Selected short papers from

The Seventh Annual Controversies in Dialysis Access

28-29 October 2010

The Westin St. Francis
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USA

Course Directors

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SoDA

SIMULATION OF DIALYSIS ACCESS (SoDA) HANDS-ON SIMULATOR TRAINING COURSE

The use of simulators for surgical training is gaining popularity. SoDA promises the first-ever intensive examination of how simulation training can advance the field of dialysis access management.

WEDNESDAY, OCTOBER 27

Session I: **Didactic Approach to Simulation** — Moderators: **Drs. Davidson, Dolmatch and Gallieni**

1:30 p.m.	Welcome to SoDA	**Dr. Davidson**
1:45 p.m.	Lessons from the Flight Deck	**Mr. Browne**
2:15 p.m.	Simulation in Healthcare	**Dr. Peden**
2:30 p.m.	Surgical Simulation	**Dr. Slakey**
2:45 p.m.	Central Vein Simulation Models for Catheter Placement	**Dr. Pittiruti**
3:00 p.m.	Simulation of Interventional Procedures	**Dr. Dolmatch**
3:15 p.m.	Refreshment Break	

Session II: **Hands-on Simulation of Dialysis Access** — Moderator: **Dr. Davidson**

3:30 - 5:30 p.m.		
	Simulation of Interventional Dialysis Access	**Dr. Dolmatch**
	Ultrasound Anatomy of Veins in Arm and Neck	**Dr. Pittiruti**
	Ultrasound-guided Cannulation of a Large-vessel by Home-made Simulator	**Dr. Biasucci**
	Ultrasound-guided Dialysis Access Cannulation by Home-made Simulator	**Ms. O'Rear**
5:30 p.m.	Panel Discussion and Questions from the Audience	
	Panelists: **Drs. Biasucci, Davidson, Dolmatch, Gallieni, Peden, Pittiruti and Slakey and Mr. Browne**	
5:45 p.m.	Adjourn	

THURSDAY, OCTOBER 28

Session I: Effective Dialysis Access — Moderator: **Dr. Davidson**

7:30 a.m.	Welcome and Introductory Polling	**Dr. Davidson**
7:40 a.m.	The Art of Controversy	**Drs. Davidson and Dolmatch**
	THE CONTROVERSIES in Initial Access	
7:50 a.m.	Peritoneal Dialysis (PD) First: We Should Insist that PD Be Considered First	**Dr. Work**
7:56 a.m.	Graft First: For Some Patients We Should Insist on Grafts First	**Dr. Allon**
8:02 a.m.	Fistula First: When Does the Fistula First Breakthrough Initiative (FFBI) Think that an AVF Should NOT Be Considered First?	**Dr. Spergel**
8:08 a.m.	Discussion: Achieving National Standards for "First" Permanent Access	Panelists: **Drs. Allon, Spergel and Work**
8:20 a.m.	How to Convert Good Imaging to Good Surgical Results - Bridging the Information Gap	**Dr. Labropoulos**
8:30 a.m.	60% AVF Immaturity (Dialysis Access Consortium) and 81% Catheter Initiation of Hemodialysis: Can FFBI Fix This?	**Dr. Spergel**
	The CONTROVERSIES in Who Should Create Arteriovenous Fistulae (AVF) and Where Is the Optimal Setting?	
8:40 a.m.	Surgeon: Why Surgeons Should Create AV Access in a Hospital-based Setting	**Dr. Ross**
8:46 a.m.	Nephrologist: How Nephrologists Can Safely Create AV Access in an Outpatient Center	**Dr. Mishler**
8:52 a.m.	Discussion: Availability, Safety and Suitable Training of Physicians for AV Access Placement	Panelists: **Drs. Mishler and Ross**
9:00 a.m.	The Center Effect: Speaking of the Unspoken Impact of Teamwork	**Dr. Davidson**
9:10 a.m.	CASE PRESENTATIONS: Will This AVF Mature?	Moderator: **Dr. Dolmatch**
		Panelists: **Drs. Allon, Falk, Labropoulos, Mishler, Ross and Spergel**
9:40 a.m.	Refreshment Break and Visit Exhibits	

Session II: AVF Immaturity — Moderator: **Dr. Falk**

	The CONTROVERSIES in AVF Immaturity: Whom Can We Blame?	
10:00 a.m.	Surgical Training Programs	**Dr. Henry**
10:06 a.m.	We Really Don't Know How to Use Pre-op Vascular Mapping to Further Reduce Immaturity Rates	**Dr. Labropoulos**
10:12 a.m.	Discussion: Let's Agree to Blame Bad Blood Vessels - They Won't Complain!	Panelists: **Drs. Glickman, Henry, Labropoulos, Roy-Chaudhury and Spergel**
10:20 a.m.	Some AVF Veins Dilate and Some Don't: Why?	**Dr. Roy-Chaudhury**
10:30 a.m.	The Balloon that Dilates the Vein that Doesn't Dilate: Balloon-assisted Maturation	**Dr. Miller**
10:40 a.m.	Accessory Veins: What Are They and When Do They Matter?	**Dr. Mishler**
	The CONTROVERSIES in Accessory Veins as a Cause of Immaturity - Fact or Fiction?	
10:50 a.m.	Fact: Accessory Veins Are a Real Cause of Immaturity	**Dr. Beathard**
10:56 a.m.	Fiction: There's No Proof that Accessory Veins Cause Immaturity	**Dr. Trerotola**
11:02 a.m.	Discussion: How Can We Tell If an Accessory Vein Really Causes Immaturity?	Panelists: **Drs. Beathard and Trerotola**
11:10 a.m.	Inflow Stenoses: Etiology and Treatment of Arterial and Juxta-anastomotic AVF Stenoses	**Dr. Falk**
11:20 a.m.	CASE PRESENTATIONS: Immature AV Fistulae - What Would the Experts Do?	Panelists: **Drs. Beathard, Falk, Labropoulos, Miller, Roy-Chaudhury, Saad and Trerotola**
12:00 noon	Lunch and Visit Exhibits	

Session III: Treatment of Mature AV Access Dysfunction — Moderators: **Drs. Dolmatch and Haskal**

1:00 p.m.	Access Patency Following Percutaneous Transluminal Angioplasty (PTA) of AV Circuit Venous Outflow Stenosis: Good Enough?	**Dr. Josephs**
1:10 p.m.	Bare Metal Stents in AV Access: Update on Patency Results and Implications for Use	**Dr. Dolmatch**
1:20 p.m.	Covered Stents for Access Intervention: From Here to Where?	**Dr. Haskal**
1:30 p.m.	Does the Infected Access Need to Be Removed?	**Dr. Davidson**
1:40 p.m.	CASE PRESENTATIONS: Treating Problems in Mature AV Access	Panelists: **Drs. Davidson, Haskal, Josephs, Mishler, Peden, Saad and Salman**

Session IV: Cardiovascular Disease in the ESRD Patient — Moderators: **Drs. Davidson and Warner**

2:30 p.m.	Incidence of Peripheral Arterial Disease (PAD) in Hemodialysis Patients	**Dr. Peden**
	The CONTROVERSIES in Who's Responsible for Vascular Disease Care in the Dialysis Patient?	
2:40 p.m.	The Patient's Clinical Nephrologist	**Dr. Allon**
2:46 p.m.	A Vascular Specialist	**Dr. Peden**
2:52 p.m.	Discussion: What Should We Do About the Greatest Risk for Our Dialysis Patients?	Panelists: **Drs. Allon, Peden and Warner**
3:00 p.m.	Refreshment Break and Visit Exhibits	
3:20 p.m.	Cardiac Function in the ESRD Patient	**Dr. Warner**
	The CONTROVERSIES in AVF Flow and Its Effect on the Heart	
3:30 p.m.	Good Flow in an AV Access Is Detrimental to the Heart in the ESRD Patient	**Dr. Crawford**
3:36 p.m.	Good Flow in an AV Access Is an Excellent Afterload Reducer and Helps Cardiac Function in ESRD Patients	**Dr. Warner**
3:42 p.m.	Discussion: Does a Good Fistula Provoke a Bad Heart?	Panelists: **Drs. Crawford and Warner**
3:50 p.m.	Chronic Rhythm Management Devices (CRMD) and Leads	**Dr. Salman**
	The CONTROVERSIES in Subclavian CRMD Leads and Stents	
4:00 p.m.	Don't Ever Stent Over that Lead!	**Dr. Salman**
4:06 p.m.	There Are Times to Stent Over that Lead!	**Dr. Saad**
4:12 p.m.	Discussion: How to Treat Lead-related Stenosis Now, and How to Avoid It in the Future	Panelists: **Drs. Saad and Salman**
4:20 p.m.	IT'S ACCESS ACADEMIC!	
	Surgery Team	Panelists: **Drs. Chemla, Slakey and Spergel**
	Nephrology Team	Panelists: **Drs. Allon, Beathard and Roy-Chaudhury**
	Interventional Radiology Team	Panelists: **Drs. Falk, Haskal and Trerotola**
5:00 p.m.	Adjourn	

FRIDAY, OCTOBER 29

Session V: Arteriovenous Grafts (AVGs) — Moderator: **Dr. Davidson**

7:30 a.m.	Welcome and Introductory Polling	**Dr. Davidson**
7:40 a.m.	The Achilles Heel, Toe, and Floor of AVGs: What Causes AVG Venous Anastomotic Stenosis?	**Dr. Roy-Chaudhury**
7:50 a.m.	What We've Learned from the Dialysis Access Consortium Regarding AVGs	**Dr. Allon**
8:00 a.m.	What Is Being Done to Improve AVG Primary and Cumulative Patency	**Dr. Glickman**
	The CONTROVERSIES in Percutaneous Transluminal Angioplasty Versus PTA/Stent Graft for AVG Venous Anastomotic Stenoses	
8:10 a.m.	PTA Unless a Covered Stent Is Needed	**Dr. Beathard**
8:16 a.m.	PTA with Covered Stent as Primary Treatment If Anatomy Permits	**Dr. Haskal**
8:22 a.m.	Discussion: Selection of Therapies for Maintaining AVG Patency	Panelists: **Drs. Beathard and Haskal**
8:30 a.m.	AVG Cannulation "Pseudoaneurysms": My Approach	**Dr. Ross**
	The CONTROVERSIES in the Treatment of AVG Cannulation Pseudoaneurysms	
8:40 a.m.	Covered Stents When Possible	**Dr. Vesely**
8:46 a.m.	Surgery Is the Gold Standard	**Dr. Henry**
8:52 a.m.	Discussion: What's the Role of Covered Stents in Repair of AVG Cannulation Breakdown?	Panelists: **Drs. Falk and Henry**
9:00 a.m.	CASE PRESENTATIONS: Strategies to Maintain AVG Function	Panelists: **Drs. Falk, Glickman, Henry, Miller, Ross and Vesely**
9:40 a.m.	**Refreshment Break and Visit Exhibits**	

Session VI: The Swollen Arm in AV Access — Moderators: **Drs. Beathard and Dolmatch**

10:00 a.m.	How Bad Is the Problem of Central Vein Obstruction in the Dialysis Population?	**Dr. Chemla**
10:10 a.m.	A National Strategy to Avoid Catheters	**Dr. Beathard**
	The CONTROVERSIES in When You See a Central Vein Occlusion on the Side of Intended AV Access Creation	
10:20 a.m.	Treat the Stenosis Before Surgery or Consider a Graft-catheter	**Dr. Miller**
10:26 a.m.	Place the AV Access and Worry About the Obstruction If It's a Problem	**Dr. Chemla**
10:32 a.m.	Discussion: Timing of Central Vein Intervention in Relationship to AV Access Creation	Panelists: **Drs. Chemla, Miller and Work**
10:40 a.m.	The Swollen Arm (Due to Central Venous Obstruction): What We Know and Don't Know	**Dr. Dolmatch**
10:50 a.m.	Percutaneous Techniques for Reconstruction of the Occluded Central Vein	**Dr. Josephs**
11:00 a.m.	Surgical Techniques for Central Vein Reconstruction	**Dr. Peden**
11:20 a.m.	CASE PRESENTATIONS: Treatment of Symptomatic Central Vein Obstruction	Panelists: **Drs. Chemla, Josephs, Peden and Trerotola**
12:00 noon	**Lunch and Visit Exhibits**	

Session VII: Clinics

1:10 p.m.	Issues in the Dialysis Unit	Moderator: **Mr. LaMendola** Panelists: **Drs. Allon, Beathard, Gallieni and Work**
1:10 p.m.	Percutaneous AV Access Techniques	Moderator: **Dr. Dolmatch** Panelists: **Drs. Falk, Haskal, Miller, Saad and Salman**
1:10 p.m.	Surgical AV Access Techniques	Moderator: **Dr. Davidson** Panelists: **Drs. Chemla, Glickman, Henry, Mishler, Ross and Slakey**
2:00 p.m.	**Refreshment Break and Visit Exhibits**	

Session VIII: Catheters for Hemodialysis — Moderators: **Drs. Davidson and Vesely**

2:20 p.m.	The Emperor's New Clothes: Are the Effects of Catheter Coatings and Surface Treatments Visible?	**Dr. Vesely**
	THE CONTROVERSIES in Catheter Coatings: Do Biologically Active Catheters Represent an Advance?	
2:30 p.m.	Yes	**Dr. Vesely**
2:36 p.m.	We're Still Not Sure	**Dr. Gallieni**
2:42 p.m.	Discussion: Time to Switch to a Coated Catheter? What Will Convince You?	Panelists: **Drs. Allon, Gallieni, Trerotola, Vesely and Work**
2:50 p.m.	National Standards for Suspected Catheter Infection and Catheter Revision	**Dr. Work**
3:00 p.m.	Is Heparin the Best Solution? Other Options for "Locking" Catheters	**Dr. Gallieni**
3:10 p.m.	A Hybrid Graft/Catheter Device: Are We Smarter Now that We've Used It for Two Years?	**Dr. Glickman**
3:20 p.m.	CASE PRESENTATIONS: Tips, Maneuvers and Complications of Central Venous Catheter Access	Panelists: **Drs. Gallieni, Glickman, Vesely and Work**
3:50 p.m.	Closing Remarks	**Drs. Davidson and Dolmatch**
4:00 p.m.	**Adjourn**	

7th Annual Controversies in Dialysis Access - San Francisco, USA - October 28-29, 2010

Controversies in Dialysis Access (CiDA) Simulation On Dialysis Access (SoDA)

The 7th Annual CiDA Meeting In San Francisco

Welcome back to San Francisco, the town that shakes up its people every 50-100 years or so. This is our 7th annual CiDA, Controversies In Dialysis Access. In fact, we are back a third time, as the CiDA meeting in 2006 and last year 2009 were also held here, in the same historic St Francis Hotel at Union Square.

What makes the CiDA meetings unique? First, we are not affiliated with a specific ESRD, dialysis or governing medical societies. In fact, all dialysis access interests are represented in the audience, among speakers 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. 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 Pro/Con sessions are aimed to expose and enlighten different viewpoints, the Art of Controversy. Special attention will be devoted to the perhaps most underutilized but powerful tool in the planning of dialysis access modality and hemo-access site. We are referring to duplex Doppler Sonography vascular mapping.
Two new exciting learning tools will appear at CiDA this year: First, we have expanded the meeting by dedicating one half day, Wednesday afternoon, to Simulation on Dialysis Access (SoDA), with equally divided time between lectures and hands on training using US guided peripheral and central vein cannulation as well as dialysis access cannulation with US guidance. An Interventional dialysis procedures computerized simulator has been designed and introduced at the SoDA Wednesday session.
Then, the Friday lunch breakout session will bring to life simulated surgical and interventional cases with a panel of critical expert opinions and the audience powerful polling opinions.

We are deeply grateful to our sponsors and exhibitors making your attendance more affordable. Please spend time and visit the exhibit hall and show our sponsors your appreciation. Several new dialysis access tools and devices will be exposed at the meeting.
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 highly professional, clear, crisp and timely delivery.

Finally, this meeting is unique because we are in San Francisco. Although we want you to be present at every meeting session, 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*

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7th Annual Controversies in Dialysis Access - San Francisco, USA - October 28-29, 2010

The Art of Controversy

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Controversies reflect our values, education, profession, nationality, upbringing, background, religion, to mention a few. (Tab. I). It is the very fabric of our lives and gives us meaning and something to discuss and talk about. Without divert opinions, life would be boring, a human experience so well captured by the ideal trouble-free easy life in the "Happy Valley" in Samuel Johnsons world classic book, first published in 1759 (1).

There are many quotes and sayings that infer to controversy. Margaret Thatcher said: **"Standing in the middle of the road is very dangerous; you get knocked down by the traffic from both sides"**. Likewise **"Caught in Crossfire"** refers to being attacked from many sides, although the subject may be innocent; which takes us to **"**...**being in the wrong place at the wrong time"** or, when we say **"We have come full circle,** meaning **"a 360 degree turnaround"** giving the false impression that we tried, but did not like 180 degrees paradigm, which would have implied a change of mindset. The 360 turn around could also mean that we are **"still confused but at a higher level".** The one quote perhaps used most implying controversy is: **"...being caught between a rock and a hard place".**

The Art of Controversy and its resolution travels through several stages ranging from disgust and hate to disagreements, on to negotiation steps from **"we see things different"-** to **consensus** - and finally **unanimous** agreement and to a comfort level where the "parties" will **agree to work together** (Fig. 1). The correct linguistic tools in talk negotiations, when stakes are high, are crucial, and takes a book to explore (2). It is the core beliefs of CiDA that we can and must discuss controversies and come to a consensus in order to be able to move on (Tab. II). There will always be new and undisclosed differences of opinion, which ensures another CiDA gathering in 2011.

