period of time (weeks to months). The overlying skin may be shiny or even ulcerated. There is often prolonged bleeding or bleeding between dialysis sessions. While the aneurismal area may be pulsatile, there is often an underlying thrill and the adjacent graft material may be normal. If the graft is pulsatile in addition to the pseudoaneurysm, then there is likely an outflow stenosis exacerbating the lesion. These lesions can rupture, and since the graft has no intrinsic ability to constrict as a severed vessel would, exsanguinations can occur, making rupture of these lesions a true emergency.

Management of graft PA should be based on the clinical need. These lesions may be asymptomatic and as long as they do not limit puncture sites, have skin breakdown or bleeding, they can be left alone per K/DOQI guidelines. If there is prolonged bleeding after puncture and an underlying stenosis, treating the stenosis with PTA may return the pseudoaneurysm to asymptomatic status. The overwhelming majority of these lesions need no treatment and placing a stent graft in them without good cause is only likely to shorten patency, since the patency associated with this practice is very poor. In one of the few publications on the topic, Vesely showed a 6-month primary patency of 20%. While Gupta et al reported better patency in fistula “pseudoaneurysms”, the lesions treated were actually aneurysms.

So do stent-grafts have any utility in cannulation pseudoaneurysms? We have used them as emergency treatment in the setting of bleeding or impending rupture. Since most emergency surgery for such lesions consists of ligation of the access, using a covered stent to temporize and allow elective revision or planning for a new access during the short life of the stent graft may be a very good use of the technology. It must be emphasized this is a rare event; in our busy practice such a need develops only a few times a year. In that setting we find stent grafts very useful.

References

1. Vesely TM, Use of stent-grafts to repair hemodialysis graft-related pseudoaneurysms. J Vasc Interv Radiol 2005; 16: 1301-7.
2. Gupta M, Rajan DK, Tan KT, Sniderman KW, Simons ME. Use of expanded polytetrafluoroethylene-covered nitinol stents for the salvage of dysfunctional autogenous hemodialysis fistulas. J Vasc Interv Radiol 2008; 19: 950-4.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

The PD First Breakthrough Initiative – "Clinical Benefits of PD First"

Maurizio Gallieni

Nephrology and Dialysis Unit, San Paolo Hospital, University of Milan, Milan - Italy

Peritoneal dialysis (PD) has been advancing in terms of technique, new exchange systems, and a new generation of solutions. We now have abundant evidence (1, 2) that PD is not inferior to hemodialysis (HD) as a renal replacement therapy (RRT). However, most patients in the USA and Europe are treated by HD. Many patients could be treated sequentially with both dialysis methods, as well as with a kidney transplant, and therefore the best possible sequence of the treatment options is important to establish (Fig. 1) (3). The best approach to RRT would be to consider the available treatments (PD, HD, transplantation) as complementary, rather than competitive. Indeed, only a minority of patients has absolute contraindications for either HD or PD, and the choice should be based on advantages and disadvantages of the two methods, for the individual patient, at the specific stage of her/his renal disease, based on medical, social, and logistic considerations. In this perspective, the concept of "integrated care" is particularly interesting (1). It advocates that centers providing RRT should offer all the available treatment modalities in an unbiased way to the patient.

There are several advantages of PD that should be considered when offering RRT to chronic kidney disease (CKD) patients (Tab. I). The argument regarding infection risks (peritonitis), should be critically viewed considering that incidence of central venous catheter related bacteremia in HD patients is higher than peritonitis in PD patients (4).

Preservation of vascular access sites is of great importance, and by starting RRT with PD the use of veins can be delayed 2 to 6 years (5).

Non-clinical factors limiting PD use should also be challenged: all nephrology training programs should offer adequate training in PD; conflict of interest in RRT choice should be avoided (eg physicians having ownerships in HD units should not be in charge of RRT choice).

Given the success of the Fistula First initiative, a "PD First Breakthrough Initiative" could be instrumental in ameliorating the clinical status of our patients, as well as in decreasing costs of providing dialysis.

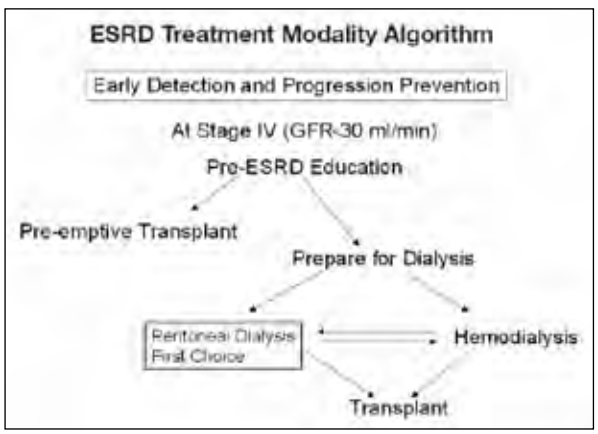


Fig. 1 - *A patient driven (optimal) ESRD modality sequential treatment strategy, emphasizing the benefits of peritoneal dialysis as the first option. Reprinted with permission from ref 3.*

TABLE I - ADVANTAGES OF PERITONEAL DIALYSIS (PD)

- Longer preservation of residual renal function
- Improved early graft function after renal transplantation
- Avoidance of blood-borne infections (eg HCV)
- Financial and logistic advantages
- Improved QoL and higher employment rates
- Preservation of vascular access sites
- Reduced need for erythropoietin treatment

References

1. Van Biesen W, Davies S, Lameire N. An integrated approach to end-stage renal disease. Nephrol Dial Transplant 2001; 16 (suppl): s7-9.
2. Tokgoz B. Clinical advantages of peritoneal dialysis. Perit Dial Int 2009; 29 (suppl): s59-61.
3. Davidson IJ, Gallieni M, Saxena R, Dolmatch B. A patient centered decision making dialysis access algorithm. J Vasc Access 2007; 8: 59-68.
4. Gallieni M. The fistula second initiative. J Vasc Access 2008; 9: 172-4.
5. Chiarelli G, Beaulieu M, Cozzolino M, et al. Vascular access planning in peritoneal dialysis patients. Perit Dial Int 2008; 28: 585-90.

PRO-CON: Who is Unwilling or Unable to use PD, the Nephrologist or the Patient? Nephrologists Could Do a Better Job

Maurizio Gallieni

Nephrology and Dialysis Unit, San Paolo Hospital, University of Milan - Italy

In Europe and North America 80-95% of patients with end-stage renal disease (ESRD) requiring dialysis are treated with hemodialysis (HD), indicating that peritoneal dialysis (PD) is underutilized. North-American (1) and European (2) nephrologists agree that the prevalence of PD should be much higher than it is now.

Charest and Mendelssohn (1) found that both in the USA and in Canada nephrologists believe that ideally about 40% of prevalent ESRD patients should be on PD to optimize cost-effectiveness, survival, wellness, and quality of life. Bouvier et al (2) found that nephrologists working in public centers believe that the optimal rate of PD in incident dialysis patients should be 29%, while those working in the private sector indicated a significantly lower number, 14%. Therefore, based on questionnaire results, while some nephrologists in private practice might be biased in favor of HD, most do not appear to be biased against PD.

Other external factors may shape modality distribution more than the opinions and attitudes of physicians. Bouvier et al (2) suggest that PD utilization rates in France might be low due to the lack of nurses available for patient care (48%), low reimbursement of PD (25%), limited training of physicians (23%) and hospital care facilities (23%). On the contrary, another non-medical factor involved in the underutilization of PD is the availability of HD resources: when center HD capacity is high, there is an incentive to use that capacity rather than place patients on home dialysis (3).

Establishment of a pre-dialysis patient education program is of paramount importance, as a well-balanced presentation of all therapeutic options is associated with a higher selection of PD as first therapy (4). Indeed, 50% of patients without medical contraindications for PD or HD selected PD (5). However, currently only half the new dialysis patients followed by nephrologists had education on dialysis modalities, despite being monitored mainly by ESRD-specific units (4). Regarding physician education, the number of PD patients treated in teaching hospitals is too small to guarantee adequate training of nephrology fellows (6).

Incorporating a PD access placement program into the pre-dialysis education program doubled the prevalence of PD (from 43-80 patients) in an 18-month period, a dramatic impact on patient choice and PD growth (7).

The potential of PD remains significantly underutilized in terms of both its lower cost and its ability to deliver excellent outcomes, particularly in the early years of dialysis. Nephrologists appear to be ready to increase the number of ESRD patients starting PD rather than HD. Could they do a better job? It is proposed that dialysis program directors help in starting or in developing a well structured PD team. This should be in close contact with the pre-dialysis and the dialysis access teams, for correct counseling given to ESRD patients on the benefits of the PD program. Correction of non physician-related factors is also necessary to deliver a more balanced and cost-effective dialysis.

References

1. Charest AF, Mendelssohn DC. Are North American nephrologists biased against peritoneal dialysis? Perit Dial Int 2001; 21: 335-7.
2. Bouvier N, Durand PY, Testa A, et al. Regional discrepancies in peritoneal dialysis utilization in France: the role of the nephrologist's opinion about peritoneal dialysis. Nephrol Dial Transplant 2009; 24: 1293-7.
3. Just PM, de Charro FT, Tschosik EA, Noe LL, Bhattacharyya SK, Riella MC. Reimbursement and economic factors influencing dialysis modality choice around the world. Nephrol Dial Transplant 2008; 23: 2365-73.
4. Marrón B, Martínez Ocaña JC, Salgueira M, et al. Analysis of patient flow into dialysis: role of education in choice of dialysis modality. Perit Dial Int 2005; 25 (suppl): S56-9.
5. Prichard SS. Treatment modality selection in 150 consecutive patients starting ESRD therapy. Perit Dial Int 1996; 16: 69-72.
6. Mehrotra R, Blake P, Berman N, Nolph KD. An analysis of dialysis training in the United States and Canada. Am J Kidney Dis 2002; 40: 152-60.
7. Asif A, Byers P, Gadalean F, Roth D. Peritoneal dialysis underutilization: the impact of an interventional nephrology peritoneal dialysis access program. Semin Dial 2003; 16: 266-71.

Patients Could Consider PD More Often

Miguel A. Vazquez

UT Southwestern Medical Center, Dallas, TX - USA

Peritoneal dialysis (PD) offers several advantages when compared to hemodialysis (HD). PD allows for more gentle fluid removal and provides more frequent dialysis clearance (1). PD also allows for better preservation of residual renal function, provides more flexibility for patients, and is associated with lower costs. In addition, PD patients do not require a vascular access; therefore, avoiding all the complications and morbidity associated with vascular access immaturity and vascular access failures. The risk of acquiring blood-borne infections is much lower for patients treated with PD than for those patients treated with HD.

The proportion of patients with end-stage renal disease (ESRD) in the United States treated with PD has declined markedly over the last decade (2). Several factors are likely responsible for the lower utilization of PD as a renal replacement modality in the United States. One possible explanation for the lower use of PD is that some studies have raised concerns about dialysis outcomes for certain patient groups treated with PD (3). Limited exposure to PD during nephrology training results in less familiarity with PD and less use of PD as a treatment when nephrologists go out into practice (4). Recently, the ownership of dialysis units by some large for-profit dialysis organizations has also been noted to be associated with lower utilization of PD (5). Other factors, such as the large increase in the number of HD units, proliferation of smaller dialysis centers, shortages of nurses with skills on PD, and inadequate dialysis unit infrastructure to support PD can all contribute to the lower utilization of PD (6).

Patient education plays a major role in the selection of a renal replacement therapy modality by patients (7). Important issues that affect quality of life for dialysis patients, including physical and emotional discomfort as well as availability of time for work, family, and social activities can be affected by the choice of dialysis modality (8). Patients who are younger, have higher education, and have fewer comorbidities tend to select home dialysis treatments involving self-care (including PD) more often than other patients (9). Some studies suggest that early nephrology follow-up may enhance selection of self and home-based dialysis care (9). Nevertheless, despite evaluation and ongoing care by nephrologists, a substantial proportion of patients lack a perception of treatment options for chronic

kidney disease and ESRD (10).
New approaches, such as patient-centered education and increased availability of home care assistance, could allow patients to develop a better understanding and comfort with their treatment options and increase the proportion of patients choosing PD for treatment of ESRD (11, 12).