CiDA (Controversies in Dialysis Access) was born in Lisbon in 2003 (3). The CiDA Logo (Fig. 2) has been created from the **talking concepts** displayed in Figure 1. (Tab. II) SoDA, an offspring of CiDA was conceived in Rome 2009 and will be delivered multiple times, first in San Francisco on August 27, 2010.

Controversy is good and healthy. The ESRD patient population is a moving target. New territories are explored. There is a melting pot, a common ground. Emotions carry across generations (4). The humans made it over the Neanderthals, despite their bigger brains, because we developed social and cultural interchange, and traveled for trading, and learned from each other's inventions and ideas. That is collective intelligence (5, 6). That's why CiDA keeps prospering. Let the exchange begin!

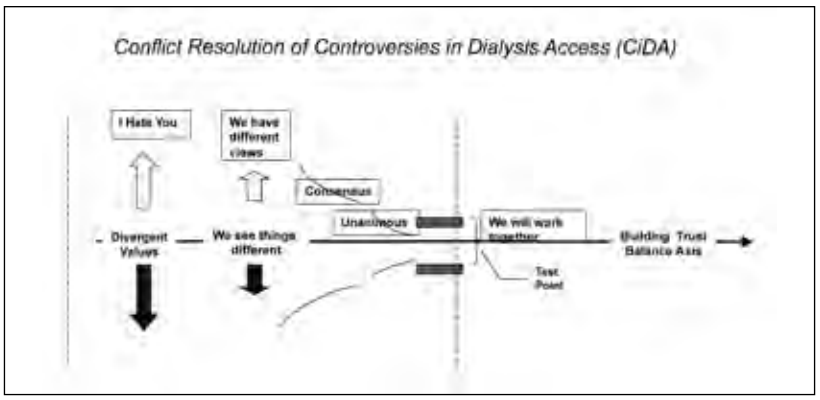

Fig. 1 - *Although our differences sometimes may seem insurmountable, negotiations through constructed facilitated "talking", must lead to unanimous agreement, a stage where we agree to work effectively together for the common good.*

Fig. 2 - *The CiDA logo was inspired and designed from the talking concept thinking displayed in Figure 1.*

TABLE I - EXAMPLES OF LIFE'S NORMAL RANGE (CONTROVERSIES) AND EXTREMES (WITHIN BRACKETS)

- Cold vs. warm (Range: -270 °C to the glowing volcano)
- Hierarchy vs. Flat Organizations (Communism to free floating "Hippy" democracy)
- Novice vs. Mature (Beginner to Master)
- Love vs. Hate (Mother Theresa to Terrorism)
- Greetings (From "Hi" to Rape)
- Wind speed (Calm to Tornado)
- Win vs. Lose (Alive to Dead)
- Obstruction vs. Cooperation (War vs. Synergy)

TABLE II - EXAMPLES OF CONTROVERSIES IN DIALYSIS ACCESS

- Grafts vs. AVF vs. PD
- IR vs. Surgery vs. Interventional Nephrology
- Balloon vs. Stenting vs. Surgery
- Transplant vs. Dialysis
- One vs. two stage Vein Transposition
- FFBI vs. ISPD
- VAS vs. VASA vs. ASDIN
- US vs. EU

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PD First: We should insist that PD be considered first

Jack Work

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HAMLET ACT 3 SCENE 1: *To be, or not to be, that is the question:* Whether 'tis nobler in the mind to suffer The slings and arrows of outrageous fortune, Or to take arms against a sea of troubles And by opposing end them.

"To PD or not to PD, that is the question:" Whether 'tis nobler in the mind to suffer The first 90 days with a hemodialysis catheter, Or to take arms against a sea of convention And by opposing them choose PD.

John Burkart posited this question in an editorial in Seminars in Dialysis (1). He noted that unfortunately in the US with less than 10% prevalent patients on peritoneal dialysis, the answer has been "not to PD." He goes on to point out that a randomized trial comparing similar patients on either peritoneal dialysis or hemodialysis would best address the question of whether or not the low prevalence of PD in the US is justified based on medical outcome.

Most observational studies support peritoneal dialysis as having an initial survival advantage over hemodialysis (2-4). In a Netherlands observational study, all patients on ESRD were included starting from the first day of treatment unlike USRDS data which starts on day 91. This study found that although the survival advantage of peritoneal dialysis changes over time, similar to USRDS data, this survival advantage over hemodialysis persists for one and half years (4). Several factors may contribute to the initial survival advantage of peritoneal dialysis over hemodialysis. One factor in the early high mortality on hemodialysis is the frequent initial use of central venous catheters for hemodialysis access. A study, which examined mortality during the first 90 days of dialysis replacement therapy, found that 21.9% of the patients with a hemodialysis catheter died versus 6.4% of patients with a peritoneal dialysis catheter. (5) Another factor is the better preservation of residual kidney function with peritoneal dialysis. Residual kidney function has been strongly correlated with survival in dialysis patients (6,7).

There are multiple other factors favoring a peritoneal dialysis first approach to ESRD. Patients, who receive a renal transplant while on peritoneal dialysis, have both better short-term and long-term outcomes compared to patients who are on hemodialysis prior to the transplant (8,9). Peritoneal dialysis is associated with better quality of life or patient satisfaction (10). Patients are more easily able to continue to work on peritoneal dialysis compared to in-center hemodialysis. The cost of peritoneal dialysis is substantiality less compared to in-center hemodialysis. Peritoneal dialysis catheter- the GOOD Catheter- costs per person per year are significantly less compared to patients with other access types including working fistulas. In addition, per person per year access event costs, by access type, are significantly less for the GOOD catheter (USRDS 2009 data).

Although a randomized controlled trial would be optimal in resolving the questions regarding a comparison of peritoneal dialysis with hemodialysis, it is unlikely such a study will be completed. Indeed, Korevaar and associates attempted to perform a randomized study comparing peritoneal dialysis with hemodialysis. The study was discontinued because after receiving full informed consent, only 38 patients agreed to be randomized. Importantly, of the 735 patients eligible for the study, 95% did not want to be randomized but wanted to make an informed choice of modality. Fifty two percent chose hemodialysis and 48% chose peritoneal dialysis (11). Perhaps PD First would accomplish the same if all patients were given a fully informed choice.

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Graft First: For Some Patients We Should Insist on Grafts First

Michael Allon

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Ten years ago only 24% of U.S. hemodialysis patients were using fistulas, as compared with 80% of European hemodialysis patients (1). This huge disparity resulted in the Fistula First Initiative to promote increased fistula use (http://www.fistulafirst.org). The initiative has been hugely successful in achieving its primary goal. Thus, over the past 10 years, fistula use has increased dramatically from 24 to 55%, whereas graft use decreased from 58 to 21%. However, an unanticipated effect has been the concurrent increase in catheter use from 17 to 24%. Prolonged catheter dependence is associated with frequent episodes of catheter-related bacteremia, as well as central vein stenosis.

A major obstacle to increasing fistula use is the high proportion of new fistulas that fail to mature adequately to be cannulated successfully for dialysis. The frequency of fistula non-maturation has increased substantially, and is currently observed in 30-50% of new fistulas, and was as high as 60% in the recent Dialysis Access Consortium (DAC) study (2, 3). Several clinical factors have been associated with an increased likelihood of fistula non-maturation, including female sex, older age, vascular morbidity, and forearm location. Preoperative vascular mapping, by identifying suitable vessels for fistula creation, clearly increases *fistula placement*. Unfortunately, *fistula non-maturation* persists despite preoperative mapping, particular in women, older patients, and forearm fistulas (4).

Why are fistulas superior to grafts? The first major justification is that fistulas have better cumulative survival than grafts. This is true when one analyzes only those accesses that are successfully used for dialysis. However, grafts have a much lower primary failure rate than fistulas. Thus, when one includes all patients (including those with primary failures), long-term survival is similar for fistulas and grafts (2, 5). In fact, graft survival is better than that of fistulas for the first 1.5 years. This consideration is particularly relevant for older patients, whose expected survival is only 1-2 years (6).

A second justification for fistulas is that they require fewer interventions than grafts to *maintain* their long-term patency for dialysis (2). However, fistulas require more interventions than grafts to *achieve* maturation. In fact, immature fistulas that require $\geq$2 interventions to achieve maturation have a shorter survival and require more interventions after maturation, as compared to fistulas not requiring interventions for maturation (7).

A mature fistula is better than a graft, but an immature fistula with prolonged catheter dependence is worse than a working graft. The optimal vascular access type in a given patient depends on the (1) likelihood of fistula non-maturation, (2) likelihood of catheter-related bacteremia and central vein stenosis; and (3) expected patient survival. A young pre-dialysis patient with low vascular comorbidity is the ideal candidate for a fistula. On the other hand, an older patient with vascular comorbidity and a short life expectancy, who is already dialyzing with a catheter, may be better served by receiving a graft.

We should recognize that the Fistula First guidelines are largely opinion-based, and are not based on randomized clinical trials comparing fistulas to grafts. Until such studies are performed, the selection of vascular access type should be based on the clinical judgment of the nephrologist and surgeon. This means that a subset of patients will appropriately receive a graft rather than a fistula.

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Fistula First: When Does the FFBI Think that an AVF Should NOT be Considered First?

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It has been well established that the autogenous arteriovenous fistula (AVF) is superior to other access types in all categories: patency, complications, interventions required, mortality and costs. Further, the need for an AVF initiative in the US was underscored 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 US. "Fistula First", a moniker for the A-V Fistula First Breakthrough Initiative (FFBI), was established as a coalition of ESRD Stakeholders whose objective is that all incident and prevalent hemodialysis patients have the opportunity to be evaluated and considered for an AVF first, utilizing best practices, including vessel mapping. This objective follows the recommendations of the NKF-KDOQI Clinical Work Group. Although some erroneously believe that the FFBI objective is to have an AVF in everyone receiving HD, in fact the goal set by the FFBI Work Group was to have at least 66% of prevalent HD patients dialyzing by a well-functioning AVF. A 66% goal is conservative based on the experience in other developed countries as well as many centers in the U.S. The fact that the FFBI goal is 66% AVFs and not higher is based on the recognition by the FFBI Clinical Work Group, that not all ESRD patients are suitable candidates for an AVF. Patient selection is the key to providing each patient with the optimal renal replacement therapy as well as the optimal hemodialysis access when HD is chosen. With older and sicker patients starting hemodialysis, patient selection becomes even more important, albeit much more challenging. There are a number of clinical scenarios where an AVF may not be the optimal access option, and where peritoneal dialysis, an arterio-venous graft (AVG), or even a central venous catheter (CVC), might be a better option. Examples of such scenarios with alternate or preferential options to an AVF, are shown in Table I. Finally, it should be noted that a fairly new access device called the Hero Device, which combines a PTFE graft for cannulation connected internally to a catheter segment for outflow, may be an ideal option to a CVC, and possibly an arterio-venous graft (AVG), as it appears to have the benefits of an AVG without the high infection rate associated with CVCs.

TABLE I

Fistula First

Not everyone is a candidate for an AVF

Patient Selection is critical!!

Clinical Condition	AVF Alternatives
1. Poor Overall Prognosis	1. AVG or CVC
2. Poor/exhausted vasculature	2. PD or AVG
3. Low ejection fraction/low BP	3. PD or CVC
4. No suitable upper extremity superficial veins & questionable transposition veins	4. Initial forearm AVG/ later AVF conversion when AVG fails
5. No suitable forearm veins, arm veins suitable	5. Can consider forearm AVG to mature arm veins vs. arm AVF **only** if surgeon included in ongoing mgt s/p AVG

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How to Convert Good Imaging to Good Surgical Results - Bridging the Information Gap

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Creation of hemodialysis access requires good planing with imaging being an important part of this process. Physical examination and duplex ultrasound (DU) alone or in combination are the two main ways for evaluating the blood vessels. The former can determine the integrity of the arteries such as feeling a good pulse or the status of the palmar arch but it cannot give details for the diameter of the vessels, the presence of calcification and cannot determine the optimal site for the anastomosis. The performance of the physical exam is often not sufficient to evaluate the veins as it cannot assess proximal vein obstruction, identify areas with wall thickening, stenosis and thrombosis in the cephalic and basilic veins nor it can depict the variant anatomy. Therefore, it is becoming more clear that DU is a significant component for the creation of the dialysis access.

This method is optimal for evaluating extremity vessels (1,2). It has allowed for increased utilization of veins and may also decrease the early access failure (3-5). Despite of improvements in imaging creation of dialysis access has been hampered with variable maturation rates. In order to obtain optimal results all previous interventions, thrombotic episodes and central catheterizations are noted. This is very imortant as it will help to identify pathology or changes in the normal anatomy of the vessels. The imaging involves assessment of the arteries and the veins with high resolution linear array transducers. The patient is placed in the supine or sitting position with the arm extended on the side of the bed or on a table. The examination starts from the nondominant upper extremity where the access is created first. Then the contralateral extremity is imaged next. If there are no options in the upper extremity for creating an access then the lower extremities are assessed.

The brachial, radial and ulnar arteries are imaged and measurements of their diameters are obtained. If there is a triphasic waveforf in the brachial artery then there is no need to image the proximal arteries. Wall and luminal pathology such as thickening, calcification, focal dilatation, aneurysms, stenosis and thrombosis are noted in detail. Anatomic variations such as superficial course of the brachial artery, hyoplasia and aplasia or high origin of the ulnar and the radial arteries and status of the palmar arch are noted.

The veins are imaged in supine or sitting position with the upper limb resting on a table. Tourniquets may be used when the diameter of the veins is smaller than 3 mm. The sitting position is superior to supine as the veins dilate more. Optimal imaging is achieved when the extremity is heated with warm towels or beter with warm water immersion (6). With this technique the maximal vein diameter is obtained. The cephalic and basilic veins are imaged throughout their length. Major tributaries of these veins that can also be utilized for dialysis access are mapped and reported. Focal changes in routine vein mapping are often missed.

Special attention should be given in these veins as previous puncture may have cause local wall changes that may impact the maturation of the fistula. The central veins (axillary, subclavian and brachiocephalic) should be image routinely even in the absence of swelling as previous catheterizations may have causes

stenosis or thrombosis. With experienced use central veins can be imaged adequately with DU (7). When imaging of these veins is not optimal with DU then a venogram should be performed.
It is very important to have a common language and a great communication between the diagnostician and the specialist who performs the surgery. Only in this way the imaging will result in the best possible plan for creating a dialysis access and give the opportunity to maximize the use of the veins.

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60% AVF Immaturity (DAC) and 81% Catheter Initiation of HD. Can FFBI Fix This?

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The incidence of arterio-venous fistulas that fail to mature is reported to be from less than 20% to 60% (1-5). Based on the information and guidelines provided by the A-V Fistula First Breakthrough Initiative (FFBI) (1) and the National Kidney Foundation/Kidney Diseases Outcomes Quality Initiative (NKF-KDOQI) (2), the definition of an arteriovenous fistula (AVF) that fails to mature is one that does not permit routine, event-free, 2-needle dialysis with the prescribed needle gauge and at the prescribed machine blood flow rate (BFR) by 3 months. If a new AVF does not display evidence of progressing maturation by 4-6 weeks, or exhibits evidence of maturation but fails to meet the 3-month requirement of event-free, 2-needle dialysis, immediate investigation and remedial intervention are required to avoid prolonged central venous catheter use (1,2). The findings of the DAC Fistula Study as well as recent reports in the literature suggest that failure of fistula non- maturation is now the main obstacle to successful fistula use (5-7). The etiology of fistula non-maturation is multi-factorial, which explains why there is such wide variation in the incidence of this complication. Major factors affecting maturation are discussed.
For the most part, they are centered around patient and vessel selection. They include: failure to adequately assess the vessels for suitability, including proper vessel mapping; vessels with unidentifiable disease related to prior trauma or co-morbid conditions; the use of marginal vessels in an attempt to increase AVF prevalence; wide variation in surgeon skill and experience / technical errors at surgery; inadequate inflow due to local lesion(s) or low ejection fraction; clinic staff inexperienced in early AVF cannulation. Low flow is a common cause for early failure, although it is often overlooked when an anatomic cause is not found, with resulting delays in intervention, thrombosis and the prolonged use of catheters. Once an AVF is identified as not having adequately matured, and depending on the etiology, surgical or endovascular intervention are usually indicated, both of which have produced excellent remedial outcomes. The FFBI has developed educational material on this problem as well as guidelines and recommendations. Since there will be a proportion of AVFs that fail to mature for unknown or unidentified reasons, it is critical to have a monitoring (and possibly surveillance) program in place to identify and problems early, since this will both avoid prolonged use of a CVC as well as increase the likelihood of successful intervention. One of the

most important recommendations made by the FFBI on this problem is a mandatory exam of the new AVF at each dialysis session plus an assessment specifically for maturation at 4 weeks (1). If maturation is not progressing at this time, the patient is referred for investigation and treatment, as indicated. This practice is extremely important, since the success rate for salvage procedures is considerably higher if the dysfunctional AVF is still patent. This 4-week interval is based on reports and opinions that the majority if not all of the causes of AVF dysfunction are readily identifiable by this time, most on physical exam alone (1,2,10). In addition, it is reported that the majority of AVFs reach maximum flow by 4 weeks (2,9,11). Patient and vessel selection are critical in reducing the incidence of non-maturity, especially in the elderly with multiple co-morbidities. Assessment and investigation of the cause of non-maturity must be based on vessels utilized, the site chosen, type of AVF construction, systemic factors and surgeon and staff experience.
The ongoing problem of approximately 80% of incident hemodialysis (HD) patients initiating HD with a catheter is again a multi-factorial, challenging one that not only adversely impacts the patient's chance of receiving the optimal permanent access in a timely manner, but significantly increases the risk of morbidity and mortality. Three major categories of barriers to placement of permanent access, especially an AVF, are: re-imbursement issues; delay in treatment due to delays in patient contact with a physician and renal specialist; delay in referral by the practitioner, for permanent access placement. Strategies developed by the FFBI that address these issues will are discussed.

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Why Surgeons Should Create AV Access in a Hospital Based Setting

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The decision making process for selection of the appropriate setting for access creation is dependent upon the consideration of the following variables:

- Type of access
- Body habitus of patient
- Hemodynamics of patient (cardiac status, HR, BP)
- Prior access history

- Comorbid patient factors (sleep apnea, coagulopathy)
- Anesthesia requirement
- Anxiety level of patient
- Possibility of urgent post procedure hemodialysis
- Volume of surgical accesses per day

The venue of access placement depends on the aforementioned variables. Certain access choices, Category I procedures, lend themselves to local and conscious sedation. Caveats to Category I selection in a nonhospital based setting are BMI, comorbity, and anxiety exhibited by the patient.
Risk factors may dictate classification of procedures as Category II or III procedures. Category II and III procedures may well be better performed in a hospital setting. The services provided in a hospital based setting may outpace the availability in a free standing setting.
The complexity of the planned access creation impacts classification. A combination of endovascular and open surgical intervention may be somewhat difficult in a nonhospital based setting. Complex access creations rate a minimal of a Category II classification.
The experienced access surgeon or "nephro-surgeon" can easily accommodate patients who are candidates for Category I procedures in a non hospital based facility. However, the added complexity of comorbid risk factors and/or procedures may well dictate the appropriate venue as a hospital based facility.

How Nephrologists Can Safely Create Arterial-Venous Access in an Outpatient Center

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At the 2009 Controversies in Dialysis Access (CiDA) meeting, Dr. Lawrence Spergel reported the Fistula First results as of December 2008. In the United States, 51.6% of prevalent dialysis patients had arteriovenous fistulae (AVF) in use as their vascular access. 21% were using an arteriovenous graft (AVG) and 26% had central venous catheters (CVC). This represented an over all 63% increase in avf since December 2003. The goal for 2009 was to achieve functional use of AVF in 66% of prevalent dialysis patients (1).
The following data is from two dialysis units in northwest Arizona and represents access data that was reported to ESRD Network 15. Hemodialysis unit (HDU) A has had a population between123-141 patients from March of 2008 through January 2010. In March 2008, 56.9% of patients were dialyzing with AVF, 16.2% with avg and 26.9% with CVC. In January 2010**,** 72.1% of patients were using functional AVF**,** 11.8% were using AVG and 16.2% had CVC as their vascular access.
As of July 2010, the 124 vascular accesses in HDU A were distributed as follows: 93 AVF were present and represented 75% of all accesses. 54 of these (58% of AVF) were created by Arizona Kidney Disease and Hypertension Center (AKDHC) interventional nephrologists (IN). 39 of the AVF (42% of AVF) were placed by physicians out side of AKDHC, 14 patients (11%) were using AVG and 17 patients (14%) were using CVC.
HDU B has had a population of 30-39 patients from October 2008 through March 2010 In March 2008, 54.1% of patients were using AVF for dialysis, 24.3% were using avg and 21.6% were using CVC. In March 2010 the unit had 79.5% functional AVF, 12.8% avg and 7.7% CVC.
As of May 2010, the 36 vascular accesses in HDU B were represented as follows: 28 AVF were present and represented 78% of all accesses. 13 of these (46% of all AVF) were placed by AKDHC IN. 15 of these (54% of AVF) were placed by other physicians. 5 patients were using AVG (14%) and 3 patients were using CVC (8%).

The combined data for HDU A and B are as follows:
- N=160
- AKDHC IN placed AVF: 67 (56% of AVF)

- Other placed AVF: 54 (44% of avf)
- Total AVF: 121 (76% of total vascular accesses)
- AVG: 19 (12%)
- TDC: 20 (12%)

The AVF in use in prevalent patients in these HDUs far exceeds the Fistula First goal of 66%. How was this possible in 18-24 months? The over arching principle is that a system is in place with in the AKDHC practice and dialysis units to promote the placement of avf and the removal of CVC on a timely fashion. A significant piece of this system is to remove barriers to surveillance and intervention. This approach has proven quite successful for endovascular management of vascular access problems and was expanded to include vascular access surgery (2). AKDHC IN have been creating AVF since September 2004 in the Phoenix, AZ and since October 2008 in Bullhead City, AZ. Training of primary operator for AKDHC is described as follows.
The physician is a US trained nephrologist with 12 years of interventional experience. Starting in 2004 the IN was trained in AVF creation by a US vascular surgeon who is active in vascular access creation and management. The IN scrubbed 70 cases with the surgeon and then completed 25 cases as primary (solo) operator supervised by the training surgeon in order to fulfill medical malpractice requirements for coverage. This training was accomplished in a free stranding ambulatory surgery center (ASC) that provides comprehensive vascular access care. Subsequently, additional training was obtained onsite on 3 occasions with a German nephrologist who has performed more than 5000 vascular access procedures during his career.
Initial outcomes of this IN physician's work were recently published (3). A summary of complications are as follows: 117 consecutive AVF creations in 116 patients as solo operator from September 2004-September 2005 were reported. Complications were few. Four brachial artery AVF caused steal syndrome. Two of these were banded with relief of symptoms and are in use for dialysis One access was ligated with relief of symptoms. One avf had mild symptoms and required no treatment. All 4 were managed by IN in the asc. No ER visits or hospitalizations occurred as a result of the access surgery. These initial complication outcomes have been validated by subsequent CQI that is performed on a quarterly basis at the AKDHC ASC over the past 5 years.
From the data presented, it is clear that a US IN can safely and effectively create AVF in an outpatient center. AVF creation by IN augments a focused IN approach to improve AVF rates and decrease CVC use.

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The Center Effect: Speaking of the Unspoken Impact of Teamwork

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The overall outcome of dialysis access is the product of many healthcare workers efforts or teams of individuals in a complex balancing act of therapeutic interventions. These include (kidney failure) prevention measures, treatment of hypertension, infections, cardiovascular and other co-morbidities, social and psychiatric care, to mention a few. The purpose of this communication is to highlight select areas, where improvement is attainable through effective teamwork inspired by an interdependent mindset.
Algorithms for Dialysis access selection. Controversy surrounds the establishment of proper planning, placement and management of dialysis access. These include how to select the dialysis modality i.e. Hemodialysis (HD) vs. Peritoneal Dialysis (PD), type and site of HD access, timing of access placement and who places the access. The lack of and the difficulty of performing randomized studies with many confounding factors, in a heterogeneous and rapidly changing demographics in the end stage renal disease

(ESRD) population, partly explains the dialysis access conundrum. Add to this the rapidly developing and competing technologies, the wide spectrum of professional experience, bias and socio-economic forces, making the dialysis access multivariate and complex (1) (Tab. I).

The individual making the Right Decisions. Dialysis access outcome depends on all stakeholders individual efforts. Some people (including doctors) appear to be more effective and successful. Are these accomplished individuals just struck by good luck? Or, is there something else that makes some individuals (professionals) more accomplished than others? In other words, what does it take to become a world class expert? (2) (Tab. II). There are certain professions or activities more easily recognized as having special or exceptional skills and hence referred to as "experts" (2) (Tab. III). In reference to dialysis access surgery and interventional procedures, certain specific highly technical skills and knowledge are required to perform the necessary tasks. Also, for maximal individual professional success an interdependent mindset with

TABLE I - FACTORS INFLUENCING DIALYSIS MODALITY SELECTION GENERAL FACTORS

- Patient desire, including lifestyle, profession
- Socioeconomic factors, education
- Patient education on dialysis issues and options
- Nephrologists' education (Equal education on HD and PD)
- Comfort level with dialysis modality
- Co-morbidity severity
- Surgical experience and technical support
- Stage of chronic kidney disease (CKD)

Favoring HD

- Patient restrictions to learn the PD technique
- PD training facility availability
- Abdominal stoma (i.e. colostomy)
- Previous (multiple) abdominal surgeries
- Recurrent abdominal inflammatory events
- Severe obesity, hygiene issues

Favoring PD

- Presence and status of vein and arteries, hemodialysis intolerance
- Travel distance to dialysis facility
- Heparin intolerance
- Lower cost

TABLE II - CHARACTERISTICS OF AN "EXPERT"

- Be at the Right Place
- Born and be around at the Right Time (year)
- IQ of about 115
- Have resources
- Practice passionately for 10.000 hours

TABLE III - EXAMPLES OF EASILY IDENTIFIED "EXPERT" (PROFESSIONAL) ACTIVITIES

- Violin player
- Tennis player
- Opera singer
- Computer programmer
- Air Line Pilot
- Surgeon
- Interventional radiologist
- Nephrologist

seamless, uninhibited flow of information between treating departments and the decision making governing bodies will improve the effectiveness and outcome (3, 4). Some personal attributes defining team players and leaders have been linked to brain cell physiology (3,4) (Tab. IV). From this we may hypothesize that when people work in concerted synergy as a team, safety and quality improve and several individual "experts" have created a natural "Center of Excellence". However, good leadership may suffer negative consequences by organizations dominated with legal-rational authority, a style characterized by "blame and shame" culture (5, 6). True expertise develops when professionals openly report and share mistakes that everyone can learn from without risk of punishment (6).

The Center Effect. Like individual "experts", some hospitals and healthcare corporations proclaim and advertize themselves as "Centers of Excellence", implying they are better than the one you work at. This review highlights some factors that may come into play promoting optimal outcome and maximize safety in the care of the ESRD patients in general and specifically for dialysis access procedures. The ESRD patients represent a challenging population with an overall annual mortality of 20 % in the US. The timing and choice of dialysis modality, the type and site of hemodialysis access may mean death or survival for an individual patient. It will certainly impact longevity. A center's administrative leadership style, and culture (5,6) will affect the center overall success. The quality of protocols and policies in place and how well they are adhered to along with a rigorous continuous quality improvement process as well affect the outcome. Preoperative duplex Doppler ultrasound evaluation with the surgeon present or performing the study is one example of such an outcome improvement driven policy (7, 8).

The transplant community has long recognized the outcome variability between kidney transplant centers reported annually by UNOS (United Network for Organ Sharing) (9). This center difference phenomenon is known as the "Center Effect", a concept generally accepted in the transplant community, although it is difficult to pinpoint what specific factors make a center do better or worse. Likewise Dialysis practices and outcomes vary greatly around the globe as well in the US (10). More specifically dialysis access outcome such as early arterio-venous fistula (AVF) clotting thrombosis at 6 week may vary between centers from 6-28 %. (Unpublished data) (11). Likewise the primary patency with PTFE grafts is reported as high as 69 % at one year (12) while others report graft function of 23-27 % (13).

The causes of success it is clearly multi-factorial. In fact, it may represent the popular "Tipping Point"

TABLE IV - WHAT MAKES AN EFFECTIVE LEADER?

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

TABLE V - "CENTER EFFECT" FACTORS THAT MAY AFFECT ACCESS OUTCOME

- Leadership including hospital administrative support.
- Crisis vs. planned Dialysis access management style
- Access team members' skill, knowledge and attitude
- Policies and protocol sophistication and level of adherence
- Continuous quality improvement process
- Pre-ESRD education program
- 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)

phenomenon as described by Caldwell in his book with the same title (14). 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, every team member has to do many (small) "rights" to each and every patient by every team member to make a **Center of Excellence**. The more "rights" the better Center (Tab. V)! From daily experience most healthcare workers and hospitals are far away from this imaginary goal. A fistula failure rate of 60% to mature, usable for dialysis (11) likely reflects a multitude of system factors problems ("error chain") leading to failure (6).

Examples of Specific Dialysis Access Areas to Improve the Center

Optimal Managing of Hand Ischemia. Hand ischemia or "steal" after dialysis access placement occurs in up to 10 % of cases when the distal brachial artery is used as inflow (15-17), and carries severe morbidity, including tissue or limb loss, if not recognized and treated.
Three distinct etiologies include: 1) blood flow restriction to the hand from arterial occlusive disease either proximal or distal to the AV access anastomosis. 2) True steal may occur from excess blood flow through a large AV access conduit. 3) 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. Tailoring the management and treatment of "steal" from diagnostic findings and patient characteristics are likely to prevent many cases and also improve outcome. The aging ESRD population has made the management of hand ischemia more challenging. There are five treatment option outlined in a recent review article (19). First, observation of developing symptoms in mild cases. Second, balloon angioplasty and possibly stenting is the appropriate treatment for an arterial stenosis, performed as part of the diagnostic arteriogram as inflow stenosis is seen in a third of "steal" cases. At least three distinct surgical corrective procedures exist to counteract the physiology of steal. These are Distal Revascularization and Interval Ligation known or DRIL (16). Then, the Proximalization of Arterial Inflow (PAI) was popularized by Zanow (17). Finally, controlled Banding of the access to restrict access blood flow guided by intra-operative finger-pressure measurements and 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 often devastating cardiovascular co-morbidities (18).The authors have 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. Making the correct diagnoses and the right treatment selection will relieve suffering, prevent ischemia induced impaired function and tissue loss and perhaps prolong life in up to 5-10% of the hemo-dialysis population (19).
Heparin Bonding to artificial surfaces such as ePTFE with prolonged bioactivity retention (CBAS® technology) has evolved into a clinically useful technique. A preliminary non-randomized report in survival estimates showed a 15-20% improved primary graft patency in 83 heparin bonded grafts when compared to 67 control e-PTFE grafts. At 6 and 12 months, patency for the heparin bonded graft group was 88% and 78%, which is also significantly higher than that of 69% and 58% for the control group, respectively (p=0.007). The overall combined clot-free survival for all 150 e-PTFE grafts was 69% at 12 months (12), which compares favorably with 23-28 % in a recent US multicenter study (13).
Early Referral and Vein Preservation. Two measures would markedly improve the outcome of dialysis access. First, early referral to the nephrology specialist and to the access surgeon for evaluation increases the likelihood for PD or having a usable Hemo-access i.e. a native AVF or graft and avoiding morbidity from prolonged central vein catheter placement. Therefore, when kidney glomerular filtration rate approaches 30 ml/min, (CKD Stage 4), patient education about renal replacement therapy and dialysis access must begin and referral for preemptive transplant and dialysis access consideration be made. Second, preserving veins by preventing veno-punctures and intravenous lines in potential future dialysis access veins for AVF placement also increases the chances for a useable native vein AVF. There is much abuse of potential AVF veins from IV lines and blood draws. Only the dorsal aspect of the hands should be allowed for venous blood access. Patient undergoing HD can have blood draws done during dialysis treatment to preserve veins. These are simple policy decisions made by individuals with the vision and power to implement the right thing. PICC lines (Peripherally Inserted Central Catheters) must never be used in patients with expected dialysis need. The use of subclavian veins for dialysis catheters has universally been abandoned. In this context our cardiology colleges also must change the practice pattern from using the subclavian to the internal jugular vein for long-term pacemaker device placements. Vein preservation also entails much patient education, compliance and understanding. Intense concerted education of hospital workers and patients must take place for these measures to become universally applied and effective.