References

1. Saxena R. Peritoneal dialysis: a viable renal replacement therapy option. Am J Med Sci 2005; 330: 36-47.
2. US Renal Data System: Annual Data Report, US Department of Public Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD. 2008.
3. Jaar BG, Coresh J, Plantinga LC, et al. Comparing the risk for death with peritoneal dialysis and hemodialysis in a national cohort of patients with chronic kidney disease. Ann Intern Med 2005; 143: 174-83.
4. Mehrotra R, Blake PG, Berman N, Nolph KD. An analysis of dialysis training in the United States and Canada. Am J Kidney Dis 2002; 40: 152-60.
5. Mehrotra R, Khawar O, Duong U, et al. Ownership patterns of dialysis units and peritoneal dialysis in the United States: utilization and outcomes. Am J Kidney Dis 2009; 54: 289-98.
6. Blake P. Proliferation of hemodialysis units and declining peritoneal dialysis use: an international trend. Am J Kidney Dis 2009; 54: 194-6.
7. Mooney A. Decision making around dialysis options. Contrib Nephrol 2009; 163: 257-60.
8. Bro S, Bjorner JB, Tofte-Jensen P, et al. A prospective, randomized multicenter study comparing APD and CAPD treatment. Perit Dial Int 1999; 19: 526-33.
9. Piccoli GB, Mezza E, Burdese M, et al. Dialysis choice in the context of an early referral policy: there is room for self care. J Nephrol 2005; 18: 267-75.
10. Finkelstein FO, Story K, Firanek C, et al. Perceived knowledge among patients cared for by nephrologists about chronic kidney disease and end-stage renal disease therapies. Kidney Int 2008; 74: 1178-84.
11. Manns BJ, Taub K, Vanderstraeten C, et al. The impact of education on chronic kidney disease patients' plans to initiate dialysis with self-care dialysis: a randomized trial. Kidney Int 2005; 68: 1777-83.
12. Oliver MJ, Quinn RR, Richardson EP, Kiss AJ, Lamping DL, Manns BJ. Home care assistance and the utilization of peritoneal dialysis. Kidney Int 2007; 71: 673-8.

What Causes AV Access Related Hand Ischemia?

Frederick Schild, Joseph C. Fuller, Patrick Collier

University of Miami Miller School of Medicine, Miami, FL - USA

Vascular access is quickly becoming the most common surgical procedure performed in the USA and the rest of the world. Therefore, it is important to look at the causes of complications, and how to effectively treat the problems. Severe steal syndrome occurs in 1-10% of vascular access procedures and should be addressed immediately, as it can lead to very serious complications (1). Risk factors include peripheral arteriosclerosis, age, previous ipsilateral arteriovenous fistulas (AVF) and high flow AVF (2). The literature describes methods of predicting severe steal syndrome (3). In my experience, this complication occurs most commonly in elderly patients with diabetes, severe distal vascular disease and occurs more often in females than in males.
Prior to surgery, extensive work-up should be carried out including bilateral arterial and venous stud-

ies of the upper extremities, making sure that both the radial and ulnar arteries are patent. Exceptional attention should be paid to the distal skin noting the color of the fingers, making sure there is adequate circulation to the hand prior to creating an access in that limb. It is very important in these particular patients that a large arteriovenous anastamosis is not created. Increased shunting of blood from borderline vessels can lead to ischemia of distal tissues (4). The usual anastamosis should be approximately 5 mm in diameter. Before completing the procedure, one should immediately check the distal pulses and flow to the hand and fingers, both manually and with the latest technology (5).

If apparent steal is evident intra-operatively, measures can be taken to decrease the flow. First, banding can be performed in several ways. The venous outflow can be narrowed with sutures, non-penetrating titanium clips or by wrapping with PTFE to narrow the outflow without clotting the fistula. If there is no improvement, one can perform a DRIL procedure, a modified distal revascularization and interval ligation (DRIL) procedure, or as a last resort, ligate the fistula (6). If a steal syndrome is suspected within the first 24 hr post-operatively, diagnosis can be made by noting a cold, painful hand with no evidence of radial or ulnar pulse. The patient should be taken immediately back to surgery to correct the problem. Any delay in treatment can lead to serious complications, including irreversible nerve damage with wrist drop or gangrenous changes. Some patients, after a period of time on dialysis, may present with a delayed steal syndrome (7). Although not as emergent as the acute type, it should be dealt with expeditiously. Treatment requires revision as previously noted.

Some patients have been treated by interventionalists with angioplasty and/or stenting, but the long-term results need further evaluation (8). Many of these patients have severe arteriosclerosis which could make successful angioplasty and stenting difficult.

Prompt diagnosis and treatment of severe steal syndrome extends beyond curative measures alone. Because of the irreparable damage that may occur, there are increased claims being filed against surgeons and hospitals. This demonstrates the importance of proper pre-operative evaluation, early diagnosis and adequate treatment.

References

1. Schanzer H, Schwartz M, Harrington E, Haimov M. Treatment of ischemia due to steal by arteriovenous fistula with distal artery ligation and revascularization. J Vasc Surg 1988; 7: 770-3.
2. Tordoir JH, Dammers R, Van der Sande FM. Upper extremity ischemia and hemodialysis vascular access. Eur J Vasc Endovasc Surg 2004; 27: 1-5.
3. Tynan-Cuisinier, Berman SS. Strategies for predicting and treating access induced ischemic steal syndrome. Eur J Vasc Endovasc Surg 2006; 32: 309-15.
4. Zanow J, Krueger U, Reddemann P, Scholz H. Experimental study of hemodynamics in procedures to treat access-related ischemia. J Vasc Surg 2008; 48: 1559-65.
5. Schanzer A, Nguyen LL, Owens CD, Schanzer H. Use of digital pressure measurements for the diagnosis of AV access-induced hand ischemia. Vasc Med 2006; 11: 227-31.
6. Huber T, Brown M, Seeger JM, Lee WA. Midterm outcome after the distal revascularization and interval ligation (DRIL) procedure. J Vasc Surg 2008; 48: 926-32.
7. Lazarides MK, Staramos DN, Kopadis GK, Maltezos C, Tzilalis VD, Georgiadis GS. Onset of arterial "steal" following proximal angioaccess: immediate and delayed types. Nephrol Dial Transplant 2003; 18: 2387-90.
8. Asif A, Leon C, Merrill D, et al. Arterial steal syndrome: a modest proposal for an old paradigm. Am J Kidney Dis 2006; 48: 88-97.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Simplifying Non-invasive Assessment of Hand Ischemia

Danny Chan

Department of Radiology, Division of Interventional Radiology, UT-Southwestern, Dallas, TX - USA

Hand ischemia is a serious and well known complication of arteriovenous (AV) access creation. It occurs in 5-10% of all cases of AV creation, especially when the brachial artery is used as the inflow (1-3). AV induced hand ischemia causes significant pain and discomfort, as well as potentially leading to digit or even hand loss. The development of ischemic symptoms distal to an AV access can occur in the early or late post-operative interval. Three distinct etiologies of hand ischemia have been reported; (a) arterial occlusive disease proximal or distal to the AV anastomosis causing blood flow restriction; (b) excessive flow into the AV conduit with or without arterial occlusive disease; and (c) lack of vascular collateralization to the increased flow demand (4). In other cases, distal arteriopathy as a result of generalized vascular calcification and diabetes is the cause.

Treatment should start with a detailed history and physical examination to help rule out other non-ischemic causes of hand pain. Non-invasive testing is the next crucial step in the diagnosis of hand ischemia. A variety of non-invasive exams such as digital pressure measurement, digital/brachial index (DBI) measurement, digital plethysmography and duplex ultrasonography, are available to assist in the evaluation of hand ischemia.

Confirmatory testing can be performed utilizing digital photoplethysmography (PPG) with the fistula open and after manual compression of the fistula. Although it is normal to have a reduction in the amplitude of digital waveforms distal to a patent proximal fistula, the non-ischemic hand should demonstrate normal pulsatile waveforms (5, 6). Patients with pronounced ischemia have monophasic, or flat, waveforms that augment with the compression of the fistula. Once confirmed, non-invasive testing can also be utilized with a high degree of accuracy to access for the cause of the ischemia and may in some cases, replace the need for angiography (7). The presence of a proximal inflow stenosis contributes to the steal syndrome in 20-30% of patients who present with distal extremity ischemia (8). Duplex imaging is ideal for evaluating hemodynamically significant stenoses of inflow vessels, as well as within the AV circuit. Evaluation of the blood flow volume and hemodynamics of an AV access can be performed with high reliability and relative ease. The use of a DBI of less than 0.6 has been reported as a reliable predictor for symptoms of steal syndrome after surgery (9).

Non-invasive testing is a critical and important step in the evaluation and treatment of hand ischemia. It is important to have a clear understanding of the causes of AV access induced hand ischemia. It is also critical to have knowledge of the normal and abnormal parameters for an upper extremity non-invasive examination. A systemic approach with a clearly defined protocol and algorithm can help improve efficiency and outcomes in the diagnosis and treatment of hand ischemia.

References

1. Zibari GB, Rohr MS, Landreneau MD, et al. Complications from permanent hemodialysis vascular access. Surgery 1988; 104: 681-6.
2. Odland MD, Kelly PH, Ney AL, et al. Management of dialysis-associated steal syndrome complicating upper extremity arteriovenous fistulas: use of intraoperative digital photoplethysmography. Surgery 1991; 110: 664-9.
3. Goff CD, Sato DT, Bloch PH, et al. Steal syndrome complicating hemodialysis access procedures: Can it be predicted? Ann Vasc Surg 2000; 14: 138-44.
4. Malik J, Tuka V, Kasalova Z, et al. Understanding the dialysis access steal syndrome. A review of the etiologies, diagnosis, prevention and treatment strategies. J Vasc Access 2008; 9: 155-66.
5. Strandness DE Jr, Gibbons GE, Bell JW. Mercury strain gauge plethysmography: evaluation of patients with acquired arteriovenous fistulas. Arch Surg 1962; 85: 215-9.

6. Byrne JP, Stevens LE,Weaver DH, et al. Advantages of surgical arteriovenous fistulas for hemodialysis. Arch Surg 1971; 102: 259-62.
7. Malik J, Slavikova M, Maskova J. Dialysis access-associated steal syndrome: the role of ultrasonography. J Neprol 2003; 16: 903-7.
8. Morsy AH, Kulbaski M, Chen C, Isiklar H, Lumsden AB. Incidence and characteristics of patients with ischemia after hemodialysis access procedure. J Surg Res 1998; 74: 8-10.
9. Papasavas PK, Reifsnyder T, Birdas TJ, Caushaj PF, Leers S. Prediction of arteriovenous access steal syndrome utilizing digital pressure measurements. Vasc Endovascular Surg 2003; 37: 179-84.

Undoing the Sin of Stealing: Treatment Options for Hand Ischemia

Ingemar J.A. Davidson

University of Texas Southwestern Medical Center and Parkland Memorial Hospital, Dallas, TX - USA

Hand ischemia or "steal" after dialysis access placement occurs in up to 10% of cases when the distal brachial artery is used as inflow, which is 10 times more often compared to that seen with wrist radio-cephalic arteriovenous fistulas (AVFs) in less than 1% of cases (1-4). It is usually seen in older women with diabetes, and carries severe morbidity, including tissue or limb loss, if not recognized and treated. Three distinct etiologies include: first, blood flow restriction to the hand from arterial occlusive disease either proximal or distal to the AV access anastomosis. Secondly, true steal may occur from excess blood flow through a large AV access conduit, and thirdly, the lack of vascular (arterial) adaptation or collateral flow reserve (i.e. atherosclerosis) to the increased flow demand from the AV conduit may bring on hand ischemic symptoms from inadequate tissue perfusion. The three causes of steal may be present alone or in concert.