Peritoneal Dialysis (PD) first, Hemodialysis (HD) Second. The concept of "PD First" implies that whenever feasible PD should be offered as the first dialysis modality. PD provides a survival benefit for the first several years after dialysis initiation in the majority of patients (20-27). Moreover, individuals who receive a transplant, while on PD have better long and short-term transplant outcomes compared to those patients who are on HD immediately prior to kidney transplant (28, 29). While on PD, plans can be made to place a native vein AV fistula. The PD option allows extra time for the AVF to mature and for creative access options such as two-stage surgical procedures to optimize the hemo-access outcome effectiveness. As all dialysis access modalities have a certain failure rate over time, proactively placing a native vein AVF in a PD patient serves as a "life insurance", should the PD modality later fail. The benefits of the PD First and HD second must not be seen as competitive therapies (30, 31), but rather complementary, where over time the dialysis access options are considered as integral parts of thoughtful long-term planning. In addition to overall survival benefit of PD over HD, data from Canadian, Dutch and the US registries show that the characteristics of the PD Center or the "Center Effect" significantly impacted outcomes (32-34). A correlation was observed between patient and technique (catheter) survival and the number of patients treated at a specific center. Using data from the comprehensive Dutch End-Stage Renal Disease Registry (RENINE), Huisman et al showed low technique survival rates occurred in centers with less than 20 patients on PD, with a relative risk for failure of 1.68 compared with larger centers (33), suggesting that the degree of experience and specialization in a center has a strong impact on PD outcomes. It is suggested that propensity to exploit technical and non-technical advances in PD increases directly with experience and the centers become more adept at selecting patients to receive PD and treating their complications (2, 34). This is illustrated by the PD catheter survival rates at our PD center, which is one of the largest PD centers in the USA treating about 125 patients (35). In our retrospective study of 315 patients, examining various risk factors associated with the survival of first PD catheters placed between January 2001 and September 2009, the 1, 2 and 3-year PD catheter survival was 92.9%, 91.9% and 91.1%, respectively. On further investigation of different variables, the PD catheter-related non-infectious complication was the single covariate that significantly reduced the catheter survival time (Fig. 1). Each PD catheter-related problem increased the risk of catheter failure more than 3 times (Hazard ratio 22.467; Beta estimate 3.112). No demographic (age, gender or race) or other clinical characteristics (BMI, diabetic status, co-morbidities, previous abdominal surgeries or infections (peritonitis, exit-site or tunnel infections) did significantly impact PD catheter survival.

Training the Dialysis Team by Simulation. The concept of Dialysis Access Simulation training is relatively new. The authors have developed a comprehensive, multidisciplinary training curriculum,

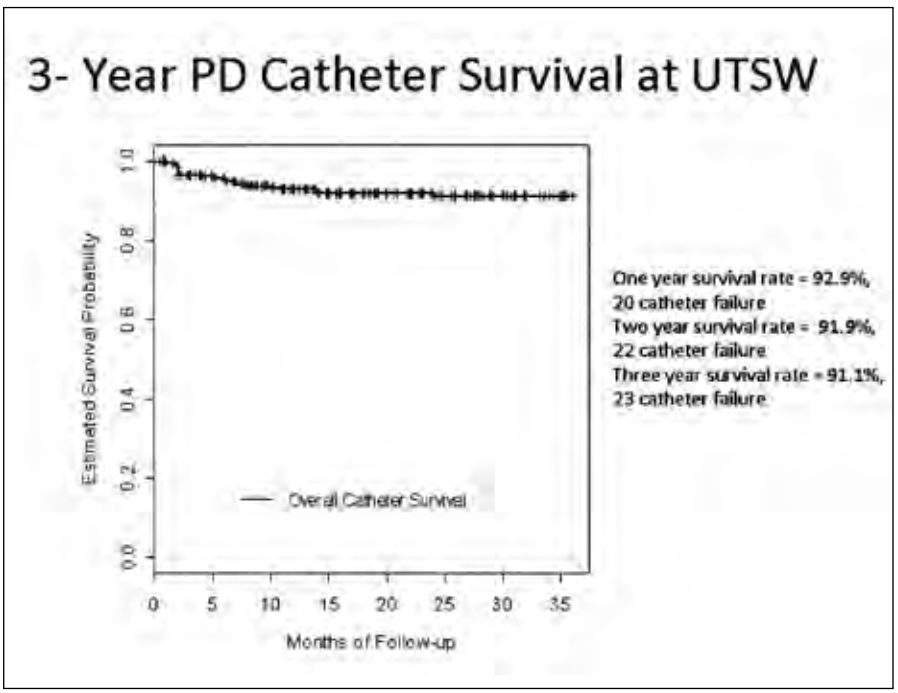

Fig. 1 - *Kaplan Meier curve for overall first time PD catheter survival probability. One, two and three year catheter survival rates were 92.9% (20 catheter failures), 91.9% (22 catheter failures) and 91.1% (23 catheter failures) respectively. Reproduced with permission from (34).*

using didactic, interactive, e-based learning, and virtual reality simulation technologies to improve the safety, quality and efficiency of dialysis access procedures, including dialysis needle cannulation skills for hemo-dialysis nurses and technologists. The primary goal of the simulation training is to reduce errors and maximize patient comfort and safety. The simulation based training program allows for multi-disciplinary research designed to improve, validate and enhance each aspect of dialysis access procedures and techniques.

Dialysis Access Simulation training will embrace new educational paradigms, with team training techniques, new methods of simulating surgical and non-surgical delivery methods and will set national standards for the dialysis access training and education. The dialysis access simulation curriculum will be able to teach, train and certify local, regional and international healthcare professionals caring for ESRD patients. Its emphasis on distance learning will increase its reach and availability as sites to test new medical devices and techniques.

In a real-life environment, participants will receive intensive instruction and hands-on training in the latest medical procedures, devices and standards, enabling them to reduce medical errors and provide the most effective patient care. Comprehensive and multidisciplinary in its scope and approach, the **Simulation Training** is a new resource tool for medical professionals caring for dialysis access patients. Several competencies comprise this new learning paradigm. It must and will have the traditional old knowledge based type learning by reading, and clinical technical skills by repeat practice (2); new teaching encompasses the concept of social intelligence (formerly emotional intelligence), which is best describe by words as attitude, professionalism, trust, leadership, interdependent mindset to mention a few (3, 4). Finally and perhaps most importantly, is the learning about understanding safety and error prevention, an individual perspective as well as system based design error prevention. Here the healthcare industry is slowly picking up the half a century ever progressing experience from the aviation safety programs that is, at least partly, responsible for the unprecedented safety record of the North American commercial airlines.

In the broadest term, practice patterns correlate to outcomes including patient survival and access longevity as well as cost to society at large. Individuals, institutions, governments, and specialty societies may directly or subliminally influence the selection of the preferred or chosen dialysis modality. The most visible and widespread effort in this regard is the CMS (Center for Medicare and Medicaid Services) Fistula First National Vascular Access Improvement Initiative (30). Similarly, the ISPD (International Society for Peritoneal Dialysis) is stressing the underutilization of the PD modality, especially in the Western societies (31). The selection of dialysis access is of critical importance in planning a successful transition to dialysis treatment of patients approaching ESRD. A sound long-term dialysis access algorithm is designed to maximize patient quality of life, improve survival and be cost-effective. Rather than emphasizing the doctrine of one modality fitting all, doing the right thing for each patient, each time, is ethically and morally the better model. The issue is not who places the access but who does it right, every time, to everyone, and everywhere. It should be outcome and patient driven. The decision-making algorithm for two similar patients may therefore vary, based on individual circumstances summarized in Table I (1). Different dialysis modalities and access types must not be seen as competitive but rather complementary, where over the lifetime the dialysis patient may utilize both PD and several types of HD access sites and most importantly receive a functioning transplant. However, only a fraction or 2.7 % of the dialysis population receives a kidney transplant annually not only because of shortage of organs. More commonly patients on dialysis do not qualify for transplant because of severe co-morbid conditions.

Summary

The **Center Effect** infers a complex set of interfacing and contributing factors ranging from the individual healthcare performance to complex system interference and the institutional culture. Adherence to sound policy manuals, and the use of procedure checklists are central safety measures in a simulation training environment, mirroring their successful use in commercial aviation. The same principles apply to maintenance of access for longevity. As a lifelong access utilization strategy, peritoneal dialysis must be considered as the first dialysis modality in all cases, followed by appropriately planned hemodialysis. Duplex Doppler Ultrasonography examination is the logical step following history and physical examination for pre-operative vascular mapping in determining the optimal hemodialysis access type and site. Also, Duplex US testing will diagnose the majority of vascular access complications and direct the proper surgical or interventional radiology management.

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Surgical Training Programs

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Training programs in vascular access procedures serve two primary purposes. First, they prepare surgeons in training to perform access placement and repair for their future practice. Second, these training programs allow the opportunity to teach, in a relaxed and comfortable setting, the practice and principles in vascular surgery in general. As many vascular surgical procedures are being replaced by contemporary endovascular procedures, these teaching opportunities have become even more important. In fact, the supervisory bodies in the surgical education world have allowed residents to count vascular access procedures as major cases for their surgical logs that previously weren't allowed.

While various societies have put forth curricula for training in vascular access, they are widely diverse in their content. That has led to similarly diverse experiences in their residencies/fellowships. Ultimately, the quality of the training of surgical residents is found in the interest, experience, contemporary training and volume of their vascular/transplant/general surgical mentors.

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We Really Don't Know How to Use pre-op Vascular Mapping to Further Reduce Immaturity Rates

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Despite of advancements in imaging and the larger experience in creating dialysis access fistulae a significant number of them fail to mature. Several factors are important for the failure. One important reason is the lack of imaging or a choice of creating the fistula without using any imaging but relying only on clinical examination. When imaging is performed often there is a miscommunication between the staff performing and interpreting the imaging with the specialists who create the fistula. There is also lack of complete protocols that may be discussed from both sides so the imaging offers exactly what the specialists wants in order to optimize the procedure. Several examples in the everyday practice exist as even when a complete mapping the basilic and cephalic veins exists there may be inadequate investigation of the arteries and the proximal deep veins. Often there is a high origin of the radial and the ulnar artery or proximal deep vein obstruction that both can affect the outcome of procedure.

If it is assumed that the imaging is "perfect" and the specialist has all the information needed to create a dialysis access fistula still there is a problem of how to translate the findings. A major disadvantage on this is that the decision based mostly on experience and less on science. Clearly, there is lack of research in this area where many variables should be taken into account to determine prospectively the success of fistula maturation. Obviously there are cases where everything favors fistula maturation such in those patients with intact arteries and veins having both good diameters. However, many of the patients may have suboptimal vessels, with small or borderline diameters and heavy calcification. For example if a patient is scheduled for a radiocephalic fistula has a radial artery with a diameter of 2.0 mm that is calcified and a cephalic vein in the forearm measuring 3.0 mm (that is a frequent scenario), the fistula may fail to mature even in the absence of stenosis in the outflow vein. Competitive flow from other tributaries and failure of the artery to dilate may be responsible for the lack of maturation. Other factors include areas with focal thickening intrinsic to the vein or due to puncture or thrombosis that are often ignored. These areas may develop stenosis when high flow runs through and fail to dilate as the normal adjacent vein segments do. Usually a secondary procedure is needed to take care of the stenosis but it is not known how this will impact the long term outcome of the fistula.

Current guidelines are very helpful but far from being adequate in determining the success of maturation. Education is needed for the staff that performs the imaging and the specialists who perform the surgery as there is a great margin for improvement at a national level. Furthermore, prospective studies should be performed to solve many of the unanswered questions of how to translate the vascular mapping into good outcome. Therefore, the vessel characteristics determined during vascular mapping should be identified as optimal, poor and those who may or may not lead into a successful maturation. Then targeted research should allow progress on this field and hopefully reduce significantly the immaturity rates.

Some AVF Veins Dilate and Some Don't, Why?

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Arteriovenous (AV) Fistula non-maturation is currently a huge clinical problem with up to 60% of new AV fistulae being unsuitable for dialysis at between 4-5 months following surgery (1). At a radiological level AV fistula non-maturation is characterized by a peri-anastomotic stenosis (2), while at a histological level we have described the presence of an aggressive neointimal hyperplasia in such patients (3). In addition to neointimal hyperplasia, it is likely that the type of vascular remodeling (outward or inward) also plays an important role in determining why some veins dilate while others do not.

What are the reasons for this wide variation in the ability of the vein to dilate following AV fistula creation? Can we identify such patients based prior to surgery; and most importantly, are there therapies that we can use

to enhance venous dilation? Unfortunately, the answer to these three critical questions remain unknown.
We hypothesize that there are both traditional and non-traditional risk factors for AV fistula maturation failure. Traditional risk factors include parameters such as small vessels, obesity and female gender. Non traditional risk factors on the other hand include endothelial dysfunction, hemodynamic stress, process of care parameters and surgical skill/technique. Interestingly, it may be easier to modulate some of these non-traditional risk factors as compared to traditional risk factors. Of note, the National Institutes of Health have recently launched a multi-center study which is focused on the identification of clinical, demographic, hemodynamic and biological risk factors for AV fistula maturation failure.
In conclusion, it is likely that AV fistula non-maturation is a complex process that spans basic biology, clinical parameters and process of care issues. Further investigation into the pathobiology of AV fistula non-maturation is likely to be the only way to develop future therapies for this important clinical problem.

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The Balloon that Dilates the Vein that Doesn't Dilate: Balloon-assisted Maturation

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Background: Thrombosed immature fistulas have historically been considered unsalvageable (1). However, advances in procedure and balloon catheter technologies have expanded the scope of endovascular treatments (2-5). This study investigates the efficacy, functionality and cost associated with the use of percutaneous techniques for the salvage of thrombosed immature fistulas.
Methods: Over a 2-year period and from a population of 18,000 hemodialysis patients, 140 consecutive patients with thrombosed immature fistulas underwent attempts at salvage via thrombectomy procedures. All fistulas had thrombosed following access creation and had never been used for hemodialysis. Multiple approaches were utilized to gain access to the fistula, including trans-fistula cannulation, distal arterial puncture and proximal retrograde venous access. Thrombectomy was performed via balloon maceration and aspiration. Accelerated maturation was achieved through sequential angioplasty of diffusely stenotic veins and elimination of competing branch vessels (6-8). Primary access, primary assisted, and secondary access patencies were calculated at 3, 6, 12, and 24 months. A cost analysis was performed based on procedure statistics and the 2009 Medicare reimbursement schedule, and compared to data from the 2009 United States Renal Data Survey.
Results: Thrombectomy was successful in 119 (85%) immature clotted fistulas and hemodialysis adequacy was achieved in 111 (79%) fistulas. The average maturation time from thrombectomy to cannulation for dialysis was 46.4 days, with an average of 2.64 interventions per patient. There were 5 (3.5%) cases of angioplasty-induced rupture, all of which were treated with stent placement. Clinically significant pseudoaneurysm formation occurred in 4 (2.8%) of patients. At 12 months, secondary access patency of salvaged accesses was 90%. Based on 2009 Medicare outpatient billing rates per patient per initial access-year and the maturation times observed in the New York area, percutaneous salvage of thrombosed immature fistulas costs $4,881 to $14,998 less than access abandonment and new access creation.
Conclusions: Endovascular techniques can be used for the salvage of thrombosed non-maturing fistulas (6). When analyzed within the initial access-year, this approach yields a significant cost savings over access abandonment.

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Accessory Drainage Veins (ADV): What Are They and When Do They Matter?

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First of all a simple definition of accessory drainage veins (ADV) is in order. According to Dr Gerald Beathard, the vein that is to become an AVF is ideally a single conduit but may have side branches. These side branches are referred to as accessory veins, which represent normal anatomy. These veins may be single or multiple and many are visible. The consequence of these braches is that they may also enlarge and ideally, the patient may develop more than one channel that is suitable for cannulation. A second possibility is that the veins may all develop in a suboptimal fashion such that cannulation is difficult.

Other veins that may develop in addition the primary conduit are collateral veins (CV). These vessels are signs of pathology, namely a significant stenosis or total occlusion of the primary out flow channel down stream from the CV. In some situations a down stream stenosis may cause a true ADV to enlarge as well. These CV will not be discussed at this time.

An example of an ADV in a simple direct AVF created at the wrist with a radial artery-cephalic vein anastomosis might the median antebrachial vein which is a branch of the forearm cephalic vein in many patients. If this vein enlarges along with the forearm cephalic vein but is too deep to cannulate easily, it may compromise the function of the cephalic vein as the primary conduit due to inadequate blood flow through the primary conduit (1, 2).

Examples of an ADV in an avf created at the elbow using a brachial artery- cephalic vein or median antebrachial vein anastomosis might be the basilic vein or brachial veins. A Gracz fistula which is an autologous fistula constructed between the brachial artery and a branch of the medial antecubital vein, the perforating vein, below the elbow would be a specific example of these types of accesses. If either of these venous systems is allowed to compete with the cephalic system for blood flow from the brachial artery, it is possible that the cephalic system may not develop adequately. These potentially competitive veins should be addressed to the extent possible by the operating physician at the time of the AVF creation (3). Particular attention should be paid to flow through the median basilic and or perforating veins after the anastomosis is closed and the new avf is running. It is also possible to intervene at a later time using either endovascular or open techniques depending on the situation.

In summary, why (when) should we care about ADV? ADV may decrease critical blood flow in the primary dialysis conduit thus compromising AVF function and maturation. Problems attributed to ADV may be manifested as well by confusing physical examination and difficult cannulation of the AVF due to many veins being perfused. Judicious ligation or occlusion of these braches may result in improved AVF function and maturation (4).

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Fact: Accessory Veins Are a Real Cause of Immaturity

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The optimum anatomy for the creation of a fistula (AVF) is a single vein without side branches. Unfortunately, this is not always the case. The vein that is to become an AVF may have side branches. These side branches, referred to as accessory veins, are normal anatomy. Since there is a generally paucity of side branches in association with upper arm fistulas, the accessory vein is primarily a problem of radial-cephalic fistulas. These veins must be distinguished from collateral veins which are pathological anatomy and always associated with a downstream (antegrade) stenosis. When performing an angiogram to look for or evaluate a side branch, one must take care. Occluding the fistula to perform a retrograde injection can cause veins not normally present to appear and those that are normally present to appear much larger than usual.