The diagnosis of steal is based on an accurate history and physical (H&P) examination and confirmed with tests including an arteriogram, duplex ultrasound evaluation (DUE) including finger pressures as mandated by the H&P findings.

Treatment options of steal include observation of developing symptoms in mild cases. Balloon angioplasty and possibly stenting is the appropriate treatment for an arterial stenosis performed as part of the diagnostic arteriogram. At least three distinct surgical corrective procedures exist to counteract the physiology of steal. These are distal revascularization and interval ligation known or DRIL (1-4). Secondly, the proximalization of arterial inflow (PAI) was popularized by Zanow et al (5). Thirdly, controlled banding of the access to restrict access blood flow guided by intra-operative finger-pressure measurements and DUE with blood volume flow to relieve the ischemic pain is often the only option, short of ligating the access, in this very fragile patient population with multiple cardiovascular co-morbidities (6). The author has in recent years increasingly used arterial inflow higher up towards the axilla which could be considered a pre-emptive PAI procedure. The ultimate treatment strategy depends on severity of symptoms, the extent of patient co-morbidity, and the local dialysis access technical team support and skills available. A full review paper on hemodialysis-access induced hand ischemia by Malik et al was published in this journal last year (7).

References

1. Wixon CL, Hughes JD, Mills AL. Understanding strategies for the treatment of ischemic steal syndrome after hemodialysis access. J Am Coll Surg 2000; 191: 301-10.
2. Knoz RC, Berman SS, Huges JD, et al. Distal revascularization - interval ligation: a durable and effective treatment for ischemic steal syndrome after hemodialysis access. J Vasc Surg 2002; 36: 250-6.
3. DeCaprio JD, Valentine RJ, Kakish HB, et al. Steal syndrome complicating hemodialysis access. Cardiovascular Surg 1997: 5: 648-53.
4. Berman SS, Gentile AT, Glickman MH, et al. Distal revascularization-interval ligation for limb salvage and maintenance if dialysis access in ischemic steal syndrome. J Vasc Surg 1997; 26: 393-404.
5. Zanow J, Kruger U, Scholz H. Proximalization of the arterial inflow: a new technique to treat access-related ischemia. J Vasc Surg 2006; 43: 1216-21.

6. Murray BM, Rajczak S, Herman A, Leary D. Effect of surgical banding of a high-flow fistula on access flow and cardiac output: intra-operative and long-term measurements. Am J Kid Dis 2004; 44: 1090-6.
7. Malik J, Tuka V, Kasalova Z, et al. Understanding the dialysis access steal syndrome. A Review of the etiologies, diagnosis, prevention and treatment strategies. J Vasc Access 2008; 9: 155-66.

Flow Reduction for the Treatment of Recurrent Cephalic Arch Stenosis in Brachiocephalic Hemodialysis Arteriovenous Fistulas

Gregg Miller[1, 2], **Alexander Friedman**[2]

[1]Columbia University, College of Physicians and Surgeons, New York, NY
[2]American Access Care, Brooklyn, NY - USA

Brachiocephalic fistulas are much more likely to develop cephalic arch stenoses than other types of fistulas (1, 2). Cephalic arch stenosis (CAS) has been implicated in 2% of radiocephalic and 39% of brachiocephalic fistula failures (1). Stenoses at the cephalic arch have been found to be resistant to angioplasty (2) and it has been suggested that high flow is a major cause of venous intimal hyperplasia (3, 4).

Banding is a technique that has commonly been used to reduce flow in hypervolemic accesses. The Minimally Invasive Limited Ligation Endoluminal-assisted Revision (MILLER) is a method of banding that uses intraluminal angioplasty balloons to precisely adjust the size of the band and does not require open surgery (5).

Banding has previously been used to treat venous intimal hyperplasia in arteriovenous grafts. Fillinger et al. (6) has demonstrated that banded grafts have lower rates of venous intimal hyperplasia than unbanded grafts, suggesting that a significant reduction in flow results in a decrease in venous intimal hyperplasia.

We are presenting a study that examines the effect of fistula flow reduction on recurrent CAS. A retrospective analysis of patients who had undergone the MILLER banding procedure (5) to treat Steal syndrome and hypervolemic accesses was conducted. The patient inclusion criterion was recurrent CAS prior to the time of banding, defined as 3 or more percutaneous interventions (angioplasty / stent) at the cephalic arch within 6 months. A paired t-test was used to evaluate the effect of MILLER banding on the frequency of interventions at the cephalic arch, with subjects serving as their own controls.

14 patients (6 male and 8 female) with brachiocephalic fistulas were included in this study. The average patient age was 59; the rate of diabetes and hypertension was 38% and 71%, respectively. The average band size was 4mm (range, 3-5mm). Flow measurements were obtained in 2 patients, and the average flow reduction was from 2713mL/min to 1235mL/min (54% reduction). The average rate of interventions at the cephalic arch was reduced from 5.4 to 1.0 per access-year following the banding procedure (paired t-test, $t = 4.55$, $p < 0.01$; Table I). The lesion patency was 83%, 71%, and 71% at 3, 6 and 12 months (Fig. 1). The secondary access patency was 100% at 12 months. The average follow-up time was 12 months (range, 0.25-33 months).

We observed a statistically significant reduction in the rate of CAS following banding ($p < 0.01$). As such, we consider flow reduction to be an effective treatment for CAS. When angioplasty and stent placement fail to achieve durable cephalic arch patency, the MILLER banding procedure provides the interventionalist with an alternative treatment which is reversible and minimally invasive.

TABLE I - OBSERVATION TIMES AND RATES OF CEPHALIC ARCH STENOSIS BEFORE AND AFTER THE BANDING PROCEDURE

	Prior to banding	**Post-banding (follow-up)**
Average observation time, range (months)	11.3, 1.9-22	12, 0-33
Average rate of cephalic arch stenosis (occurrences per patient-year)	5.4	1.0

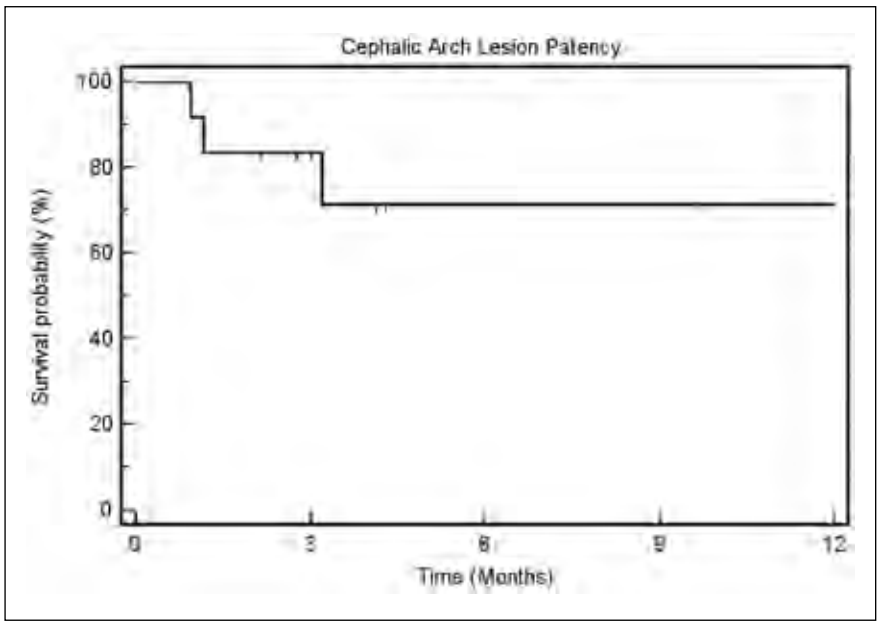


Fig. 1 - *Cephalic arch lesion patency.*

References

1. Rajan DK, Clark TW, Patel NK, et al. Prevalence and treatment of cephalic arch stenosis in dysfunctional autogenous hemodialysis fistulas. J Vasc Interv Radiol 2003; 14: 567-73.
2. Kian K, Asif A. Cephalic arch stenosis. Semin Dial 2008; 21: 78-82.
3. Heise M, Schmidt S, Kruger U, et al. Local haemodynamics and shear stress in cuffed and straight PTFE-venous anastomoses: an in-vitro comparison using particle image velocimetry. Eur J Vasc Endovasc Surg 2003; 26: 367-73.
4. Jaberi A, Schwartz D, Marticorena R, et al. Risk factors for the development of cephalic arch stenosis. J Vasc Access 2007; 8: 287-95.
5. Goel N, Miller GA, Jotwani MC, et al. Minimally invasive limited ligation endoluminal-assisted Revision (MILLER) for treatment of dialysis access-associated steal syndrome. Kidney Int 2006; 70: 765-70.
6. Fillinger MF, Reinitz ER, Schwartz RA, Resetarits DE, Paskanik AM, Bredenberg CE. Beneficial effects of banding on venous intimal-medial hyperplasia in arteriovenous loop grafts. Am J Surg 1989; 158: 87-94.
7. Kian K, Unger SW, Mishler R, et al. Role of surgical intervention for cephalic arch stenosis in the "fistula first" era. Semin Dial 2008; 21: 93-6.

The Clotted AVF – Are There any Indications for Surgical Thrombectomy?

Surendra Shenoy

Washington University School of Medicine, Barnes Jewish Hospital, St. Louis, MO - USA

Low flow state (venous stasis), hypercoagulability and inflammation are the precipitating causes for intravascular thrombosis. An arteriovenous fistula (AVF), a direct communication (usually 5-7mm in diameter) between a small or medium sized artery and a peripheral vein, is a high flow system. Increased cardiac output is a normal response of the body to overcome the acute loss of resistance produced by the AV communication and responsible for this high flow. Majority of this increase in the blood flow happens immediately and within the first few days after AVF creation. Hence a well functioning

AVF that has a flow of 800 - 2000 ml/min is at very low risk of thrombosis.
For management purposes, AVF thrombosis can be classified into (early) thrombosis i.e. thrombosis in a non-mature fistula and (late) thrombosis i.e. thrombosis in a mature fistula (a fistula that has functioned well for a period of time).
Early thrombosis is sometimes seen at the time of surgery. In this situation, a patent fistula with a good thrill at the completion of anastomosis starts losing it during closure. Often times this early thrombosis could be a result of technical issues such as redundant outflow vein with a kink or twist at the swing point or a back walled suture at the anastomosis. In the absence of the technical issues, this early thrombosis could also be the result of undiagnosed underlying hypercoagulability or acute platelet activation occurring during the surgical procedure. In such situations, use of intra-operative systemic anticoagulation followed by intra-operative surgical thrombectomy could help to keep the fistula patent. A post-operative evaluation of the coagulation profile is often useful to decide on the duration of anticoagulation. It is our practice to maintain these patients on anticoagulation with either coumadin or clopidogrel bisulfate or both till the fistula matures unless there is an indication to continue them.
The majority of early thromboses (thrombosis in a non-mature fistula) however, tend to occur early (1-4 weeks) after fistula creation. Ultrasound evaluation in such situations generally reveals variable inflammatory wall thickening and luminal thrombus which generally ends near a point where a tributary enters the main outflow vein. The outflow vein beyond the tributary usually remains patent due to blood flow from the tributary. While interventional attempt of thrombectomy in early thrombosis situations may be complicated by the presence of recent surgical anastomosis and non-mature narrow veins that are at a risk of injury, results of surgical thrombectomy are also poor. However, occasionally (in a minority of patients) surgical thrombectomy may be beneficial when US evaluation shows a large outflow vein engorged with thrombus with very little wall thickening with a patent anastomosis. Exploration in such situations usually reveals a valve stenosis at the site where the thrombus ends. Using the tributary to patch this stenotic segment after excising the valve is a useful technique to help such AVF mature after early thrombectomy.
Late thrombosis (thrombosis in a well functioning AVF) is an uncommon event. Most late thromboses occur in fistulae that have undetected underlying problems. The most common causes of such undetected underlying problem include inflow or outflow stenosis. Development of stenosis in an AVF tends to be slow and progressive over a period of time.
Outflow stenosis (stenosis beyond needle access segment) tends to produce increasing stasis with a gradual and continuous increase in the intra fistula pressure. Increased intra access pressure results in development of aneurysmal dilation at needle access segments or in development of tortuosity of the vein proximal to the stenosis. This increasing stasis accompanied by a combination of factors including inflammation, lymphokine activation, hypotension, low flow and hemoconcentration induced by dialysis results in hypercoagulability that culminates in AVF thrombosis. Being a chronic process complete thrombosis is often preceded by development of chronic mural thrombus in large dilated needle access areas of the AVF.
AVF that have thrombosed in this fashion often contain large thrombus burdens. While the acute thrombus can be potentially liquefied and aspirated by pharmaco mechanical devices, the chronic thrombus is resistant to both. Surgical thrombectomy in these situations allows the operator to remove all the acute and chronic thrombus from the AVF (1). It eliminates the risk of embolic problems that could result from dislodging the clots/platelet plug into the circulation. It also provides an opportunity to identify the area of stenosis and correct the precipitating cause for thrombosis. Surgical venoplasty is a definitive longer lasting solution for the outflow vein stenosis.
Inflow stenosis (stenosis proximal to the needle access segment) on the other hand decreases the blood flow in the fistula. Juxta anastomotic stenosis (JAS) is the most commonly encountered cause for late fistula thrombosis due to an inflow problem. In this situation the outflow vein generally tends to remain patent beyond the first patent tributary (which maintains the flow in the outflow vein). Thrombus burden tends to be small. JAS is amenable for interventional thrombectomy and dilation. However depending on the chronicity of the JAS the result of interventional dilation tends to be variable (2, 3). Surgical thrombectomy in this situation tends to provide a definitive solution. Based on expertise and

anatomy the surgeon has the option of performing a patch venoplasty of the JAS or proximalization of the anastomosis after thrombectomy (4). Both these surgical procedures provide a more definitive solution for the problem.

Occasionally a thrombosed needle stick segment is encountered beyond a stenosis in the fistula with the fistula anastomosis itself remaining patent. This is always the result of a flow diverting tributary proximal to the stenosis that maintains fistula flow. In this situation measurement of brachial artery flow by ultrasound usually show good AVF flows. Surgical repair provides a permanent solution to the problem in such situations. The tributary that diverts the flow provides excellent autologous material to repair the stenosis using it for patch venoplasty. This will increase the luminal diameter of the stenotic segment and provide a large diameter conduit to channelize all the flow into the main outflow vein of the AVF.

In summary, surgical thrombectomy with treatment of the underlying cause for fistula thrombosis provides a definitive treatment option for managing a thrombosed AVF (4, 5). Surgical thrombectomy is useful in selected cases of early AVF thrombosis. Surgical intervention can revive most fistulae with late thrombosis and provide excellent results.

References

1. Palmer RM, Cull DL, Kalbaugh C, et al. Is surgical thrombectomy to salvage failed autogenous arteriovenous fistulae worthwhile? Am Surg 2006; 72: 1231-33.
2. Jain G, Maya ID, Allon M. Outcomes of percutaneous mechanical thrombectomy of arteriovenous fistulas in hemodialysis patients. Semin Dial 2008; 21: 581-3.
3. Rajan DK, Clark TW, Simons M Kachura JR, Sniderman K. Procedural success and patency after percutaneous treatment of thrombosed autogenous arteriovenous dialysis fistulas. JVIR 2002; 13: 1211-18.
4. Ponikvar R. Surgical salvage of thrombosed native arteriovenous fistulas for hemodialysis by interventional nephrologists. Ther Apher Dial 2009; 13: 340-44.
5. Lipari G, Tessitore N, Poli A et al. Outcomes of surgical revision of stenosed and thrombosed forearm arteriovenous fistulae for hemodialysis. Nephrol Dial Transplant 2007; 22: 2605-12.

Is it Ever Too Early or Too Late to Attempt AVF Declotting?

Scott Trerotola

University of Pennsylvania Medical Center, Philadelphia, PA - USA

Fistula declotting is both challenging and rewarding. Depending upon the type of fistula and the experience of the operator, fistula declotting may be more technically challenging and more time consuming, yet offer better long-term patency than graft declotting and the personal satisfaction of restoring a fistula, the acknowledged best form of access, to function.

It is very important when discussing fistula declotting to distinguish between in situ and transposed fistulae. In general, transposed fistulae are relatively easy to declot and in many respects are like grafts. The clot volume in these fistulae is usually relatively small compared to what can be very large volume in very mature in situ fistulae. This comes into play when discussing whether it is ever too late to declot a fistula, as discussed below. Often, especially with two-stage transpositions, maturity is less of an issue and the question of whether it is ever too early to declot a fistula is perhaps easier to answer, if not moot.

The question of whether it is ever too early to declot a fistula relates to maturity. Should a fistula that has never been used be declotted? I prefer to address this question in a different way, namely, should a fistula that has never matured be declotted? The reason for this is that it is not uncommon for a fistula to have matured yet clot before initial use, and as long as the fistula is mature, even if not used, the arguments about declotting immature fistulae (below) do not apply in this situation. Therefore, the

interventionalist should examine the "clotted, never used" fistula to determine if there is a palpable or visible mature vein and if there is, declotting should proceed as usual.

If there is not a visible or palpable vein, the next step is to determine whether there is a collapsed vein with high grade stenosis or short segment occlusion in the inflow, a readily treatable lesion, versus complete occlusion of the inflow with either a very short or very small segment of vein and no vein beyond this. In my opinion, as well as that of Turmel-Rodrigues et al, these fistulae are not salvageable and even if patency can be restored, the long-term results are poor. Conversely, the results associated with short segment occlusions, as reported by Liang et al, are excellent. Incidentally, we prefer not to refer to these as "declots" because of the tiny clot burden associated with them (Shatsky et al). However, in order to make this distinction, one may need either an ultrasound exam or fistulogram (may need to be performed with 3F arterial puncture), as the physical examination may be inadequate to detect a collapsed but still viable vein beyond the occlusion.

The question of whether it is ever too late to declot a fistula is often politically charged as it is often asked in the context of weekend procedures. Unfortunately, there is little evidence basis to address this question. There are two subcomponents to the question, in my opinion. The first is, "is there any downside to waiting up to 72 hours to declot a fistula", and the second is, "is there a time point beyond which fistula declotting should not be attempted". To my knowledge, no one has ever specifically addressed either of these two questions scientifically. We can draw on the deep vein thrombosis (DVT) thrombolysis literature for some answers to the latter question. In a review of over 250 published DVT lysis procedures, Grossman et al reported 88% success if done within 4 weeks of onset of symptoms and 60% if done after 4 weeks. The proposed reason for this is development of synechiae between the clot and vein wall as organization occurs. Extended to a living in situ fistula, one can argue that the success rate for fistula declotting might drop at around 4 weeks, and it has been my personal experience that this drop is precipitous. However, this might not apply to a transposed fistula in which disruption of the vasa vasorum might delay the organization process. In clinical practice, it is rare to be presented with a fistula that has been clotted for more than a week; occasionally patients with functioning transplants and fistulae may present like this. My approach has been to examine the fistula and if there is palpable, spongy clot I attempt declotting; if there is only a cord or very firm clot I do not do so. Obviously, contrast considerations may arise in this setting as well.

In answering the former question, relating to any adverse consequences of waiting a few days to declot a fistula, the available literature, as well as my personal experience, suggests no. Initial reports described declotting within 24 hr and recommended not waiting, however with experience we have learned that this recommendation appears invalid. In the study of Liang et al, admittedly mostly with small clot burden fistulae, more than half of the declots were performed in the 24-72 hr window, and a quarter after 72 hr (4-9 days). They strongly argue, based on the above DVT case, that declotting should be attempted after 72 hr, and I agree. They do not stratify their results by duration of thrombosis, however, since they addressed this issue so directly, I infer they did not see any effect or they would have reported it. Turmel-Rodrigues, who has perhaps more experience with fistulae than any other interventionalist, states that he performs declots up to 3 weeks, and argues it may well make sense to wait several days until an experienced interventionalist is available to perform the declot. Lipari et al, in reporting surgical management of thrombosed fistulae, performed all procedures within 72 hr and did not stratify results by duration of declotting; likewise Schon et al and Zaleski et al reported success up to 72 hr. Rajan et al performed all of their procedures within 48 hr except one done at 7 days; again none of these investigators stratified by duration of thrombosis. One of the main reasons for this is that the vast majority of clotted fistulae will come to light within a short period of time as they are needed for dialysis. The lack of publications showing any benefit of a 24 hr approach over a 72 hr one indirectly suggest there is no benefit, at least in this window, and even with weekend considerations virtually all declots can be scheduled within that window. This will remain a question to be answered by future studies, however.

Therefore, is it ever too early to declot a fistula? Yes, if truly not mature, and no if mature. Is it ever too late to declot a fistula? Yes, rarely. Most importantly, is there any downside to waiting up to 72 hr to declot a fistula? Probably not.

References

1. Grossman C, McPherson S. Safety and efficacy of catheter-direct thrombolysis for iliofemoral venous thrombosis. AJR Am J Roentgenol 1999; 172: 667-72.
2. Liang HL, Pan HB, Chung HM, et al. Restoration of thrombosed Brescia-Cimino dialysis fistulas by using percutaneous transluminal angioplasty. Radiology 2002; 223: 339-44.
3. Lipari G, Tessitore N, Poli A, et al. Outcomes of surgical revision of stenosed and thrombosed forearm arteriovenous fistulae for haemodialysis. Nephrol Dial Transplant 2007; 22: 2605-12.
4. Rajan DK, Clark TW, Simons ME, Kachura JR, Sniderman K. Procedural success and patency after percutaneous treatment of thrombosed autogenous arteriovenous dialysis fistulas. J Vasc Interv Radiol 2002; 13: 1211-8.
5. Schon D, Mishler R. Salvage of occluded autologous arteriovenous fistulae. Am J Kidney Dis 2000; 36: 804-10.
6. Shatsky JB, Berns JS, Clark TW, et al. Single-center experience with the Arrow-Trerotola Percutaneous Thrombectomy Device in the management of thrombosed native dialysis fistulas. J Vasc Interv Radiol 2005; 16:1605-11.
7. Turmel-Rodrigues L, Pengloan J, Rodrigue H, et al. Treatment of failed native arteriovenous fistulae for hemodialysis by interventional radiology. Kidney Int 2000; 57: 1124-40.
8. Turmel-Rodrigues L, Raynaud A, Louail B, Beyssen B, Sapoval M. Manual catheter-directed aspiration and other thrombectomy techniques for declotting native fistulas for hemodialysis. J Vasc Interv Radiol 2001; 12: 1365-71.
9. Turmel-Rodrigues LA. Declotting a thrombosed Brescia-Cimino fistula by manual catheter-directed aspiration of the thrombus. Cardiovasc Intervent Radiol 2005; 28: 10-6.
10. Zaleski GX, Funaki B, Kenney S, Lorenz JM, Garofalo R. Angioplasty and bolus urokinase infusion for the restoration of function in thrombosed Brescia-Cimino dialysis fistulas. J Vasc Interv Radiol 1999; 10: 129-36.

Symptomatic Chronic Central Vein Obstruction: PTA +/- Stenting Results

Sanjoy Kundu

Scarborough General Hospital, Scarborough, Ontario - Canada

Central venous stenoses in patients undergoing hemodialysis are considered to be due to high flow states in contrast to the normal low flow physiologic state and typically occur at sites of turbulence such as valves or acute kinks in the vessel (1, 2). Injury during or after insertion of a dialysis access catheter placed via a jugular or subclavian route has also been recognized as a risk factor for central venous obstruction with a reported prevalence as high as 40% (3, 4). The most common clinical presentation is symptomatic shunt dysfunction or upper extremity swelling.