In an ideal situation the presence of an accessory vein may be viewed as an advantage, the patient may develop an additional venous channel suitable for cannulation and its presence may prevent access thrombosis if stenosis of the main channel develops. It is only a problem in cases with failure of the fistula to develop where its presence may be a contributing cause. Fistula development is primarily dependent upon flow. With a large accessory vein, flow that should be directed into a single channel is partitioned into two or more channels, each receiving less than the total. The accessory vein may also cause problems with ease of cannulation by the dialysis facility staff.

The challenge in evaluating the presence of an accessory vein is to determine its significance to the patient's problem, i.e., failure to mature. The first point that needs to be emphasized is that if the patient's fistula has not failed, the accessory vein is not likely to be a significant problem. Secondly, if a downstream stenosis is present, the significance of the vein cannot be evaluated until the stenosis has been resolved. Doing so will generally result in either a complete or a marked reduction in the vein.

In the case with failure of fistula development and no evidence of downstream stenosis, a determination of the significance of the accessory vein is somewhat subjective. There are three variables that are helpful – checking augmentation of the fistula with manual occlusion of the side branch, assessing flow in the vein in comparison to the main trunk of the fistula with a puff of radiocontrast and an evaluation of the accessory vein's size.

Of these, size comparison would appear to be the most objective; however, Poiseuille's Law is not applicable. It would if the two channels, the accessory and the main fistula, were straight, non-branching tubes. Unfortunately they are not. The accessory vein frequently leads to a branching field of veins. Additionally, the angles of branching have an effect on laminar flow. These factors reduce size comparisons to a subjective level also.

The treatment of accessory veins has been controversial. There are those who feel that it is of no value and there are others who recognize the benefits of such treatment in appropriate cases (1-4). As with all issues

of this sort one should resort to an evidence based medical approach to resolve the question. This requires the integration of best research evidence, clinical expertise and patient values. All three are important.
The best research evidence is always a randomized controlled study, properly designed and properly conducted. It is unfortunate that no such studies are available to shed light on this issue and there it is not likely that there will be. This statement is based upon several facts. Firstly, there are many variables – only seen with radial-cephalic fistulas, often associated with other lesions, frequency is variable, criteria for determining significance is not standardized. Secondly, the sample size required is almost prohibitive when one considers the frequency of the lesion when it occurs alone and the variables that would need to be controlled for. Thirdly, since it would need to be done in cases of fistula failure, a control group would be committed to prolonged catheter based dialysis, raising ethical issues with the performance of the study.
There are a number of clinical studies that have been performed. Unfortunately most have been small studies, less than 100 cases. Only three have been this large or larger. These have shown salvage rates ranging from 74 to 92%. However, these cases have included lesions in addition to accessory veins. In one small study involving the detection of large accessory veins, prior to surgery, the presence of these structure was found to have sensitivity and specificity of 80 and 100 for non-maturation of radial-cephalic fistulas (4). Clinical studies in which no accessory veins were treated have in general been even smaller but have shown almost identical salvage rates.
Irregardless of the absence of randomized control trial or large clinical studies that deal with only accessory veins, clinical experience has shown that in appropriately selected cases with an inability to dialyze because of failure of a fistula to mature, treatment of an accessory vein has resulted in the fistula being usable. This experience has taught that these venous structures should be looked for in cases that present with maturation failure. If an accessory vein is present and can be shown to meet reasonable criteria for significance, it should be obliterated.

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Fiction: There's no proof that accessory veins cause immaturity

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The role of so-called competing veins in AV fistula maturation remains controversial. After an initial spate of publications describing fistula maturation procedures in the early part of the last decade, such reports have become less common as the practice of fistula maturation enhancement has itself become mature. Nonetheless there remains no consensus as to whether PTA of offending lesions alone is adequate or whether competing vessel treatment improves results, either immediate or long term. While this would seem to be an ideal area for a prospective randomized trial, to date no such trial has been reported or to my knowledge even initiated.
In the absence of level 1 evidence, one must rely on the available level 2 evidence, which can be divided fairly simply between those reports in which vessel occlusion has been part of maturation techniques (for the sake of brevity I will call these "CLOSURE") and those in which PTA alone has been used ("PTA"). The initial reports from the CLOSURE camp seemed to offer higher 1 year patency (1-4) than the PTA camp (5-8). However, a close examination, where possible, of the literature from the CLOSURE camp shows that the results are not reported on an intent to treat basis (4), whereas all PTA camp papers have been. Further,

when an intent-to-treat definition is applied, the one year results from the CLOSURE camp are much more in line with those of the PTA camp, although the treatment of "competing veins" continues to differ dramatically: Clark et al (7) reported 0% venous ligation or embolization (4 cases, 1 embolization and 3 ligation were excluded from analysis to examine the outcomes of PTA only) and Nasser et al reported 29% (4). Thus, if one applies the SIR reporting standards for patency (applied in all PTA camp series) to all of these papers, the results are nearly identical in those papers in which this can be determined. Thus, not only can one argue that there is no evidence that accessory veins cause immaturity, one can actually argue that there is evidence that they do not. Note, there are very rare exceptions to this rule, not only do I acknowledge these, I can estimate a frequency based on the work of Clark et al (from my institution) whose 4 excluded cases from 93 total would argue a maximum 4% rate of competing vessel treatment (7). In our current practice, competing vessel treatment occurs with even less frequency, less than 1% of immature fistulae. Contrast this to the 29%-100% use of such treatment in the CLOSURE camp (1-4).

I have previously argued in this forum that the sole reason competing vessel treatment is done is an economic one, because the treatment, at least by embolization, of such vessels carries a high reimbursement. While I wish this were not the case, no evidence to the contrary has emerged. As we move further into the era of evidence based medicine, and perhaps spurred by a "prove it or we don't pay for it" approach emerging from Washington, perhaps the CLOSURE camp will proceed with a prospective randomized trial to prove the value of vessel closure as part of our armamentarium of fistula maturation techniques. Until such evidence emerges, "competing vessels", whether true accessory veins or unnamed vessels, should be left alone.

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Arteriovenous Fistula Immaturity: Inflow Stenoses – Etiology and Treatment of Arterial and Juxta-anastomotic Stenoses

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Early fistula failure is frequently due to anatomic lesions that may exist anywhere within the access circuit. These include inflow stenoses: arterial, arterial anastomotic and juxta-anastomotic/swing point segment lesions. See Table I.

Arterial inflow lesions (from the aortic arch to one cm above the arterial anastomosis) may be due to anatomically small vessels and atherosclerotic disease, which are found in an increasing portion of the elderly, and patients with hypertension and diabetes. Arterial anastomotic (within 1 cm of the anastomosis) and venous swing point stenoses (juxta-anastomotic) are acquired lesions, as these are the sites of surgical creation and mobilization of the artery and vein. These lesions may be due to surgical trauma at the time of fistula creation, hemodynamic sheer stress, a genetic predisposition to vascular constriction and neointimal hyperplasia (secondary to oxidative stress, inflammation and endothelial dysfunction) (1).

Treatment approaches to these lesions include balloon angioplasty (sequential dilation), stent placement (uncommon) and surgical revision. The endovascular approaches may be either transarterial or transvenous.

The arterial approach for diagnosis (retrograde brachial artery puncture) is useful when reflux of contrast cannot visualize the inflow artery, proximal lesions may be missed and when the sharp angulation of the anastomosis cannot be crossed from a venous approach.

When a transvenous approach for treatment fails the arterial approach (antegrade brachial or retrograde distal radial artery puncture) for treatment should be considered, providing an excellent picture of anatomy and flow, facilitating crossing of the anastomosis and treating all lesions from one puncture site.

Multiple lesions (inflow, outflow and side branches) are common in 25-70% of immature fistulas. Therefore, the reported salvage rates of 75-95% and 1 year secondary patency rates of 75-95% refer to treatment for the entire access circuit. Technical success, clinical success and patency rates specific to inflow lesions are not known.

Often, more that one procedure is required to salvage a fistula and repeat angioplasty is necessary to maintain function. Through careful surveillance and repeat intervention these fistulas can increase the prevalence of autogenous accesses, helping the dialysis community meet the goals of K/DOQI and Fistula First.

TABLE I

Author	Number of Immature Fistulas	Frequency of Stenosis Locations		
		Arterial Inflow	Arterial Anastomosis	Swing Point
Turmel-Rodrigues et al., 2001 (2)	69		6%	55%
Beathard et al., 2003 (3)	100	4%	38%	43%
Falk, 2006 (4)	65	8%	6%	25%
Nassar et al., 2006 (5)	118	5%	47%	64%
Clark et al., 2007 (6)	101	6%	4%	38%
Miller et al., 2009 (7)	122	11%	34%	16%

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Access Patency Following PTA of AV Circuit Venous Outflow Stenosis - Good Enough?

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As the number of arteriovenous fistulae have increased, there has been an additional increase in need for interventions in these arteriovenous fistulae. Dysfunctional or "failing" fistula is noted by any fistula that has an increased venous pressure during dialysis, abnormal urea recirculation, decreased dialysis flow or abnomal physical exam. Patients with these findings in a fistula are referred for evaluation with planned intervention. Juxta-anastomotic stenoses are the most common lesion observed in primary fistula. In a recent study by Asif et al, in 112 procedures, 98 (88%) lesions were described as juxta-anastomotic, with only 39 (35%) lesions seen on the venous side (1). Multiple stenosese within the fistula was common in this study with 44% of patients having both a peri-anastomotic stenosis as well as a coexisting stenosis elsewhere within the circuit. In the 209 procedures on 63 mature fistula reported by Falk (2), 83% of patients underwent venous angioplasty to help maintain patency with only 44 procedures involved stenosis within the draining arm vein. The majority of venous lesions (55) were located at the cephalic arch. Patency rates in this study also include PTA performed to assist maturation of fistula. Primary patency rates at 90, 180, and 360 days was 71%, 69%, and 64%, with secondary patency rates of 73%, 72%, and 68%, respectively.
Distribution of stenosis was evaluated by Badero et al (3) as well. The most frequent site of stenosis was in what they referred to as "swing zone" or those sites where the vein extends around a curve such as the juxta-anastomotic site, or the cephalic arch. 45% of the stenosis in their study group were in these swing segments, primarily within the juxta-anastomotic location. Only 30% of the stenoses were in the draining vein, primarily within the puncture zone.
Overall, data on stenosis within fistula not involving the peri-anastomotic region is lacking. These lesions are less frequent than those within the peri-anastomotic zones. It can be theorized that a stenosis in this primarily straight segment undergo different shear stresses than those along the curved, swing-zone or peri-anatomotic segments. Often, the initiator of stenosis, may be repeated punctures at the site. Further study is needed to see if these lesions respond differently to angioplasty.

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Bare Metal Stents in AV Access: Update on Patency Results and Implications for Use

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Both arteriovenous fistulae (AVF's) and arteriovenous grafts (AVG's) are prone to fail, often due to the development of stenosis. Surgical and percutaneous options can be used to treat stenosis and maintain AV access patency. Percutaneous transluminal angioplasty (PTA) has been widely adopted as a first line therapy since it is less invasive and can be readily scheduled and performed.

The problem with AV access PTA is that it isn't very durable. Recoil and neointimal proliferation at the PTA site frequently lead to recurrent AV access dysfunction within several months after PTA. Based upon many reports, K/DOQI's Vascular Access Clinical Practice Guideline 19 recommends a target goal of "50% unassisted patency at 6 months" after successful PTA of an AVG stenosis (1). In one of the few prospective series on AV access angioplasty, Vesely et al followed a control group of 94 patients with AVG stenoses who underwent PTA. They found 6-month clinical circuit patency of only 40.9% (2). The reality is that less than half of the patients who underwent PTA of stenosis in that study maintained a clinically functional AV graft at 6 months – below the 50% clinical patency threshold recommended in the K/DOQI guidelines.

There was optimism that bare metal stents, introduced into clinical practice in the late 1980's, could improve upon PTA in AV access intervention. However, various reports from the 1990's demonstrated that stents offered no advantage over successful AV access angioplasty (3-5). More recently, Vogel and Parise (6) studied use of nitinol self-expanding stents for post-PTA bailout in AVGs. While they reported a 97% technical success, the development of flow-limiting in-stent restenosis in peripherally placed AV circuit stents was not much different than prior reports with the Wallstent. Six-month patency was 51% and one-year patency was only 20% for peripheral stents. Additional analysis showed that when a site had been previously PTA'd, patency of the nitinol self-expanding stent at that site was inferior to use of stents at a site that had not been previously PTA'd.

In a recent look at the Wallstent, Kariya et al (7) compared the Wallstent for salvage of failed PTA and compared the results with successful PTA. At 6-months, the Wallstent's 39% primary patency was statistically inferior to 73% primary patency in the successful PTA group (p=0.028). This result, similar to the inferior stenting results that Vogel and Parise reported for stenting of previously PTA'd sites, suggests that stenting may afford worse patency compared to successful PTA.

So, while stents can indeed snatch victory from the jaws of PTA-related technical defeat, the long-term patency following "bail out" stenting is probably no better, and perhaps worse, than results reported where PTA was successful and uncomplicated. Today, the overwhelming opinion regarding stents is no different than it has been for the past decade, best summarized in the K/DOQI Vascular Access Clinical Practice Guideline 19 (1), "stents are useful in selected instances (e.g., limited residual access sites, surgically inaccessible lesions, contraindication to surgery) when PTA fails."

Development of in-stent restenosis (neointimal hyperplasia within the stent) can be inhibited by covering the stent with graft material. One large, prospective study has now shown unequivocally better outcome for PTA with immediate placement of a covered stent compared to PTA, alone in AV grafts (8), and early single center work suggests a role for covered stents in AV Fistulae (9-10). Therefore, the real role of the bare metal stent in AV access will likely be as one structural component in specifically designed AV access covered stents, rather than as a bail out device following unsuccessful PTA or PTA-induced rupture.

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Covered Stents for Access Intervention: From Here to Where?

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The problem of venous anastomotic stenoses plagues the majority of arteriovenous access grafts. 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 (e.g. 20%, 24% at 6 months). Further, prospective studies of primary graft patency after initial placement have proven far worse than retrospective assessments (AVG 25% in a recent NEJM trial, Dixon et al). The reality of poorer durability of solitary balloon-based therapies (than previously described) is partly a result of retrospective studies using differing definitions of patency, incomplete patient follow up, and reporting bias.

Balloon angioplasty is a potent tool, but one with many limitations, including and unclear propensity, in some patients, for early recoil, sometimes even prior to discharge from the interventional lab. The latter observation alone can explain the original enthusiasm for bare metal stents - the improved initial technical and anatomic outcome by virtue to control of elastic recoil. This early effect is obviated by the later, routine, marked transstent intimal hyperplasia that is provoked by the stent. It is unsurprising that no bare stents are labeled for peripheral AV access use, nor are any trials currently planned to this end. It is, rather, surprising, that their continued off-label use in this application persists, given their demonstrated reliable failure mode.

To date, one prospective study, by Haskal et al, showed a notably statistically significant improvement over balloon angioplasty for venous anastomotic stenoses in AV grafts (the "FLAIR trial", NEJM February 2010). Its results, superior to 210 days, have spurred a currently underway longer-term controlled trial comparing angioplasty with the stent graft, to 2 year follow up (RENOVA Trial). A separate controlled trial assessing the Viabahn is underway assessing its value at the same treatment site in dialysis patients (REVISE trial).

The use of PTFE stent grafts in AV access has forever changed our management of grafts and access. The tools are being increasing used as treatments for graft pseudoanuerysms, ruptures, and central veins or cephalic arch stenoses in access patients. Their advantage is the ability to non-surgically and immediately treat the affected area with minimal to no interruption in access use, thus limiting the need for interim catheter placements. These uses remain largely uncontrolled, and most will remain sop because of the sporadic nature of the treated event. Increasing anecdotal and feasibility published experience supports their value and will grow. Trials have been designed to assess the role of stent grafts in the central veins in patients with recurrent intrastent stenosis. Finally, the hybrid conversion of failing segments of mature native arteriovenous fistulae to grafted segments (using stent grafts), also known as the "graftula" or "fist-u-graft" are an area needing continued and dedicated study and reporting.

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Does the Infected Access Need to Be Removed?

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Dialysis access infections occur in up to 35% over the lifetime of the hemo-dialysis access (1-2). Early infections are associated with the surgical procedure, while dialysis needle cannulations commonly induce later events. Sixty to 70% of infections are caused by gram-positive bacteria (*Staphylococcus Aureus, coagulase negative Staphylococcus, Enterococcus*) (3, 4). Twenty to 30% involve gram-negative bacteria (*Klebsiella, Pseudomonas, Enterobacter*, and *Escherichia Coli*) (3, 4). Empiric antibiotic combinations include Vancomycin for gram-positive bacteria and Timentin or Zosyn for broad gram-negative coverage to be modified based on bacteria identification and susceptibilities reports within 48-72 hours. In the event of an infection with multiple gram negative organisms and extended spectrum agent, i.e. beta-lactamase or carbapenem, is recommended.

The increasing severity and management of access infections are exemplified in the scenarios below.