Historically, central venous obstruction secondary to hemodialysis has been treated with percutaneous balloon angioplasty (PTA) (5). PTA usually provides excellent initial results, but the long-term primary patency is not optimal. One of the larger studies to date, demonstrated an initial success rate of 89%, followed by primary 6-month patency of only 25% (5). Another study of 26 patients, demonstrated a technical success rate of 96%, with primary patency rate of 70% at 3 months, 60% at 6 months, and 30% at 12 months (6). This has led to a number of studies assessing the efficacy of bare stent placement for central venous stenosis or occlusion. All the studies have demonstrated excellent technical results with mixed patency outcomes.

One of the larger bare stent studies utilizing the Wallstent™ performed by Haage et al (4) demonstrated 3-, 6-, 12-, and 24-month primary patency rates of 92%, 84%, 56%, and 28%, respectively. The cumulative overall stent patency was 97% after 6 and 12 months, 89% after

24 months and 81% after 36 and 48 months. A second large bare stent study utilizing the Wallstent™ performed by Vesely et al (7) demonstrated primary patency at 1-, 3, 6-, and 12-month primary patency of 90%, 67%, 42% and 25%. The primary assisted patency at 3, 6 and 12 months was 88%, 62% and 47% with a cumulative patency at 3, 6, 12, 24 months of 89%, 64%, 56% and 22%. The literature clearly demonstrates the moderate results with bare stent placement for central venous stenosis and obstruction requiring close clinical surveillance and multiple reinterventions to maintain patency. This has led to the placement of bare stents for central venous stenosis in the setting of suboptimal angioplasty or refractory stenosis.
In conclusion, PTA for central venous stenosis has had very good initial results, with poor primary patency. Bare metal stents have had moderate results for central venous stenosis and occlusion in hemodialysis patients with their use reserved for suboptimal angioplasty or refractory stenosis. Covered stents are a new treatment alternative for this difficult problem with little supporting evidence to date.

References

1. Glanz S, Gordon DH, Butt K, Hong J, Lipkowitz G. The role of percutaneous angioplasty in the management of chronic hemodialysis fistulas. Ann Surg 1987; 206: 777-81.
2. Schwab SJ, Quarles LD, Middleton JP, Cohan RH, Saeed M, Dennis VW. Hemodialysis-associated subclavian stenosis. Kidney Int 1988; 33: 1156-9.
3. Surrat R, Picus D, Hicks M, et al. The importance of preoperative evaluation of the subclavian vein in dialysis access planning. AJR Am J Roentgenol 1991; 156: 623-5.
4. Haage P, Vorwerk D, Werner P, Schuermann K, Guenther RW. Treatment of hemodialysis related central venous stenosis or occlusion: results of primary wallstent placement and follow-up in 50 patients. Radiology 1999; 212: 175-80.
5. Beathard G. Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. Kidney Int 1992; 42: 1390-7.
6. Buriankova E, Kocher M, Bachleda P, et al. Endovascular treatment of central central venous stenoses and/or occlusion in hemodialysis patients. Cardiovasc Intervent Radiol 2003; 26: 27-30.
7. Vesely TM, Hovsepian DM, Pilgram TK, Coyne DW, Shenoy S. Upper extremity central venous obstruction in hemodialysis patients: treatment with wallstents. Radiology 1997; 204: 343-8.

Stenting is a Good Solution that Buys Time

John Ross

Bamberg County Hospital, Bamberg, SC - USA

Arteriovenous (AV) fistulas or grafts are preferred accesses versus long-term catheters for hemodialysis. Many patients are dialyzing on long-term catheters either because of previous recurrent AV access thrombosis resulting in abandonment or, due to central venous stenosis preventing a fistula or graft from being successfully placed in the upper extremity.
Studies of stenting for treatment of central venous stenosis report conflicting results likely due to differing methodologies and patient comorbidities, resulting in a debate over treatment strategies (Tab. I) (1-5). All studies agree that endovascular therapy is safe with low rates of technical failure but likely require re-treatment to maintain patency. Although re-treatment can be costly and inconvenient, extending the life of an upper arm AV access is almost always a better option for the patient than abandoning the access or the contralateral side in favor of dialysis with a long-term catheter due to lower adequacy of dialysis and higher bacteremia rates.

TABLE I - STENT/VEIN PATENCY RESULTS IN TREATMENT OF UPPER EXTREMITY CENTRAL VENOUS STENOSIS

	Bakken et al (1)	Maya et al (2)	Chen et al (3)	Aytekin et al (4)	Rajan et al (5)
Number of patients	26	23	18	14	6
30-day					
Primary patency (%)	76	83		93	
Assisted primary patency (%)	84				
Secondary patency (%)					100
3-month					
Primary patency (%)	46	56	100	86	83
Assisted primary patency (%)	72			100	
Secondary patency (%)		87	100		100
6-month					
Primary patency (%)	38	33	89	50	67
Assisted primary patency (%)	55			89	
Secondary patency (%)		78	93		100
12-month					
Primary patency (%)	21	19	68	14	67
Assisted primary patency (%)	46			56	
Secondary patency (%)		64	85		100

*Shaded cells indicate unreported data

References

1. Bakken AM, Protack CD, Saad WE, Lee DE, Waldman DL, Davies MG. Long-term outcomes of primary angioplasty and primary stenting of central venous stenosis in hemodialysis patients. J Vasc Surg 2007; 45: 776-83.
2. Maya ID, Saddekni S, Allon M. Treatment of refractory central vein stenosis in hemodialysis patients with stents. Semin Dial 2007; 20: 78-82.
3. Chen CY, Liang HL, Pan HB, et al. Metallic stenting for treatment of central venous obstruction in hemodialysis patients. J Chin Med Assoc 2003; 66: 166-72.
4. Aytekin C, Boyvat F, Yagmurdur MC, Moray G, Haberal M. Endovascular stent placement in the treatment of upper extremity central venous obstruction in hemodialysis patients. Eur J Radiol 2004; 49: 81-5.
5. Rajan DK, Saluja JS. Use of nitinol stents following recanalization of central venous occlusions in hemodialysis patients. Cardiovasc Intervent Radiol 2007; 30: 662-7.

Central Vein Stenting is so Bad, it Should Rarely be Done

Michael Allon

University of Alabama at Birmingham, Birmingham, AL - USA

Central vein stenosis in dialysis patients is usually a complication of an indwelling central vein dialysis catheter (1). It may be asymptomatic and discovered incidentally during a fistulogram of a dysfunctional vascular access. The most common symptom in patients with central vein stenosis is unilateral upper

extremity edema ipsilateral to the stenosis. An asymptomatic stenosis may become symptomatic after creation of an ipsilateral vascular access (fistula or graft), which increases blood flow to that extremity.
The usual treatment of central vein stenosis is an angioplasty of the lesion. Unfortunately, the benefit of angioplasty is short-lived, and the stenosis recurs within a few months, manifesting with recurrent ipsilateral edema. Stenting has been proposed as an approach to improve outcomes after central vein angioplasty.
However, four series have reported on the dismal outcomes with central vein stents. The primary patency 1 year after stenting was only 14 to 25% (2-5). A retrospective study at one institution compared the outcomes of symptomatic central vein stenosis treated by stenting (n=23) vs. angioplasty alone (n=32) (4). The two patient groups were matched in terms of age, sex, race, and co-morbidities. The primary patency after the intervention was similar between the two groups (33 vs. 38% at 6 months, and 19 vs. 20% at 1 year). Moreover, 65% of the patients undergoing stent deployment subsequently developed irreversible occlusion of the central vein, which was invariably accompanied by permanent failure of the ipsilateral fistula or graft.
In summary, the added expense of the stent ($1,000 each) simply cannot be justified given the dismal clinical outcome, which is no better than that obtained with angioplasty alone. The optimal strategy in patients with symptomatic central vein stenosis is to perform repeated angioplasties with each recurrence, until this is no longer feasible.

References

1. Yevzlin AS, Asif A. Stent placement in hemodialysis access: historical lessons, the state of the art and future directions. Clin J Am Soc Nephrol 2009; 4: 996-1008.
2. Ayetkin C, Boyvat F, Yagmurdur MC, Moray G, Haberal M. Endovascular stent placement in the treatment of upper extremity central venous obstruction in hemodialysis patients. Eur J Radiol 2004; 49: 81-5.
3. Lumsden AB, MacDonald MJ, Isiklar H, et al. Central vein stenosis in the hemodialysis patient: incidence and efficacy of endovascular treatment. Cardiovasc Surg 1997; 5: 504-9.
4. Maya ID, Saddekni S, Allon M. Treatment of refractory central vein stenosis in hemodialysis patients with stents. Semin Dial 2007; 20: 78-82.
5. Vesely TM, Hovsepian DM, Pilgram TK, Coyne DW, Shenoy S. Upper extremity ventral venous obstruction in hemodialysis patients: treatment with Wallstents. Radiology 1997; 204: 343-8.

Covered Stents for Central Venous Obstruction

Sanjoy Kundu

Scarborough General Hospital, Scarborough, Ontario - Canada

Central venous stenoses in patients undergoing hemodialysis are considered to be due to high flow states in contrast to the normal low flow physiologic state and typically occur at sites of turbulence such as valves or acute kinks in the vessel (1, 2). Injury during or after insertion of a dialysis access catheter placed via a jugular or subclavian route has also been recognized as a risk factor for central venous obstruction with a reported prevalence as high as 40% (3, 4). The most common clinical presentation is symptomatic shunt dysfunction or upper extremity swelling. Historically, central venous obstruction secondary to hemodialysis has been treated with percutaneous balloon angioplasty with mixed technical outcome, primary patency, primary assisted and secondary assisted patency (5). This has led to a number of studies assessing the efficacy of bare stent placement for central venous stenosis or occlusion (6). All the studies have demonstrated excellent technical results with moderate results for bare stent placement for central venous stenosis and obstruction requiring close clinical surveillance and multiple reinterventions to maintain patency. This has led to the placement of bare stents for central venous stenosis in the setting of suboptimal angioplasty or refractory stenosis.

CS also known as peripheral endografts have been proposed as a new treatment option for CVD. The potential advantages of a CS would include providing a relatively inert and stable intravascular matrix for endothelialization while providing the mechanical advantages of a BMS. This could potentially reduce the intimal hyerplastic response, causing restenosis post PTA or BMS placement. CSs are available in balloon expandable or self-expanding platforms. In practical terms, a self-expanding platform would be preferred, given the rigidity of the balloon expandable platforms. There is minimal literature on CS usage in the hemodialysis access circuit. Most of the literature to date has been on the treatment of graft or outflow vein aneurysms and refractory venous outflow stenoses (7-10). CS's for CVD has only been mentioned in two publications to date. Sapoval et al. in 1996 mentioned the use of a nitinol plus dacron covered stent (Craig Endopro™, Mintec, LaCiotat, France) for a in-stent restenosis of a Wallstent™, with asymptomatic recurrent restenosis after 6 months (11). A study by Quinn et al. in 2003 placed six covered stents for CVD, and eleven covered stents for venous outflow stenoses. There was a combined primary patency at 2, 6, and 12 months of: 40%, 32%, and 32%; and secondary patency at 2, 6, and 12 month of: 70%, 55% and 39%. They utilized a Palmaz ™ stent (P308, Johnson and Johnson, Warren, NJ) with an ePTFE graft material manually sewn on (12). At our institution from 2004-2007 we have placed nine CSs in eight patients for CVD with central venous obstruction. All eight patients presented, with significant clinical symptoms. We placed ten or twelve millimeter Fluency™ (Bard Peripheral Vascular, Tempe, Arizona) CSs which have a nitinol skeleton, with ePTFE lining. There was a 100% clinical and technical success rate. We have a primary patency at 3, 6, and 9 months of 100%. CS's provide an interesting treatment alternative for CVD. However, further randomized controlled trials, with long term follow-up will be necessary. In conclusion bare stents have had moderate results for central venous stenosis and occlusion in hemodialysis patients with their use reserved for suboptimal angioplasty or refractory stenosis. Covered stents are a new treatment alternative for this difficult problem with little supporting evidence to date.

References

1. Glanz S, Gordon DH, Butt K, Hong J, Lipkowitz G. The role of percutaneous angioplasty in the management of chronic hemodialysis fistulas. Ann Surg 1987; 206: 777-81.
2. Schwab SJ, Quarles LD, Middleton JP, Cohan RH, Saeed M, Dennis VW. Hemodialysis associated subclavian stenosis. Kidney Int 1988; 33: 1156-9.
3. Surrat R, Picus D, Hicks M, et al. The importance of preoperative evaluation of the subclavian vein in dialysis access planning. AJR Am J Roentgenol 1991; 156: 623-5.
4. Haage P, Vorwerk D, Werner P, Schuermann K, Guenther RW. Treatment of hemodialysis related central venous stenosis or occlusion: results of primary wallstent placement and follow-up in 50 patients. Radiology 1999; 212: 175-80.
5. Beathard G. Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. Kidney Int 1992; 42: 1390- 7.
6. Vesely TM, Hovsepian DM, Pilgram TK, Coyne DW, Shenoy S. Upper extremity central venous obstruction in hemodialysis patients: treatment with wallstents. Radiology 1997; 204: 343-8.
7. Vesely TM. Use of stent grafts to repair hemodialysis graft-related pseudoanuerysms. JVIR 2005; 16: 1301-7.
8. Naoum JJ, Irwin C, Hunter GC, et al. The use of covered nitinol stents to salvage dialysis grafts after multiple failures. Vasc Endovasc Surg 2006; 40: 275-9.
9. Hausegger KA, Tiessenhausen K, Klimpfinger M, et al. Aneurysms of hemodialysis access grafts: treatment with covered stents: a report of three cases. Cardiovasc Intervent Radiol 1998; 21: 334-7.
10. Silas AM, Bettman MA. Utility of covered stents for revision of aging failing synthetic hemodialysis grafts: A report of three cases. Cardiovasc Intervent Radiol 2003; 26: 550-3.
11. Sapoval MR, Turmel-Rodrigues LA, Raynaud AC, et al. Cragg covered stents in hemodialysis access: initial and midterm results. J Vasc Interv Radiol 1996; 7: 335-42.
12. Quinn SF, Kim J, Sheley RC. Transluminally placed endovascular grafts for venous lesions in patients on hemodialysis. Cardiovasc Intervent Radiol 2003; 26: 365-9.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Percutaneous Techniques for Central Venous Occlusion

Dheeraj Rajan

University of Toronto, Toronto - Canada

Central venous stenosis and occlusions in a hemodialysis patient is a unique clinical problem that is thought to arise mainly from previous central venous catheter insertions, particularly from the subclavian vein approach (1, 2). Although most published literature discusses treatment efficacy of central venous occlusion, a majority of lesions are not complete occlusions.

In cases of venous occlusion, angioplasty alone has been shown to be very effective in reopening the vein if the occlusion can be crossed. The typical method for crossing an area of occlusion is to identify a focal beak-like area of narrowing prior to the occlusion and attempt to pass a wire (typically a hydrophilic guidewire) across the occlusion with the aid of a directional catheter. Once the occlusion is crossed, an exchange for a stiffer wire is usually required to facilitate the passage of a balloon catheter across the occlusion. Balloon size is typically 10-14 mm. Typically, a web-like constriction is visualized and prolonged inflation and/or high-pressure balloon catheters are required to overcome the occlusion. Serial dilation starting with a small balloon diameter and increasing the balloon diameter is recommended to exclude perforation between dilation steps. Recently, the availability of extremely high-inflation pressure balloons (Atlas, Bard, Covington, GA) has enabled complete effacement of the waist of the lesion at rated burst pressures in the 18-atm range.

For occlusions that cannot be crossed with traditional methods, an alternative percutaneous approach is sharp recanalization. This method often requires an upper extremity and femoral approach and imaging in two planes to ensure that the needle used is crossing the area of occlusion (3-5). After puncturing across the occlusion, a wire is advanced and snared from the other side allowing for secure traversal of the lesion and easier passage of balloons and stents as needed. Another alternative, although only described in case reports is the use of a radiofrequency guidewire to traverse or burn across the area of occlusion (6).

Only in cases of rupture, occlusion and technical failures to improve flow do we place a self-expanding stent. Self-expanding stents have the advantage of being crush resistant and return to their normal size. Use of balloon expandable stents have been associated with compression and spontaneous migration and should not be used (7, 8). Primary patency for endovascular interventions including angioplasty and or stenting range from 43-67% at 12 months (1, 5, 9). Covered stents are another unexplored option and patency has not yet been properly studied.

If all percutaneous attempts at reopening the occlusion fail, surgical venovenous bypasses may be an option although surgical bypasses do not appear to have improved patency (10). Percutaneous occlusion of the access in the ipsilateral upper extremity will resolve extremity swelling and pain and should be the last resort for symptomatic improvement.

References

1. Maskova J, Komarkova J, Kivanek J, Danes J, Slavikova M. Endovascular Treatment of central vein stenoses and/or occlusions in hemodialysis patients. Cardiovasc Intervent Radiol 2003; 26: 27-30.
2. Oderich GS, Treiman GS, Schneider P, Bhirangi K. Stent placement for treatment of central and peripheral venous obstruction: a long-term multi-institutional experience. J Vasc Surg 2000; 32: 760-9.
3. Farrell T, Lang EV, Barnhart W. Sharp recanalization of central venous occlusions. J Vasc Interv Radiol 1999; 10: 149-54.
4. Athreya S, Scott P, Annamalai G, Edwards R, Moss J, Robertson I. Sharp recanalization of central venous occlusions: a useful technique for haemodialysis line insertion. Br J Radiol 2009; 82: 105-8.
5. Rajan DK, Saluja JS. Use of nitinol stents following recanalization of central venous occlusions in hemodialysis patients. Cardiovasc Intervent Radiol 2007; 30: 662-7.
6. Baerlocher MO, Asch MR, Myers A. Successful recanalization of a longstanding complete left subclavian vein occlusion by radiofrequency perforation with use of a radiofrequency guide wire.

J Vasc Interv Radiol 2006; 17: 1703-6.
7. Bjarnason H, Hunter DW, Crain MR, Ferral H, Miltz-Miller SE, Wegryn SA. Collapse of a Palmaz stent in the subclavian vein. AJR Am J Roentgenol 1993; 160: 1123-4.
8. Gray RJ, Dolmatch BL, Horton KM, Romolo JL, Zarate AR. Migration of Palmaz stents following deployment for venous stenoses related to hemodialysis access. J Vasc Interv Radiol 1994; 5: 117-20.
9. Kim YC, Won JY, Choi SY, et al. Percutaneous treatment of central venous stenosis in hemodialysis patients: long-term outcomes. Cardiovasc Intervent Radiol 2009; 32: 271-8.
10. Bhatia DS, Money SR, Ochsner JL, et al. Comparison of surgical bypass and percutaneous balloon dilatation with primary stent placement in the treatment of central venous obstruction in the dialysis patient: one-year follow-up. Ann Vasc Surg 1996; 10: 452-5.

What Everybody Needs to Know about Catheter Flow Rates, Pump Settings, and Successful Dialysis

Maurizio Gallieni

Nephrology and Dialysis Unit, San Paolo Hospital, University of Milan, Milan - Italy

In their seminal paper of 1999, Schwab and Beathard (1) pointed out that the availability of central venous catheters (CVCs) allowed better treatment of patients without an arteriovenous dialysis access, but at the same time they showed that CVCs also carried with them new problems. Among them, dialysis adequacy is of paramount importance and highly debated, especially when considering the difference between the prescribed and delivered dialysis dose. Factors linking vascular access and catheters in particular to dialysis adequacy are blood flow rates, recirculation, and catheter tip position (2). Treatment time is the other important factor that should be taken into consideration for adjustments of the dialysis dose.

Blood flow rate

When compared with arteriovenous access, tunneled CVCs provide slightly reduced (5-6%) flow performances and dialysis doses (3). Patient related factors may also affect blood flow rates: an increase in blood viscosity due to a rise of hematocrit or plasma protein levels can reduce catheter flow. In addition, blood volume is also a significant factor as better blood flow rates are associated with a central venous pressure >5 mmHg and to a reduced number of intradialytic hypotensive episodes (4).

Although CVC dysfunction is usually defined as a blood flow <300 ml/min, this cutoff value has been recently questioned by Moist et al (5). These authors suggest that the definition of catheter dysfunction should be revised and that it should be expanded beyond blood flow rates, as mean blood flows <300 ml/min are not commonly associated with dialysis inadequacy.

Recirculation

Although cardiopulmonary recirculation is absent in patients with CVCs, in order to prevent blood recirculation during dialysis the outflow tip is usually 2 to 3 cm longer than the inflow tip. However, the lumens are frequently reversed because of inflow failure. Whereas recirculation with standard lumens of well-functioning catheters is negligible, reversal of lumens causes considerable recirculation. Twardowski et al (6) determined that blood recirculation with standard lumens of well-functioning catheters, reversed lumens of well-functioning catheters, and reversed lumens of inflow failure catheters were 2.1%, 13.6%, and 7.1%, respectively.

Catheter tip position

Catheter function, and therefore dialysis adequacy, can be influenced by the CVC tip position. KDOQI guidelines (7) report that long-term tunneled catheters should have their tips within the right atrium for optimal flow, while short-term catheter tips can be kept in the superior vena cava. The tip of the catheter rises several centimeters when the patient stands, due to the downward movement of the

diaphragm. This makes placing the catheter tip in the center of the atrium in the supine patient even more justifiable. Femoral catheters with a suitable length (24 to 31 cm), reaching the inferior vena cava, are more likely to deliver an adequate blood flow of 300 ml/min.

How to optimize dialysis efficiency

Lambie et al (8) demonstrated that the overall function of vascular access is the single most important determinant of variability in delivered dialysis dose. In patients with vascular access problems, including those unable to reach an adequate blood flow with a CVC, a longer dialysis session and/or the use of high-efficiency convective therapies, such as online hemodiafiltration, can improve removal of small and large-molecular weight solutes

References

1. Schwab SJ, Beathard G. The hemodialysis catheter conundrum: hate living with them, but can't live without them. Kidney Int 1999; 56: 1-17.
2. Mandolfo S, Galli F, Piazza V, Imbasciati E. Blood flow rate and dialysis adequacy in patients with permanent central venous catheters. J Vasc Access 2000; 1: 46-50.
3. Canaud B, Leray-Moragues H, Kerkeni N, Bosc JY, Martin K. Effective flow performances and dialysis doses delivered with permanent catheters: a 24-month comparative study of permanent catheters versus arterio-venous vascular accesses. Nephrol Dial Transplant 2002; 17: 1286-92.
4. Jean G, Chazot C, Vanel T, et al. Central venous catheter for HD: looking for optimal blood flow. Nephrol Dial Transplant 1997; 12: 1689-91.
5. Moist LM, Hemmelgarn BR, Lok CE. Relationship between blood flow in central venous catheters and hemodialysis adequacy. Clin J Am Soc Nephrol 2006; 1: 965-71.
6. Twardowski ZJ, Van Stone JC, Jones ME, Klusmeyer ME, Haynie JD. Blood recirculation in intravenous catheters for hemodialysis. J Am Soc Nephrol 1993; 3: 1978-81.
7. Clinical Practice Guidelines for Vascular Access. Am J Kidney Dis 2006; 48 (suppl): S176-247.
8. Lambie SH, Taal MW, Fluck RJ, McIntyre CW. Analysis of factors associated with variability in haemodialysis adequacy. Nephrol Dial Transplant 2004; 19: 406-12.