1. **Minor Surgical Trauma**: Erythema and warmth along the graft sometimes noticed early after surgery lasting for days, is not caused by infection. Redness around and at the incision site early after surgery is likely related to the amount of operative trauma, i.e. excessive use of electro-cautery. Antibiotics may not be prescribed.
2. **Localized Erythema (< 1 cm):** Associated with infection around needle puncture sites. Empiric antibiotic coverage as suggested above. This site must not be used for cannulation and progress monitored closely. This scenario often precedes significant infections as outlined below.
3. **Small Fluctuant Mass (1-2 cm):** Non-pulsatile, without skin breakdown, drainage, fever or chills. Purulent material or hematoma cannot accurately be delineated by examination. An incision and drainage is indicated. Extensive dissection must be avoided, cultures taken, the content gently expressed and the wound packed with gauze. Wound care can be managed expectantly, even if a small segment of graft initially was exposed. Adjust antibiotics based upon culture results for this type of access infection and those to follow.
4. **Short Segment Access Infection (2-4 cm)**: Localized segment of erythema around a cannulation site with a history of spontaneous (pulsatile) bleeding requires surgical revision dictated by the clinical history, access anatomy and surgeons experience. Ultrasound (with the operating surgeon present) is a recommended to assess the extent of the infection and to guide surgical strategy.
5. **Long Segment Access Infection (4-10 cm)**: A longer segment of access involved in an infection is commonly associated with other local pathologic access processes, such as access stenosis, peri-access scarred tissue, hematomas, or pseudo-aneurysms from repeat cannulation trauma. Surgical strategies may include proximal and distal control with bypass grafting and excision of the infected segment.
6. **Full Length Graft Infection**: The most severe infection involves the entire access, usually a PTFE graft including the anastomoses. The most dangerous scenario is a pulsating and expanding hematoma or pseudoaneurysm. The patient is commonly septic with fever and chills or may just have positive blood cultures. Technically challenging cases occur when the anastomosis is high in the axilla or groin. Adequate proximal and distal arterial control includes exploration of the subclavian and iliac arteries, respectively. With more distal anastomotic sites the surgeon can utilize a sterile pressure-controlled tourniquet. At exploration the authors leave a short graft remnant (5-10 mm) at the arterial anastomoses covered with tissue. The majority of wounds will heal. Should infection recur, i.e. cutaneous fistula, a delayed vascular repair with removal of the entire graft remnant and artery repair is performed, now in a stable patient with less tissue inflammation.

Summary: Infected dialysis access can range from "cellulitis" that may represent post surgical reaction or trauma to completely engulfed in purulent fluid with anastomotic disruption requiring emergent operative intervention. The six scenarios represent a continuum of increasing severity requiring clinical judgment for the most optimal therapy choice.

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PAD Incidence in HD Patients

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All patients with End-Stage Renal Disease (ESRD) on dialysis are at increased risk for cardiovascular disease (1). In fact, cardiovascular disease (CVD) in its various manifestations (e.g. myocardial infarction, heart failure, stroke, lower extremity occlusive disease, amputations, etc.) is the leading cause of death in patients with ESRD, accounting for nearly 50% of deaths. (2)

After adjusting for age, gender, race, and diagnosis of diabetes, mortality from cardiovascular disease is far higher in patients with ESRD compared to the general population. (3) ESRD and cardiovascular disease have interlocking relationships and to not act as wholly independent processes. A 'synergy' exists whereby CVD can precipitate ESRD by virtue of damage to the blood vessels and kidneys from high blood pressure, circulating inflammatory factors, etc., and conversely, ESRD, arterial calcification, and the effects of its associated treatment, renal replacement therapy, or hemodialysis (HD), can be seen as a harbinger of CVD. This relationship is highly complex, involving both "traditional" and "non-traditional" CVD risk factors.

The 2005 report of the National Kidney Foundation Disease Outcomes Quality Initiative (DOQI) guidelines stresses these interactions and recommends aggressive CVD screening and treatment for all ESRD patients receiving HD (4). Several recent large-scale registry studies estimate that up to 60% of new ESRD patients have some manifestation of CVD (5). Likewise, The American Heart Association issued a statement in 2003 that recommended patients with ESRD be considered a "highest risk group" for subsequent cardiovascular disease events (6).

Like coronary causes of CVD, non-coronary causes of cardiovascular disease (e.g. lower extremity occlusive disease, cerebrovascular disease) are thought to be more prevalent in the ESRD population than among the general population, with estimates ranging from 4%-45% (depending on the definition and population studied) and are responsible for significant morbidity, disability, decrements in quality of life, and death (7).

As PAD is a strong predictor of cardiovascular mortality in the general and dialysis population, early diagnosis of PAD and aggressive medical therapy might improve cardiovascular survival in dialysis patients, but there are currently no randomized, controlled trials of any of the interventions for therapy of PAD in dialysis patients. Data is limited, as most trials of CVD treatments (e.g. lipid lowering medications, etc.) do not include people with chronic kidney disease or ESRD. Comprehensive reviews of the literature (8) indicating medical treatments of CVD (aspirin, statins and beta blockers) are underused in ESRD/HD patients and chronic kidney disease patients.

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Who's Responsible for Vascular Access Care in the Dialysis Patient? The Clinical Nephrologist

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Achieving optimal vascular access outcomes in hemodialysis patients requires close collaboration among nephrologists, access surgeons, radiologists, and dialysis nurses. The nephrologist follows the CKD patient longitudinally, determines the optimal timing of referral for access surgery, assesses suitability of access for cannulation, and refers the patient to the surgeon or radiologist because of non-maturation or access complications occurring after they are in use. The surgeon assesses the patient clinically and reviews the vascular mapping data to determine the optimal timing and location of vascular access placement. The surgeon may subsequently perform additional procedures to promote maturation of immature fistulas or intervene to treat access complications, including refractory stenosis or thrombosis, pseudoaneurysms, and infections. The radiologist performs preoperative vascular mapping, postoperative imaging of immature fistulas, and intervention to salvage immature fistulas or treat stenosed or thrombosed vascular accesses. Finally, the dialysis nurse educates patients about access care, assesses fistula maturation, identifies access complications, and determines the timing and strategy for cannulation of new fistulas. **The patient is best served when all these disciplines communicate effectively, and is poorly served when there are ongoing "turf battles"**. An access coordinator is the ideal person to facilitate communication among these disciplines.

What about specific access-related decisions?

1. *Who determines the timing of access placement in pre-dialysis patients?* Clearly, the nephrologist has the necessary training and long-term relationship with the CKD patient to determine the optimal timing for vascular access placement.

2. *Who should decide the type of access to be placed?* Notwithstanding the simplistic Fistula First guidelines, this is a complex decision that requires consideration of the likelihood of fistula non-maturation, previous access history, whether the patient is catheter-dependent, and the patient's life expectancy. This decision is straightforward in some patients, but should entail discussion by the nephrologist and surgeon regarding complex patients.

3. *Who decides when the fistula is cannulated?* Experienced dialysis nurses, in consultation with the patient's nephrologist or the unit's medical director, should make that determination. **It is unreasonable for the access surgeon to insist on a personal stamp of approval for access cannulation**. However, when there is uncertainty about the fistula maturity, the surgeon will frequently be involved in assessing and revising the fistula.

4. *What happens if the dialysis nurse has trouble cannulating an immature fistula?* **The blame game should be avoided in this situation**. It is not productive for the surgeon to blame the dialysis nurse for poor can-

nulation skills. Rather, the emphasis should be on revising the fistula so it is easier to cannulate. Imaging studies frequently identify potentially remediable problems, such as juxta-anastomotic stenosis or large accessory veins. Such abnormalities would prompt referral to the surgeon or interventional radiologist for specific interventions to promote maturation.

5. *Who refers the patients for an access problem?* Fistulas and grafts frequently develop complications during their use, which may include stenosis, thrombosis, pseudoaneurysms, and infection. The dialysis nurse usually identifies these problems and alerts the nephrologist. Such patients should be referred to the access surgeon or interventional radiologist, as indicated.

A Vascular Specialist: Who is Responsible for Vascular Disease Care in the Dialysis Patient

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I have a strong bias that the vascular surgeon should be very involved in the management of cardiovascular disease in dialysis patients. Nearly all dialysis patients will need the care of an access surgeon (who is commonly a vascular surgeon) during their lifetime. This creates a unique window of opportunity to evaluate, investigate, and intervene on cardiovascular disease for this very fragile patient population. It is clear that cardiovascular disease dominates the accelerated morbidity and mortality rates of this population.

Vascular surgeons are uniquely equipped to identify and intervene on many aspects of this problem for these patients. We commonly assess medical comorbidities as they relate to the acceleration of cardiovascular disease. We do medical management, run noninvasive vascular labs, offer long term surveillance, and can perform both minimally and maximally invasive procedures to correct vascular problems. We commonly refer patients on to cardiologists for further evaluation and treatment of cardiac disease, many times only noticed because of investigation into vascular disease.

Dialysis patients are frequently unable to see many different specialists for several different visits because of the logistics of life sustaining dialysis and often exhausted social and family networks making simple transportation incredibly difficult.

As vascular surgeons caring for dialysis patients, simple maneuvers such as good history taking, reviewing medication lists, examination for carotid bruits, removing shoes to look at the feet and evaluate the blood flow, and referral on to a cardiologist when appropriate can have a great impact in terms of reducing amputations and prolonging life. Our patients need it desperately. As vascular surgeons, we can deliver and should do so, for the benefit of the patients.

Cardiac Function in the ESRD Patient

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Cardiac dysfunction, most commonly manifested as congestive heart failure, is common in patients with end stage renal disease (ESRD), both in patients with progressive renal dysfunction and in patients undergoing hemodialysis and peritoneal dialysis. As renal function declines and dialysis is considered, approximately two-thirds of patients will have a diagnosis of congestive heart failure (1). In addition to the volume overload and difficulties with diuretic dosing that occurs in progressive renal disease, deterioration in cardiac function, as measured by assessments of left ventricular dysfunction, are frequently observed. In addition to traditional cardiac risk factors, other risk factors are known to play a role in the cardiac

function decline seen in uremia (2). Known changes seen in uremic patients with cardiac dysfunction include progression of coronary atherosclerosis, microvascular disease in which the growth of capillaries fails to keep pace with the degree of developing left ventricular hypertrophy and the development of coronary artery endothelial dysfunction. Numerous abnormalities at the cellular level have been described including increased sympathetic activity, abnormal cardiac myocyte signaling, abnormal contractile function and increased cardiac cell death. Further evidence for a role of uremic mediators of cardiac dysfunction is that correction of a uremic state by renal transplantation can result in resolution of systolic dysfunction, partial regression of left ventricular hypertrophy, and an improvement in left ventricular dilatation (3).

While symptoms of congestive heart failure are often the reason for initiating dialysis, patients treated with chronic dialysis are also at risk for developing cardiac dysfunction. While progression of atherosclerosis leading to systolic dysfunction is known in dialysis patients, the extent of morbidity and mortality observed in ESRD patients is higher than can be accounted for by accelerated atherosclerosis alone. Hemodialysis has been shown to be an independent risk factor for the development of heart failure. One cause of progressive cardiac dysfunction is dialysis-induced myocardial ischemia, known to be associated with reductions in systolic function and patient survival. Whether assessed with continuous ST segment monitoring or by regional wall motion abnormalities by echocardiography, asymptomatic ischemia during hemodialysis is well-documented and may lead not only to stunned myocardium, but permanent left ventricular dysfunction (4). Similarly, cardiac troponins may be elevated during dialysis and higher levels of troponins are associated with increased mortality. In addition to repetitive ischemic injury, high-flow vascular access has been shown to lead to high-output heart failure in select patients with normal systolic function, due to a cascade of events in which decreased peripheral vascular resistance leads to compensatory increases in cardiac filling pressures, left ventricular dilatation and systolic dysfunction(5). Thus, while dialysis may be helpful in managing many patients with end stage renal disease and concurrent congestive heart failure, many dialysis patients may develop heart failure as a result of chronic dialysis.

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Good Flow in an AV Access is Detrimental to the Heart in the ESRD Patient

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Mortality in hemodialysis patients averages 15-20% a year and almost half are due to cardiovascular disease. Also, heart failure occurs in 25-50% of dialysis patients. Myocardial ischemia and ventricular arrhythmias are frequently observed. Longer term dialysis can lead to calcific valvular heart disease and infective endocarditis. These rates of cardiovascular mortality and morbidity are staggering when compared to those observed in other diseases. Either hemodialysis causes cardiovascular disease or markedly accelerates it or both.

Hemodialysis is often associated with perturbations in blood pressure. Elevated blood pressure can

lead to left ventricular hypertrophy, diastolic dysfunction and heart failure with normal systolic dysfunction. Many hemodialysis patients have high cardiac output due to anemia, hypoalbuminemia and their arteriovenous fistula. The necessity for high cardiac output increases myocardial demand and can sometimes lead to high output heart failure. In 20-30% of hemodialysis patients hypotension is observed especially during dialysis. Hypotention can lead to myocardial ischemia, especially in patients with underlying coronary artery disease or left ventricular hypertrophy. Repeated injury to the left ventricle due to hypotension can lead to an ischemic cardiomyopathy and heart failure. Thus, hemodialysis is associated with all three types of heart failure: systolic, diastolic and high output.

Hypotension associated with hemodialysis is a predictor of mortality probably because of reduced coronary blood flow and myocardial ischemia (1). ECG ST wave depression typical of myocardial ischemia has been observed in 15-40% of hemodialysis episodes and TC 99 sestamibi imaging has shown transient myocardial perfusion defects during hemodialysis. Also, left ventricular wall motion abnormalities have been observed during hemodialysis by echocardiography. Ischemia is more likely if anemia and high cardiac output are present. Elevations in troponin blood levels have been observed and such elevations predict an increased incidence of cardiovascular events (2).

Atherosclerosis is often present in hemodialysis patients. Many have underlying risk factors for atherosclerotic cardiovascular disease (ASCVD) such as diabetes, dyslipidemia and hypertension that antedate hemodialysis. In those without antecedent vascular disease it is unclear whether hemodialysis can cause ASCVD, but there are several abnormalities observed in hemodialysis patients that could contribute to the initiation or aggravation of ASCVD. Increased tissue calcium deposition is one example. Also, hemodialysis induces a chronic inflammatory state as exemplified by elevated CRP levels (3). We know that inflammation is an important factor in ASCVD. Interestingly, statin therapy does not have the same beneficial effect in atherosclerosis associated with hemodialysis, suggesting that cholesterol has less to do with this form of ASCVD and other factors associated with hemodialysis such as elevated calcium levels and chronic inflammation are more important (4).

The final common pathway of cardiovascular mortality is often ventricular arrhythmias. Patients on hemodialysis with implantable defibrillators in place have been observed to have more appropriate shocks than those patients not on hemodialysis. This could be due to hypotension induced myocardial ischemia or some toxic effect of hemodialysis itself (5). Hemodialysis factors that could induce or sustain lethal arrhythmias include metabolic perturbations in serum sodium, potassium, magnesium, calcium and pH. Thus, hemodialysis can probably induce arrhythmias de novo and contribute to their genesis in patients with underlying heart disease.

Calcific valvular heart disease can be observed in chronic hemodialysis patients. Calcification of the mitral and aortic annuli are often observed and eventually this calcification extends into the valve leaflets and can cause significant obstruction or regurgitation. Valvular heart disease can lead to infective endocarditis and heart failure.

In summary, it is clear that hemodialysis patients have a higher mortality than would be expected for their comorbidities if they were not on hemodialysis. Almost half of this mortality can be explained by cardiovascular disease. The mortality of those with cardiovascular disease is also higher in hemodialysis patients as compared to those not on hemodialysis with similar cardiovascular disease severity. Some patients develop a unique form of vascular disease on hemodialysis that is unresponsive to the usual risk factor control such as lowering blood pressure and LDL cholesterol. Vascular disease coupled with repeated episodes of hemodialysis induced hypotension can lead to an ischemic cardiomyopathy and heart failure. Hemodialysis associated hypertension and valvular disease and a high output state can also lead to heart failure. Metabolic perturbations in hemodialysis patients especially in those with cardiac disease can lead to fatal arrhythmias. Thus, hemodialysis through a variety of mechanisms can cause or aggravate cardiac and vascular disease.

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Good Flow in an AV Access is Not Detrimental to the Cardiac Function in ESRD Patients

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Congestive heart failure is a leading cause of morbidity and mortality is patients receiving chronic hemodialysis. While many heart failure patients receiving hemodialysis have heart failure due to systolic dysfunction from coronary artery disease or chronic hypertension, other patients may have heart failure in the setting of preserved left ventricular function. In these patients, high-output heart failure due to a high-flow arteriovenous fistula is often considered as part of the differential diagnosis.