Fistula First has Resulted in an Increase in Catheter Use

Gerald Beathard

Lifeline Vascular Access, Vernon Hills, IL - USA

Although national data indicates that the utilization of catheters for hemodialysis has not increased with the advent of Fistula First, there are many local practices in which this is not the case. The exact reasons for this are not totally clear and are probably variable; however, the confluence of two well documented factors undoubtedly contributes to this adverse situation. These are 20-50% of incident patients do not present until the time when they need to start dialysis, very few of these start dialysis with a fistula (1), and (2) 20-60% of newly created fistulas fail to develop (4-6). Even in instances in which patients are seen well ahead of the time of their need for dialysis and fistulas are placed in a timely manner, a significant number may still be using catheters as long as 6 months after initiation of replacement therapy (6).

These factors create a situation of mandatory catheter based dialysis. When one considers what would be happening if synthetics grafts were placed in these patients instead of the practice currently being generated by an attempt to adhere to Fistula First goals, it becomes clearly apparent that the incidence of catheter use and the duration of their use would be significantly lower.

There are several levels at which the quality of medical care can be evaluated - global, national, regio-

nal and local. From the viewpoint of an individual patient or an individual practice, what is important is what is happening locally. In this sense it should be recognized that local interpretations of Fistula First have resulted in a decrease in the quality of medical care being provided to hemodialysis patients as catheter utilization has increased.

References

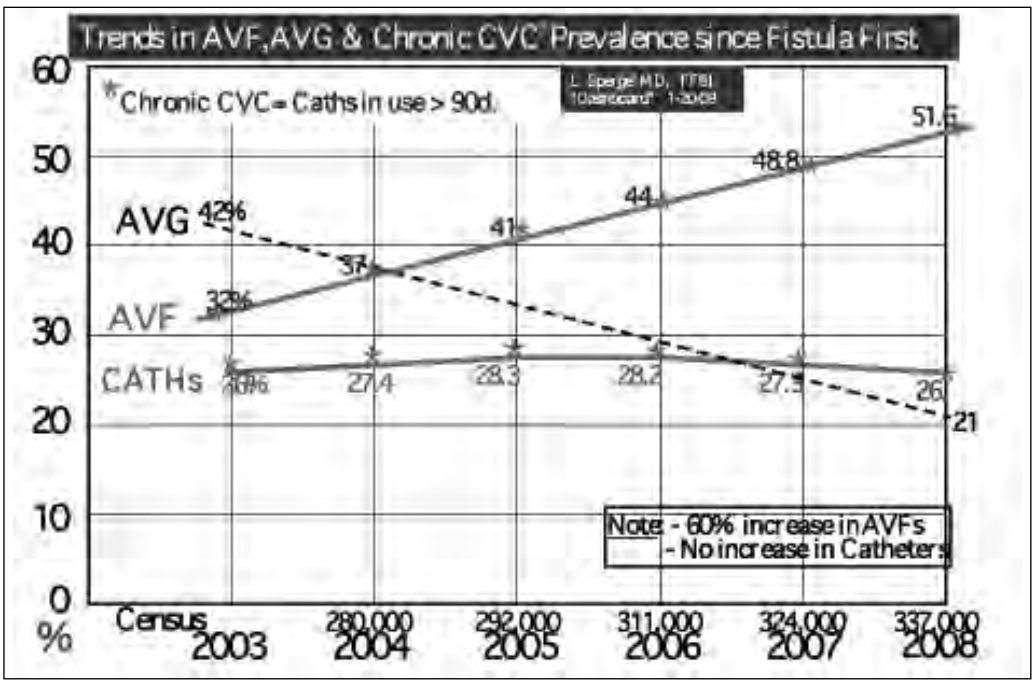
1. Friedman AL, Walworth C, Meehan C, et al. First hemodialysis access selection varies with patient acuity. Adv Ren Replace Ther 2000; 7 (suppl): S4-10.
2. Astor BC, Eustace JA, Powe NR, et al. Timing of nephrologist referral and arteriovenous access use: the CHOICE Study. Am J Kidney Dis 2001; 38: 494-501.
3. Besarab A, Adams M, Amatucci S, et al. Unraveling the realities of vascular access: the Network 11 experience. Adv Ren Replace Ther 2000; 7 (suppl): S65-70.
4. Ives CL, Akoh JA, George J, Vaughan-Huxley E, Lawson H. Pre-operative vessel mapping and early post-operative surveillance duplex scanning of arteriovenous fistulae. J Vasc Access 2009; 10: 37-42.
5. Dember LM, Beck GJ, Allon M, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. JAMA 2008; 299: 2164-71.
6. Weber CL, Djurdjev O, Levin A, Kiaii M. Outcomes of vascular access creation prior to dialysis: building the case for early referral. Asaio J 2009; 55: 355-60.

Catheters During the Fistula First Era: There's been no Increase - and I can prove it

Lawrence M. Spergel

Fistula First Breakthrough Initiative, Midlothian, VA - USA

The arteriovenous (AV) Fistula First Breakthrough Initiative (FFBI), known as "Fistula First" (FF), was launched at the end of 2003. The FFBI is sponsored by the Centers for Medicaid and Medicare Services (CMS) and consists of a broad coalition of the end-stage renal disease (ESRD) community and the 18 ESRD Networks, with the objective of ensuring that people receiving hemodialysis (HD) have the opportunity to have the optimal vascular access, which in most cases is the autogenous AV fistula (AVF). The goal is to achieve functional use of AVFs in 66% of prevalent patients - a conservative goal, considering the much higher prevalence achieved by many developed countries. Although the primary goal of FF is to increase AVF use, additional objectives were contained within the clinical "Change Package" to improve overall care for the HD patient - including reduction of central venous catheter (CVC) use. From December 2003 through to December 2008, the prevalence of functioning AVFs has increased from 32% to almost 52%, representing an increase of almost 63%. A data collection and reporting system was developed by the FFBI to track access types, and specifically to report AVF trending data on the FF website, fistulafirst.org. Catheter data is also tracked. A major area of concern, and one which the FFBI Coalition believed it could effectively impact, was the need to reduce CVC use and abuse. As a result, efforts were also initiated to review CVC-reduction strategies that have been successful, and to spread this information throughout the community. One of the expectations of the FF Work Group was that implementation of the FF "Change Package" would itself actually serve as a major long-term CVC-reduction strategy. Although expecting an initial *increase* in the short-term use of catheters in many patients as a bridge access to allow AVFs to mature, it was believed that the



increased use of AVFs would eventually lead to a *reduction* in long-term catheter use because of the lower complication and failure rate compared with the AV grafts (AVG) that were being replaced by AVFs. The FFBI catheter data shows that, as of early 2009, although there was a short period of minimal increase in CVCs early on, there has been no net increase in CVC prevalence in all categories (1) all CVCs in use for less than 90 days, (2) all CVCs in use greater than 90 days, and (3) "CVC's-only access" in use greater than 90 days (a subgroup of (2)). CVC use by category is currently (1) 6%; (2) 21%; and (3) 11.2%, respectively. Total CVC use (categories 1 plus 2) totaled 27.4% as of December 2003 and 27% as of December 2008. In addition, the CMS Clinical Performance Measures (CPM) data, reported in the United States Renal Data Survey (USRDS) Annual Data Report (ADR) closely correlates with the FF data - but lags behind the FF data by almost 2 years. Conclusion - the data provide conclusive evidence that there has been *no* increase in CVC use in both incident and prevalent patients since the AV Fistula First Breakthrough Initiative was launched.

Catheter Coatings and Lock Solutions – Are These Clinical Advances?

Michael Allon

University of Alabama at Birmingham, Birmingham, AL - USA

The two most common complications of tunneled dialysis catheters are thrombosis and infection. Thrombosis at the tip of the catheter lumen results in catheter dysfunction, manifesting with difficulty in aspiration of blood, low dialysis blood flows, or excessively negative arterial pressures (1). To prevent catheter thrombosis, an anticoagulant (heparin or citrate) is instilled into each catheter lumen after each dialysis session. When catheter thrombosis occurs, a thrombolytic agent (tissue plasminogen activator or urokinase) is instilled into the catheter lumens to restore patency. If the thrombolytic agent is unsuccessful, the catheter is exchanged for a new one over a guidewire. In addition, catheter thrombosis may predispose

to bacteremia by acting as a nidus for biofilm formation.

The clinical manifestations of catheter-related bacteremia may range from mild (isolated fever or chills) to life-threatening illness (metastatic infections, such as endocarditis, osteomyelitis, septic arthritis, or an epidural abscess) (2). The bacteremia is always treated with systemic antibiotics. Since the source of bacteremia is the biofilm lining the inner surface of the catheter, adjunctive treatment includes catheter removal with delayed placement of a new catheter, catheter exchange over a guidewire, or instillation of an antibiotic lock into the catheter lumens.

There is currently no food and drug administration (FDA) approved intervention for prevention of catheter-related bacteremia. However, instillation of an antimicrobial solution into the catheter lumens after each dialysis session may prevent bacteremia by inhibiting biofilm formation. A number of prophylactic antimicrobial catheter lock solutions have been investigated. These have included antibiotics, such as gentamicin, cephalosporins, or minocycline, as well as non-antibiotic antimicrobial agents, such as taurolidine, 30% citrate, or methylene blue. There have been seven randomized clinical trials published comparing antimicrobial lock solutions and standard heparin locks (3, 4). Five studies used an antibiotic lock, one used taurolidine, and one used 30% citrate. All seven studies observed a dramatically lower (by 50-100%) frequency of catheter-related bacteremia in the patients receiving an antimicrobial lock.

The safety of prophylactic antimicrobial lock solutions needs to be determined before widespread implementation of this approach. An aliquot of the lock solution invariably leaks into the systemic circulation, and may potentially result in toxicity. Therefore, for example, one study using a prophylactic gentamicin lock documented significant plasma gentamicin levels. A subset of patients developed symptoms compatible with vestibular toxicity (5). Likewise, several years ago the FDA withdrew 46% citrate from the market because a dialysis patient died following instillation of this solution through the catheter. In addition, the long-term use of prophylactic antibiotics may potentially select for antibiotic-resistant bacteria. This complication was not observed in the randomized studies, but patient follow-up was less than 6 months. A preliminary report observed the emergence of gentamicin-resistant bacteremia in dialysis patients within 8 months of initiating prophylactic gentamicin locks (6).

Catheter coating is another potential approach for preventing complications. Silver coating did not prevent bacteremia in a randomized study. Antibiotic coating has been shown to reduce bacteremia related to non-tunneled central vein catheters in the ICU, but has not been evaluated in dialysis catheters. Heparin coating reduces catheter thrombosis *in vitro*. Whether it also prevents thrombosis or bacteremia in patients with dialysis catheters remains to be determined.

References

1. Allon M. Current management of vascular access. Clin J Am Soc Nephrol 2007; 2: 786-800.
2. Allon M. Dialysis catheter-related bacteremia: treatment and prophylaxis. Am J Kidney Dis 2004; 44: 779-91.
3. Allon M. Prophylaxis against dialysis catheter-related bacteremia: a glimmer of hope. Am J Kidney Dis 2008; 51: 165-68.
4. Jaffer Y, Selby NM, Taal MW, Fluck RJ, McIntyre CW. A meta-analysis of hemodialysis catheter locking solutions in the prevention of catheter related infection. Am J Kidney Dis 2008; 51: 233-41.
5. Dogra GK, Herson H, Hutchison B, et al. Prevention of tunneled hemodialysis catheter-related infections using catheter-restricted filling with gentamicin and citrate: a randomized controlled study. J Am Soc Nephrol 2002; 13: 2133-9.
6. Sweet S, Gobeille S, Landry D, Haessler S, Vaidya C, Braden GL. Emergence of gentamicin-resistant bacteremia in hemodialysis patients receiving gentamicin lock catheter prophylaxis. Am J Kidney Dis 2009; 53: B74.

6th Annual Controversies in Dialysis Access - San Francisco, USA - November 12-13, 2009

Data-driven Tunneled Catheter Selection: Oxymoron?