High-output heart failure is traditionally described as a cardiac output > than 8 liters/minute or a cardiac index > 3.9 l/min/m^2. The primary physiological disturbance in high-output heart failure is reduced systemic vascular resistance(1), due to arteriovenous shunting or peripheral vasodilatation. Initial responses to these alterations include sympathetic neural activation, a compensatory rise in cardiac output and neurohormonal activation. All these perturbations lead to an increase in blood volume and subsequent rises in right atrial, pulmonary artery and left-ventricular end-diastolic pressures. These pressures rise until myocardial decomposition occurs, followed by left ventricular dilatation and/or hypertrophy, a decline in the left ventricular ejection fraction and ultimately, symptoms of congestive heart failure. While AV accesses have clearly been shown to lower peripheral vascular resistance and can initiate the cascade leading to high-output heart failure (2), this phenomenon is likely multifactorial in most dialysis patients and not due entirely to the physiology induced by the AV fistula (3). Other etiologies of high-output heart failure include chronic anemia and obesity, common in many dialysis patients. In addition, left ventricular hypertrophy, an initial compensation mechanism to the increases blood volume, may be attenuated in patients with preexisting hypertension-induced left ventricular hypertrophy and these patients may proceed directly to LV dilatation and heart failure.

While several case reports and small series have shown reversal or improvement of high-output heart failure with AV access ligation or modification, the relationships between access blood flow, development of heart failure symptoms and mortality are far from defined. Recently, Al-Ghonaim at al (4) retrospectively studied a large series of patients with measured access blood flow and found no difference in mortality in intermediate term follow-up of patients with very high (>2500 ml/min) or very low (<250 ml/min) access flows as compared with patients with flows of 500-1000 ml/min. Those observations correlate with observations in other clinical scenarios where similarly sized shunts are unlikely to lead to pulmonary hypertension or heart failure. In summary, high-output heart failure due to high AV access flow may certainly occur, however heart failure in most patients receiving chronic hemodialysis is multifactorial and a careful evaluation of contributing etiologies should be undertaken before ascribing symptoms to a high-flow AV access.

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Chronic Rhythm Management Devices and Leads

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Cardiac rhythm devices use has been the rise over the last two decades. While their benefits are well documented, their use has brought new challenges. One of these challenges is lead induced central venous stenosis (CVS). In a prospective study, Da Costa et al evaluated 229 patients (1). These investigators found that angiograms were abnormal in 64% of the patients. However, only 5.2% of these patients developed symtoms (edema and PE). In contrast, patiens with dialysis vascular access develop symtoms related to their central venous stenosis at a higher percentage (2). In one study, over 70% of the patients with dialysis Access developed sympotoms of central venous stenosis due to pacemaker leads (2).

Historically, treatment of lead induced CVS has been challenging. One option was to ligate the access to control the symptoms related to CVS (2). While the strategy was successfull in controlling symptoms it resulted in the loss of patient's lifeline and limited their future possibilities of receiving an access in the same arm.

Other option was to plan the access on the contralateral side of the device (2). While this approach gives a temporary solution it has its limitation as SVC is a common path and the development of stenosis at that level is not rare. Additionally cardiac devics leads will result in eliminating the other extremity as a possible site for future access.

Lead retrieval followed by angioplasty and stent placement and then placement of the leads through the stent has also been advocated (3). This approach require CT surgeon or electrophysiologist to be present for the lead retrieval and placement procedures. The procedure carries its own risks and complications. Importantly, stenosis can recur within the stent, before or right after the stent and elsewhere within hte central veins. Although technically achievable, it would be difficult to carry out the same procedure of removing the leads, performing angioplasty, inserting a stent and inserting the leads again.

A fourth approach was to perform angioplasty with stent placement entrapping the leads (4). This approach carries significant controvercy with it as there is a class I (level of evidence C) recommendation to retreive lead when stent is indicated to avoid entrapment of the leads (5).

Angioplasty alone has been a standard appraoch for the treatment of stenosis anywhere within the vacualr access circuit including the central veins (6). In a multicenter, retrospective study of pacemaker lead induced central venous stenosis, 28 patients were studied (6). The primary patency rates were 18% and 9% at 6 and 12 months, respectively. However, the secondary patency rates were 95%, 86%, and 73% at 6, 12, and 24 months, respectively. On average, only 2.1 procedures / year were required to maintain secondary patency.

It is important to note that epicardial cardiac rhythm devices do not use the endovascular route for lead placement and bypass the risk of central venous stenois altogether. This might be an alternative appraoch for chronic kidney disease patients stage 4, 5 and end stage renal disease patients on dialysis. We have have successully converted a series of cases from endovascular devices to epicardial ones (7). This can be considered in patients who have recurrent stenosis (less 3 months), infected endocardial system or may be as a new start for these spectrum of patients mentioned above. Epicardial leads also avoid the risk of tricuspid regurgitation.

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Don't Ever Stent Over that Lead!

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Cardiac rhythm device lead induced central venous stenosis is a common finding (1). One controversial approach that has been considered for the treatment of lead-induced central venous stenosis is percutaneous balloon angioplasty with stent placement. However, this approach can lead to entrapment of the leads. It is important to mention that Heart Rhythm Society recommends retrieving leads if stent placement is indicated (class I, level of evidence C) (2). One important reason for this recommendation is that lead retrieval will be problematic if it is entraped by a stent. There are several indications for lead removal. One important indication is cardiac rhythm device lead infections. This can happen in up to 5.7% (3). Renal patients have a higher risk of bacteremia. Hence, lead and stent infection are major issues that need to be considered in this population.

Because it bypasses the above-cited problems, angioplasty alone remains the preferred approach for treatment of cardiac rhythm device lead induced central venous stenosis with acceptable patency rates (4). Removal of the existing device and leads can be considered with placement of an Epicardial device in the event of frequently recurring lesions (less than 3 months) or elastic recoil. An endovascular stent insertion can then be considered. A major advantage of an Epicardial device is the preservation of central veins for a very well needed arteriovenous dialysis vascular access (5).

Preservation of venous real estate is critically important in dialysis dependent patients. In this context, epicardial devices might be considered as a primary procedure when indicated in dialysis patients.

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Controversies in Management of Central Vein Stenosis associated with Cardiac Rhythm Management Device (CRMD) Leads: There are Times to Stent Over That Lead!

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Hemodialysis patients with a transvenous CRMD and ipsilateral arteriovenous access are at risk for developing venous hypertension due to central vein stenosis or occlusion combined with high-flow venous return from the shunt. Optimally this situation would be avoided by careful selection of patients for CRMD implantation, thorough pre-operative vein mapping, and coordination between the vascular access surgeon, electrophysiologist, and nephrologist. Nevertheless, in the "real world" we continue to see patients afflicted by this complication ranging from mild nuisance swelling to extreme venous hypertension severe enough to limit limb and/or access function. Options for management of CRMD-associated central vein stenosis include:

1. Percutaneous angioplasty of the central veins as necessary to control symptoms and maintain access function (1)
2. Ligation of the ipsilateral access and construction of new AV access in the contralateral limb or leg, or conversion to peritoneal dialysis
3. "Banding" of high-flow AV access to reduce venous return
4. Surgical bypass to internal jugular vein or contralateral central vein
5. Observation, elevation, compression; "hope" for collateral veins to develop and relieve venous hypertension
6. Extraction of CRMD leads, PTA, stenting, replacement of CRMD leads through stent
7. Removal of CRMD leads without replacement if indications for device are marginal
8. Removal of CRMD leads and replacement via alternative route, e.g. femoral or epicardial
9. PTA and Stenting of lesion leaving CRMD leads in place

Each of these options has particular advantages and disadvantages. Some are relatively simple, benign, and inexpensive; others involve considerable risk, morbidity, and/or expense. Selecting the most appropriate solution for an individual patient requires careful consideration of multiple factors including: The quality of the current AV access; alternative AV access options; potential for long-term survival based upon age & co-morbid conditions (including nursing home status); skill and experience of available practitioners. Overall, hemodialysis patients exhibit extremely high mortality with expected five-year survival of 40% (2), likely worse in elderly ESRD patients with serious heart disease warranting a CRMD. Comparatively, colon cancer five-year survival is 59-66%, substantially more favorable than ESRD. Thus the goals of therapy must be appropriate for ESRD patients and outcome expectations established accordingly.

We have reported the use of stents while leaving CRMD leads in place (3). Fourteen patients with CRMD-associated CV stenosis (two) or occlusion (twelve) and ipsilateral AV access refractory to PTA were treated with stents or stent-grafts over a five year period. At six and twelve months respectively primary patency rates were 45.5% and 9.0%; primary-assisted patency 90.9% and 80.0%; secondary patency 100% and 90.0%. There were 42 repeat interventions performed in 12 patients; five received additional stents at the target lesion. The mean number of subsequent interventions was 3.2 per patient (2.1 per patient-year). All subsequent CRMD testing demonstrated normal function with no device or lead failure. Seven of 14 subjects died resulting in a 35.3% annual mortality. No deaths were attributable to CRMD dysfunction or lead infection and no patient required CRMD removal or exchange.

The Heart Rhythm Society guidelines advise against stenting central vein stenosis with CRMD leads in place due to potential for complications associated with future lead extraction when/if required for management of infection (4). This recommendation is based upon the authors' opinion, but is not substantiated by any reference, case report, or study. There is no mention of ESRD patients or AV access in this paper and it is not evident that there was any consideration for the unique circumstances of ESRD patients with AV access. Although we have heard reports of serious infectious complications related to entrapped CRMD leads (personal communications; Arif Asif, Miami, FL; Bruce Koplan, Boston, MA), there are no publications describing complications associated with stenting over CRMD leads, nor the solutions employed or outcomes achieved; thus the true incidence and consequences of these complications is unknown. What-

ever the rate of this complication, it must be weighed against the very real and immediate risk of CRMD lead extraction which is associated with mortality of 0.8% (5) when performed in major study centers, likely higher in common community practice. Furthermore ESRD patients are poorly represented in most studies of lead extraction making it difficult to accurately assess risks and morbidity of this procedure in this higher risk population.

Stenting of central vein stenosis with CRMD leads in place should be considered for selected ESRD patients who have an otherwise high-quality ipsilateral AV access (preferably an autologous fistula), poor alternatives for new AV access in the contralateral limb, and limited life expectancy based upon advanced age and co-morbid conditions. Our study has shown that this can be done safely with acceptable long-term patency, no impact on CRMD function, and no significant infectious complications. Critics of this approach will claim that these patients are placed at high risk for serious morbidity or death if they develop future infection of entrapped CRMD leads. However this risk must be weighed against the very real "up-front" risk of subjecting all these patients to much more invasive and morbid lead extraction/replacement in order to reduce potential for future complications which may never occur.

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The Achilles Heel, Toe, and Floor of AVG's: What Causes AVG Venous Anastomotic Stenosis?

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Arteriovenous PTFE dialysis access grafts are the second most common form of dialysis access in the United States (1). Although relatively easy to place and cannulate, dialysis access grafts have significant problems with stenosis primarily at the graft-vein anastomosis (2, 3). We have previously described that stenosis at the graft-vein anastomosis comprises an aggressive neointimal hyperplasia which is made up of primarily of smooth muscle cells and myofibroblasts (4, 5).

What are the factors that are responsible for stenosis at the graft-vein anastomosis? They include surgical injury, hemodynamic stressors, the graft itself, which generates a foreign body macrophage giant cell reaction and underlying endothelial dysfunction (3).

Despite these problems, we believe that PTFE dialysis access grafts remain the ideal clinical setting for the testing out and application of local therapies. Reasons for this include distance from vital organs, easy access to both our patients and their grafts at the time of surgery and during thrice weekly dialysis sessions and the ability to apply local therapies at the time of surgery. The latter is particularly relevant in that there are currently ongoing clinical studies of cell based, gene and chemical therapies for the prevention of PTFE dialysis access graft stenosis.

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What We've Learned from the Dialysis Access Consortium Regarding AVG's

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Arteriovenous grafts (AVG) have fairly poor longevity, with a median cumulative survival of only about 2 years. AVG are prone to recurrent stenosis and thrombosis, requiring multiple angioplasties, surgical revisions, and thrombectomies to maintain their patency for dialysis. Ultimately, most grafts fail due to irreversible thrombosis (1). We know that thrombosed AVGs almost always have an underlying stenosis, most commonly at the venous anastomosis. Moreover, hemodynamically significant stenosis can usually be identified by non-invasive surveillance methods, such as access flow monitoring or duplex ultrasound. Observational studies have reported substantial decreases in AVG thrombosis in dialysis centers after implementing a program of stenosis surveillance with preemptive angioplasty. However, the majority of randomized clinical trials did not find a difference in the frequency of AVG thrombosis between patients with surveillance and preemptive angioplasty and control patients (2).

The lack of benefit of preemptive angioplasty may be due to the rapid restenosis, which occurs in up to 40% of patients within one month of balloon angioplasty. Stents, by providing a rigid scaffold to keep the vessel open, may improve AVG patency after angioplasty. A recent randomized clinical trial compared covered stents to balloon angioplasty for management of AVG with venous anastomotic stenosis (3). Although graft stents significantly improved primary AVG patency at 6 months, they did not decrease the frequency of AVG thrombosis.

In summary, treating AVG stenosis and thrombosis as a "plumbing issue" is not satisfactory. AVG stenosis is due to aggressive neointimal hyperplasia (4). A pharmacologic approach that prevents neointimal hyperplasia may be more effective in improving AVG outcomes. Dipyridamole inhibits proliferation of vascular smooth muscle cell in vitro. A small, single-center double-blinded randomized clinical trial found that dipyridamole, with or without aspirin, decreased graft thrombosis by 40-50% (5). The Dialysis Access Consortium (DAC) graft study was designed to evaluate whether a combination of extended release dipyridamole plus low dose aspirin (Aggrenox®) would improve primary AVG patency (6).

This was a double-blinded, multi-center clinical trial, in which 649 patients with a new AVG were randomized to receive dipyridamole + aspirin or placebo. Patient enrollment occurred over 4.5 years, with an additional 6 months of followup (7). The primary endpoint was unassisted patency (AVG patency without thrombosis or intervention), and the secondary endpoint was cumulative AVG failure. The two randomized groups were well matched in their clinical characteristics and co-morbidities. Unassisted AVG patency at 1 year was 23% in the active drug group vs 18% in the placebo group (hazard ratio, 0.82; 95% CI, 0.68-0.98, P=0.03). Cumulative graft survival was 22.5 months, and did not differ significantly between the groups. In summary, dipyridamole + aspirin improved primary AVG patency, but the benefit was fairly modest

(equivalent to ~6 weeks of additional patency). Moreover, this drug regimen did not prolong cumulative graft survival. Nevertheless, this is the first pharmacologic intervention shown to improve AVG outcomes, and provides hope for additional pharmacologic interventions in the future.

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What is Being Done to Improve AVG Primary and Cumulative Patency Rates?

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Improvement in AVG primary and cumulative patency rates has been the goal since Baker's ePtfe paper in 1976. Addressing the development of venous outflow stenosis has been the hallmark for research into this field. This research has been divided into five basic categories: Geometric changes in the graft material to alter turbulence at the venous anastomosis, Changes in graft material to reduce compliance mismatch or to allow for endotheliazation into the graft thereby reducing intimal hyperplasia, placing wraps or pharmacologic alteration to the venous anastomosis in order to reduce intimal hyperplasia and lastly, altering the lining of the graft material to reduce graft thrombosis, reduce platelet adhesion with the hope to reduce the development of outflow stenosis.

Geometric Changes: Two basic concepts have been developed and studied to look at changes in the configuration of the graft in hopes to reduce turbulent blood flow and thereby reducing intimal hyperplasia. One is the development of the hooded graft concept developed by Schultz. This is presently sold as the Venoflo graft. Numerous studies have failed to show significant improvement in graft patency with this hooded concept. Only one small study from the Mayo Clinic demonstrated improved patency with the Venoflo graft in the upper arm position when compared to standard ePtfe grafts. Several large multicenter studies both in the United States and Europe failed to show significant improvement in patency rates with this hooded graft design. Another graft, the Swirl graft, is an ePTFE graft that creates a "swirling "effect of the blood flow and reduces laminar turbulent flow. In a large, prospective, randomized, multicenter study, with one year follow-up, there was no significant difference in patency rates with either the standard graft or the Swirl graft.

ePTFE has been the standard graft material for hemodialysis for nearly 35 years. Different materials have been used but improvement in patency rates has not been achieved with 12 month primary patency rates being around 42%. Materials ranging from Bovine mesenteric vein to polyurethanureas have not achieved significant improvement in primary patency. Two new graft concepts have been recently developed and

one is in study now in Europe and South America. This graft developed by Nanovasc has a biologic matrix that encourages epithelization of the graft and therefore in animal models has demonstrated a marked reduction in intimal hyperplasia. Another company, Humacyte is developing another graft for dialysis that also has a human extracellular matrix material. Human implants have not been performed as of yet.
Several different pharmacologic and genetic alteration materials are also being studied in hopes to reduce intimal hyperplasia at the venous anastomosis. These include a Sirolomus wrap which is in phase one study showing evidence of improvement of patency rates, Tirana which is in phase Three study using veg F as a genetic modulator in reducing the development of intimal hyperplasia; Pervasis which is a study that using allogenic aortic endothelial cells as a wrap that emits NO and other materials that also reduces initimal hyperplasia, and Proteon study which uses a recombinant elastase to reduced the elastin at the venous limb in hopes again to reduce the development of venous stenosis.
Lastly, changes in the inner liner layer of the ePTFE graft have also been studied in hopes to improve patency rates of the ePTFE graft. Two concepts are presently being used, carbon and heparin. In several large multicenter studies, Carbon has not been shown to significantly improve primary patency rates of the graft material. The use of heparin coating is presently being studied by multiple researchers. Definitive improvement in patency rates in AVG has not yet been shown. Several single center studies have demonstrated mixed outcomes in patency rates in grafts with heparin coating compared to standard ePTFE grafts.
Research continues in hopes to improve outcomes in AVG patency rates. Finding the key to reduce intimal hyperplasia is basic in obtaining marked improvement in outcomes in patency rates.