Michael G. Tal

Yale University, New Haven, CT - USA

In this short presentation I will try to address the following questions:
Why is there such a lack of dialysis catheter peer review data?
Who should be funding the catheter performance clinical trials?
Let's start with a hypothetical clinical trial. This would be a pivotal trial that would once and for all settle the score on which is the best dialysis catheter. What are the potential problems with this trial? It would have to be a multicenter trial. A single-center trial often suffers from bias (1). The inherent problems of multicenter trials include multiple inserters with different skill levels. A handful of insertional complications or poor catheter placement might sway the results of the trial. A multicenter trial also carries a substantial cost. What would be the cost of a randomized controlled clinical trial? This hypothetical comprehensive trial would include about five different catheters types, with 100 patients in each group. One significant randomized clinical trial was performed and published in 2002 by Trerotolla et al (2). Trerotolla et al's trial included 132 patients that were followed for up to 6 months. All procedures were performed at a single center by fellowship trained interventional radiologists. In addition, it enrolled only patients with a "virgin" right internal jugular vein, meaning no history of previous chronic catheter placement. In a typical practice about 50% of catheter placements are patients that have had a catheter before. In addition, about 20% of all dialysis patient populations are catheter dependent (3). Therefore, this hypothetical pivotal clinical trial should include all comers, young and old, those with recently diagnosed renal failure as well as catheter dependent patients.
That hypothetical pivotal trial should look not only at the immediate outcome relating to the placement and replacement of catheters, but at long-term patient outcome. It should not concentrate on "catheter survival" (2, 4) but on patients' outcome and survival. It is not the dialysis catheters that are being studied but the patients. "Catheter survival" and "catheter salvage" are the real oxymoron. In this hypothetical pivotal clinical trial patients would be followed in the dialysis units for adequacy of dialysis and use of TPA. The length of individual sessions should be recorded. Number of interruptions to the dialysis procedure should be recorded. Patients would be followed for adequacy of dialysis and laboratory values. Information should be recorded in each and every dialysis treatment.
In addition, patients would be followed after the catheter has been removed for any differences in rate and time of maturation of the fistula or graft. Patients would be followed for rates of grafts vs. fistula and survival of such. They should also be followed for a minimum of 3 years for incidence of delayed central venous stenosis or occlusion that might be related to the type of catheter placed or its coating. This pivotal trial realistically would last over 3 years. Time from inception to publication would be about 5 years. Estimated cost would be about $7-8000 per patient which includes catheter placement, immediate and long-term follow-up and associated costs. The estimated cost of such a clinical trial would likely be about $5 million.
Who should fund this clinical trial? The obvious answer is industry. Medical device industry benefits from development and sales of dialysis catheters; and therefore, has the obligation to perform those trials. However industry's first obligation is to the stock holders. The second obligation is to the customers, us, the physicians and only third comes the patient. A business entity needs an incentive and a clear benefit if they are to perform and spend substantial dollars. Let's try to look at the funding question by industry more carefully. In the dialysis catheter market as in any market there are the market leaders as well as the newcomers, those that are trying to gain market share. What is the incentive of a market newcomer to perform this pivotal clinical trial? Newcomers do not have sufficient revenue to fund a clinical trial. The US chronic dialysis market is about $100 million dollars per year. In terms of medical devices, it is considered a small market, especially when compared to the coronary stent market or pacemakers which are several billions in yearly sales. For a newcomer to fund a clinical

trial it is much easier if his yearly revenue is based on market share of 5% from a $5 billion market than 5% from a $100 million market. In addition, the outcome of this trial is largely unknown. If the market newcomers invest that money in sales and marketing and maybe product development they will fare much better than sponsoring such a clinical trial. In addition, the long delay in the results of such a clinical trial will make the trial irrelevant.

The market leader also has more to lose than to gain from this clinical trial. Market leaders are content with the status quo. Even if the clinical trial proves that their catheter is better than the new competition, by the time the trial is complete and the results published, which could be up to 5 years, more newcomers will have arrived with new catheters that will claim to be even better. The market leaders cannot conduct a clinical trial evaluating every competing catheter on the market. This makes clinical trials unprofitable for both small and big players in the dialysis catheter market. So what is the solution?

Federal grants for outcome of end-stage renal disease (ESRD) patients and diabetes are the answer. NIDDK dollars are there waiting to be tapped. Numerous meaningless studies are being funded with government funds. Many funded clinical trials have minimal impact on dialysis patient lives. A pivotal randomized multicenter trial evaluating dialysis catheters is easy to conduct and the results will have an impact on patients' lives. Dialysis catheters are a life line for our patients and catheter-related complications, both immediate and delayed, are a problem too big to leave for industry to fund. Physicians and researchers can address this problem better and in an unbiased approach. We owe this to our patients.

References

1. Egger M, Smith GD. Meta-analysis: Bias in location and selection of studies. BMJ 1998; 316: 61-6.
2. Trerotola SO, Kraus M, Shah H, et al. Randomized comparison of split tip versus step tip high-flow hemodialysis catheters. Kidney Int 2002; 62: 282-9.
3. Lee T, Barker J, Allon M. Tunneled catheters in hemodialysis patients: reasons and subsequent outcomes. Am J Kidney Dis 2005; 46: 501-8.
4. Richard H, III, Hastings G, Boyd-Kranis R, et al. A randomized, prospective evaluation of the Tesio, Ash split, and Opti-flow hemodialysis catheters. J Vasc Interv Radiol 2001; 12: 431-5.

Put that Catheter Tip where?

Michael G. Tal

Yale University, New Haven, CT - USA

Debate regarding catheter tip position has been taking place since catheters were first introduced (1). In this presentation the complications associated with tip position being too low will be discussed, as well as complications related to tip position being too high.

Catheter complications are divided into three groups: infection, thrombosis and fibrin sheathing. These are complications presenting while the catheter is still in the patient. They can present clinically or as catheter dysfunction. Delayed complications are central venous stenosis and occlusion as well as perforation, either of the central veins or the heart. Catheter function is also an important component of dialysis catheters and is influenced by catheter position.

Side holes are thought to cause damage to the intima of the adjacent vessel (2). The damage might be caused by the high pressures generated by the dialysis machine trying to aspirate large volumes of blood. This is happening at the proximal side holes of the arterial lumen of the catheter, which are located most proximally. This intimal damage might cause subsequent thrombosis and vascular stenosis (2).

It seems that the more serious catheter complications such as right atrial thrombus or cardiac perforation and arrhythmias are related to tip position being too low, physically touching the posterior wall or floor of the right atrium. Due to this the food and drug administration (FDA) issued a statement recommending that the catheter tip should not be in the heart (1). On the contrary, tip position too high can

compromise catheter function, as well as enhance fibrin sheathing and possibly subsequent central venous stenosis. Therefore, many physicians prefer inserting the catheter tip into the right atrium (1). It seems that the catheter tip causes complications associated with low catheter placement and the most proximal side holes cause complications associated with the catheter being placed too high. So where should we place the catheter tip?

In this presentation, I propose a new concept; the concept of functional catheter length. Functional catheter length is the length from the most proximal aspect of the proximal side hole to the catheter tip. The most proximal side hole is usually placed in the arterial lumen. The functional length of the catheter is the length of the catheter that is relevant to its function. The functional catheter length is the length from the most proximal side hole, where the blood is being withdrawn into the dialyzer to the catheter tip, through which the blood is returned to the patient. Everything proximal to it is just tubing, and varies according to the patient's size and total catheter length. Therefore, tip position depends on the catheter type and functional length. The tip position should be as high as possible in the right atrium as long as the proximal side hole is at the RA/SVC junction. This catheter position minimizes contact between the catheter tip and the right atrial wall. The lack of turbulent flow and aspiration of blood through the side holes in the SVC minimizes intimal damage in the SVC and subsequent complications associated with intimal damage such as thrombosis, fibrin sheathing and stenosis.

The practical lesson is that the inserter should examine the dialysis catheter before it is inserted into the patient. The inserter should measure the functional length of that particular catheter and position it such that the proximal side hole is at the RA/SVC junction. For instance, catheters with a functional tip length of 3 cm, should be placed with the tip 3 cm below the RA/SVC junction. Catheters with a 5 cm functional tip length should be placed with the tip 5 cm below the RA/SVC junction. The proximal aspect of the proximal side holes determines catheter position, not the tip.

References

1. Vesely T. Central venous catheter tip position: a continuing controversy. J Vasc Interv Radiol 2003; 14: 527-4.
2. Twardowski ZJ, Moore HL. Side holes at the tip of chronic hemodialysis catheters are harmful. J Vasc Access 2001; 2: 8-16.

A Novel Vascular Access Device for Patients with Venous Obstruction

John Ross

Bamberg County Hospital, Bamberg, SC - USA

Central venous stenosis continues to be an obstacle to successful upper extremity hemodialysis access in many end-stage renal disease (ESRD) patients. These patients often become catheter-dependent and thus subject to poor dialysis adequacy, an increased number of interventions and lower patency rates vs. conventional grafts or fistulas. Furthermore, catheter-dependent patients are at a higher risk for bacteremia, resulting in increased morbidity, mortality and hospitalization costs (1, 2). Treatment options for central venous stenosis have included percutaneous transluminal angioplasty (PTA) and stenting, which offer mixed results.

Recently, the food and drug administration (FDA) cleared a new long-term subcutaneous vascular access device called HeRO™. The HeRO device is a 6 mm ePTFE graft which attaches via a titanium connector to the 5 mm outflow component, comprised of silicone with braided nitinol-reinforcement, designed to bypass central venous stenosis by routing blood flow to the right atrium via a major central vein. The HeRO device is cannulated in the same manner as a conventional graft.

HeRO was evaluated in two prospective, FDA multicenter studies of graft-eligible patients (the patency study) and catheter-dependent patients (the bacteremia study) to evaluate safety, patency and bacteremia rates; patients were followed for a minimum of 12 months. Data from these studies (Tab. I) demonstrate that the HeRO device provides patients with improved patency, adequacy of dialysis, and bacteremia rates versus long-term catheters (3).

TABLE I - RESULTS OF HERO FDA EVALUATIONS

	Patency Study	**Bacteremia Study**
No. patients	50	36
Mean age	62.9	62.7
Mean years on dialysis	Not captured	5.1
Mean previous accesses	3.9	5.4
Mean previous bacteremias	Not captured	1.8
Diabetic (%)	65.4	68.4
Mean follow-up (mos)	18.5	10.9
Accumulated follow-up days	22,724	9,931
Primary patency at 12 months (%)	36	33
Secondary patency at 12 months (%)	70	78
Intervention rate per year	2.2	2.5
Bacteremia rate per 1,000 days	0.13	0.70
Mean Kt/V	1.6	1.7

The HeRO device was also studied in 75 consecutive patients in a multicenter, post-market study designed to evaluate implant technique and implant success rates; patients were followed through hospital discharge. The demographics of enrolled patients were similar to the FDA studies except patients had an increased number of mean previous accesses (8.9) and mean previous bacteremias (3.4) indicating physicians were targeting a significantly accessed-challenged patient population for the HeRO technology. Although these patients presented with central venous stenosis and challenging vascular pathology, the HeRO device was successfully placed in all 75 patients using standard endovascular techniques. Seventy-two (72%) of outflow component insertions were in the internal jugular vein (IJV) while 28% were placed in other central venous vasculature, demonstrating that HeRO could still be successfully placed, despite stenosis of the IJVs.

The HeRO device offers a fully subcutaneous, upper-arm, long-term vascular access to catheter-dependent patients with improved clinical outcomes compared to catheters. The HeRO device should be considered when central venous stenosis emerges as an obstacle to successful upper extremity vascular access success, and should enter the access treatment algorithm before a thigh graft due to the significant decrease in bacteremia risk.

References

1. Ramanathan V, Chiu EJ, Thomas JT, Khan A, Dolson GM, Darouiche RO. Healthcare costs associated with hemodialysis catheter-related infections: a single-center experience. Infect Control Hosp Epidemiol 2007; 28: 606-9.
2. Pastan S, Soucie JM, McClellan WM. Vascular access and increased risk of death among hemodialysis patients. Kidney Int 2002; 62; 620-6.
3. Katzman HE, McLafferty RB, Ross JR, Glickman MH, Peden EK, Lawson JH. Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients. J Vasc Surg (in press).