Fact: PTA Unless a Covered Stent Is Needed

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Superficially it would seem that the opposite consideration to PTA unless a covered stent is needed would be the use of a covered stent even if not needed. However, this is undoubtedly not the issue. The concern is using a stent routinely following an angioplasty of a dialysis access. In considering this issue, it seems that one should keep in mind the fact that as physicians we have a dual obligation and responsibility. Firstly, to our patients we have an obligation to do what is best medical practice for their welfare. Secondly, because of the extremely high cost of medical care in the United States, we have a responsibility to practice medicine in a prudent, conservative, cost-effective manner.
The routine use of a stent following angioplasty of the dialysis access represents a departure from accepted and recommended medical indications. When considering whether or not this new indication is reasonable or not there are several issues that should be addressed: 1) is the treatment effective, 2) are there alternatives, 3) how does the treatment compare to alternatives and 4) does the value gained via the treatment justify the costs?
There are three accepted indications for stenting: 1) acute PTA failure, 2) rapid recurrence of a lesion and 3) vessel rupture (1). The last of these is a salvage procedure which does work. Although one could raise questions concerning it, we will not consider it further. The former two are maintenance procedures. When the question effectiveness of therapy is critically analyzed, one is left without an answer. There is a great deal of anecdotal data, but very few randomized controlled studies. Additionally, when one compares the patency rates for stent usage with what is reported (also without benefit of randomized controlled studies) for angioplasty alone, there is complete total overlap. It is important to keep in mind that stent studies for the most part are performed on angioplasty failures and therefore represent a different population of patients than angioplasty studies. This confounding variable makes a true assessment of the value of stenting even more remote.
Recently a randomized controlled study of stenting using a unique covered stent (Flair) was reported (2). This report is touted as providing definitive data to confirm the value of routine stenting following angioplasty. However, a review of this report reveals problems that call the authors conclusions into question. Additionally, if the cost of treatment in this study is calculated based upon patients benefitted, the cost is unacceptably high.

Fistula First Breakthrough Initiative, commonly referred to simply as Fistula First, recommends that emphasis be placed upon the creation of secondary fistulas (Change Concept 6) in those patients with synthetic grafts (3). This appears to be the prudent, conservative cost-effective way to provide our patients with the best quality of medical care. Unfortunately, the placement of a stent can adversely affect the creation of a secondary fistula.

When the available data is reviewed and the obligatory goals of the physician are considered, there does not appear to be any place for the routine use of stents following angioplasty. Further, the use of any stent to preserve synthetic graft function in the dialysis patient is questionable.

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AVG Cannulation "Pseudoaneurysms"- My Approach

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Pseudoaneurysms of AV cannulation sites encompass evaluating:

- The probability of rupture
- Presence of outflow stenosis
- Skin integrity

Prior to implant of the AV graft for access the individual patient should be evaluated for his or her propensity to develop pseudoaneurysms. Individuals prone to develop pseudoaneurysms are those exhibiting the following characteristics:

- Very high blood pressure
- Poor outflow vein
- Thin skin syndrome
- "Short" AV grafts
- Type of AV graft material
- Prior history

The utilization of a multilayer pTFE graft or polyurethane graft diminishes psuedoaneurysm formation in those patients who have very high blood pressures or thin skin syndrome. Utilization of the axillary vein, not the basilic, affords the surgeon a much better outflow vein. Long straight segments of AV graft placement provide the clinic personnel with a much better "target" for cannulation, "clean sticks", and areas for cannulation rotation.

In the event a psuedoaneurysm does occur, observation and diagnostic/therapeutic interventions may be necessary. In the absence of impending rupture or rapid progressive increase in size, the AV graft can be cannulated by using sites on the side of the pseudoaneursym as well as other areas of the AV graft. It is prudent to do an angiogram to evaluate for outflow stenosis and plan for possible interposition AV graft or other access. Selective use of stent grafts with cannulation through the stent graft can be an alternative management strategy.

7th Annual Controversies in Dialysis Access - San Francisco, USA - October 28-29, 2010

Controversies in the Treatment of AV Graft Cannulation Pseudoaneurysms: Covered Stents When Possible

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A true aneurysm contains all three layers of the vascular wall; the intima, media, and adventitia. Such is the case with congenital arterial aneurysms, atherosclerotic aneurysms, and aneurysms associated with vasculitis and collagen vascular diseases. In contradistinction to a true aneurysm, a pseudoaneurysm is a focal vascular dilatation that may contain one or two layers of the vascular wall but is more often confined by neointimal or fibrous tissue.

Pseudoaneurysms are often associated with well-worn hemodialysis grafts and their development is due to the concurrence of several events including: 1) degradation of the PTFE graft material, 2) insufficient hemostasis of a cannulation site, and 3) the presence of a hemodynamically significant stenosis downstream from the cannulation site. Inadequate compression of a cannulation site can lead to persistent bleeding and the formation of a perigraft hematoma. The coexistence of a distal stenosis can increase intragraft pressure, force blood into the perigraft hematoma, and create a persistent communication between the hematoma and graft lumen. Continued bidirectional blood flow leads to the formation of a perigraft cavity or pseudoaneurysm.

Progressive enlargement of a pseudoaneurysm can compromise the integrity of the overlying skin and thereby increase the risk of vascular rupture and catastrophic hemorrhage. The National Kidney Foundation's 2006 K/DOQI Clinical Practice Guidelines for Vascular Access recommends surgical revision of a pseudoaneurysm which has the following characteristics.

1) rapidly expanding in size, 2) exceeds twice the diameter of the graft, 3) threatens the viability of the overlying skin, or 4) is infected (1). Pseudoaneurysms are a common long-term complication of both prosthetic grafts and autogenous fistulas and most do not require immediate treatment. However, the integrity of the overlying skin should be closely monitored. Appropriate sites for needle insertion and cannulation technique should be discussed with the staff at the patient's hemodialysis treatment center. Any increase in size of a pseudoaneurysm or "herald bleeding" should be cause for concern and prompt reevaluation.

Insertion of a stent graft can provide an effective treatment of an enlarging pseudoaneurysm. A stent graft provides an occlusive fabric patch which effectively seals the pseudoaneurysm and prevents further enlargement. The endoluminal radial force exerted by the stent graft can resist extrinsic compression by a perivascular hematoma and thereby maintain blood flow through the vascular access. Furthermore, as the underlying vascular injury heals the fabric layer serves as a barrier to encroachment of neointimal hyperplasia.

Insertion of a stent graft provides a simple, percutaneous method to repair a vascular access-related pseudoaneurysm. The concept is similar to the use of stent grafts for repair of abdominal aortic aneurysms; a tubular graft is percutaneously inserted and deployed across an aneurysmal or damaged segment of a vascular access. This technique is also similar to surgical revision in that the pseudoaneurysm is excluded and replaced by a new segment of PTFE graft material. Although this procedure has not yet gained widespread acceptance for management of chronic pseudoaneurysms, it is a valuable technique which can be used for rapid treatment of acute pseudoaneurysms caused by a cannulation-induced tear to a graft or fistula.

The use of stent grafts for treatment of vascular access-related pseudoaneurysms has been previously reported (2-9). The majority of these publications describe the use of the Wallgraft in case reports or small series of patients. However, the Wallgraft has been associated with an inflammatory response and is no longer the stent graft of choice for these procedures. Vesely described the use of the Viabahn stent graft for treatment of eleven patients with hemodialysis graft-related pseudoaneurysms and reported primary patency rates of 71% at three months and 20% at six months (6).

Current stent grafts are not designed to withstand repeated needle puncture. Cannulation of a stent graft with a large diameter needle can damage the underlying metal framework which supports the Dacron or PTFE fabric layer. Although several studies have reported the long-term durability of current stent grafts, a new stent graft design is needed for this specific application.

Several investigators have recommended that the stent graft should not be cannulated for 2 – 4 weeks following deployment (3, 6, 8). As is customary with surgically implanted PTFE hemodialysis grafts, a one

month delay before use allows incorporation of the graft material into the surrounding subcutaneous tissue. The development of a dense fibrous tissue layer around the graft inhibits perigraft bleeding following removal of the hemodialysis needles. Although speculative, a similar process may occur following percutaneous insertion of a stent graft to treat a pseudoaneurysm. If the stent graft is tightly sealed, thereby stopping blood flow into the pseudoaneurysm, the thrombus contained within the excluded pseudoaneurysm should undergo retraction and fibrosis thereby creating a protective, fibrotic layer along the external surface of the stent graft.

The experience of other investigators has demonstrated that the stent graft can be utilized for needle cannulation within several days after placement (5, 9). Lin et al. created an experimental model in dogs to assess the durability of the Wallgraft following repeated needle puncture (9). Using color-flow Doppler ultrasound these investigators demonstrated transient perigraft leaks following removal of the needles but these leaks were no longer detectable after 24 hours.

In summary, previous publications have substantiated the "proof of concept" for use of a stent graft to treat an enlarging pseudoaneurysm but as of yet there is no strong clinical evidence to support widespread adoption of this percutaneous technique in lieu of surgical revision.

Early cannulation of a stent graft remains an unanswered question. The conservative approach is to wait 30 days following insertion before utilizing the stent graft segment for needle insertion. Future improvements in stent graft design and materials may provide us with a more durable device for this application.

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Graft Pseudoaneurysms – Surgery is the Gold Standard

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Graft pseudoaneurysms occur as a result of interruption of the integrity of the luminal surface, with subsequent leak of the circulating blood into subcutaneous tissue planes. The surrounding response then limits the spread of the flow with a fibrotic response, creating the wall of the pseudoaneurysm. The development of these dilations is frequently associated with a venous outflow stenosis. This narrowing of the outflow results in increased intragraft pressure which tends to propagate the extra-graft flow. Repair of the pseudoaneurysm should be done for specific indications which include rapid growth, overlying skin compromise, or symptoms including pain or rarely emboli. Surgical repair addresses the underlying problems. First, the pseudoaneurysm and the effected graft can be addressed concurrently. The wall and aneurysm can be

excised, leading to a simple graft excision and interposition graft. The effected skin can also be excised further, taking that issue out of the equation, resulting in new cannulation sites and an improved cosmetic result. Second, at the same setting, a durable repair to an outflow stenosis can be accomplished. Third, surgery does not require placement of expensive covered stents, usually having to be applied in an off-label procedure.

How Bad is the Problem of Central Vein Obstruction in the Dialysis Population?

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Obstruction of central veins (CVD) in hemodialysis (HD) patients is a frequent and worrisome problem. Most cases of superior vena cava (SVC) syndrome are caused by metastatic pulmonary or mediastinal malignancy. The use of temporary HD catheters placed in the internal jugular or subclavian veins is known to be a major predisposing factor. These patients normally are asymptomatic unless a functioning fistula has been placed in one of the upper limbs; in these cases, the limb on the side of the fistula will appear swollen, and puncture of the fistula will soon become impossible. The feasibility of establishing permanent HD access may be compromised when there is obstruction from thrombosis or stenosis in the SVC and/or the subclavian veins. The problem becomes more serious in morbidly obese patients or those with diabetes or severe peripheral vascular disease.

The incidence of CVD amongst renal patients has been estimated between 25 and 40% in the literature. There is a strong association with the placement of central venous catheters reaching a very high 50% for those who have had a subclavian catheter inserted in their past medical history.

The risk factors are now well identified: multiple insertions of large catheters with long dwell times specifically on the left hand side and with a very high risk if inserted via the subclavian route rather than the internal jugular vein.

It could be asymptomatic but in 50% of cases patients will develop a large edema with collateral circulation appearing on the chest or the upper back.

The access could then become tortuous and aneurysmal and the inflow drops thus reducing the quality of dialysis adequacy. The last symptom is recirculation but usually the problem should have been detected and treated before hand.

Treatments involve either a simple surveillance or a more proactive attitude with multiple options.

Endovascular, with angioplasty with or without stent, the latter could be covered in certain indications where recoil is very likely.

Surgical with creation of a new access on the contralateral limb and ligation of the one on the side of the obstruction once the new one is ready for use in case of unilateral CVD, jump grafts or extra anatomical grafts or exotic native fistulae in case of complete SVC obstruction.

We will examine the features and treatments of this very common condition in the dialysis population.

Fact: A National Strategy to Avoid Catheters

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Although the problems associated with the use of central venous catheters is well know and extensively documented, their excessive use continues. Currently, approximately 70% of patients start hemodialysis with a catheter. Some have a peripheral access awaiting development, but the catheter is there and often remains for prolonged periods of time. The reasons for this problem are multifactorial. A significant number

of patients, present needing immediate dialysis and never having seen a nephrologist. Some patients have an unexpectedly rapid progression of their renal failure. Other patients have a fistula placed, but it does not mature quickly enough (or ever) to allow for its use at the initiation of dialysis.

We have had a national strategy to decrease catheter use, commonly referred to as "Fistula First" in place since January 2003. This initiative has been very successful in many ways, but has not solved this problem. An excessively large number of patients are still starting dialysis with a catheter. It is time that we give serious consideration to a national strategy with a slightly different focus, a national strategy to avoid catheters.

A careful examination of the problem will lead one to conclude that such a strategy is possible and would have a significant impact. At least two candidates for changes in patient management should be considered: 1) establishing a 30-20-10 rule for access placement and 2) the use of a peritoneal dialysis catheter as an alternative to a central venous catheter.

The renal function in most patients with chronic kidney disease who progress to end-stage follows a slowly declining curve. By monitoring this cure, key actions directed toward vascular access should be triggered by specific levels of renal function. When the glomerular function rate (GFR) reaches 30, a carefully structured plan of patient and family education should be initiated. This should be formal and organized. It should have a number of components related to dialysis, one of which should be dialysis access appropriate for the type of dialysis that is planned. When the GFR reaches 20, the patient should have vascular mapping immediately followed by fistula placement, if hemodialysis is to be the modality used. At a GFR or 10, the patient should be started on the dialysis that has been planned.

Except is cases with an unexpectedly rapid deterioration, this should give time for the creation and the maturation (including salvage procedures) of a useable fistula at the initiation of dialysis. There would undoubtedly be cases in whom a fistula may be created long before it is needed and some in whom an access is placed that is never used. However, an unused fistula is certainly a better alternative than a catheter.

Peritoneal dialysis (PD) is a modality that has been under utilized in the United States. The use of a temporary PD catheter to deliver short term PD as an alternative to the use of a central venous catheter is a novel idea that has not been realized on any wide spread basis. A PD catheter has several features that recommend it for this application. It can be easily placed as an out-patient; although not usually done, it can be used immediately and it is not associated with the dire complications that characterize central venous catheter use.

A PD catheter is an attractive alternative for use in those patients in whom a fistula cannot be developed (scheduled, placed, and matured) prior to the initiation of dialysis. In view of the complications associated with the usual approach to these cases, it should be considered. We have the ability to do better for our patients and they deserve it. The time for a new national strategy directed not at reducing catheters, but avoiding them has come.

Treat the Stenosis Before Surgery or Consider a Graft-catheter

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In hemodialysis patients, critical central venous stenoses and obstructed central veins precipitate repeat interventions and access failures. In such cases, a decision must be made to attempt to treat the obstructive stenosis with established procedures and preserve the access, or to place a graft-catheter (HeRO device).

The traditional treatment for central vein occlusions has been angioplasty, or angioplasty with uncovered nitinol stent placement in cases of elastic recoil. Stents were generally sized to a diameter slightly larger than the vessel lumen (1). However, this technique has yielded a 3-month primary patency of 56-67% and in many instances have caused occlusion were only stenoses previously existed (2-4). In our outpatient vascular access center, we recognized the complications of treating central veins in this manner and have developed a new treatment protocol. Two concentric stents are placed, with a size equal to the lumen diameter expected following elastic recoil. The presence of an additional stent provides the radial force necessary to resist extrinsic compression and elastic recoil from the thick walls of central veins.

A retrospective study of hemodialysis patients with recurrent central venous stenosis was performed. Pa-

tients were included if they were treated for central venous stenosis treated with two concentric uncovered nitinol stents. Seven patients were found to have been treated in this way. Indications included arm swelling (*n* = 3), breast swelling (*n* = 1), access thrombosis (*n* = 2), and new access evaluation (*n* = 1). Three patients were female, the average patient age was 65, and accesses included 3 fistulas, 3 grafts and 1 catheter. All lesions were related to prior central venous catheter placement. Stenoses were treated at the subclavian vein (*n* = 6), brachiocephalic vein (*n* = 6), and superior vena cava (*n* = 3); all stenoses were ipsilateral to the vascular access. All patients had patent central veins on follow-up (average = 5.2 months; range = 1–13.3 months). The arteriovenous accesses were preserved and the patient with a catheter had successful creation of a fistula.

By contrast, placement of a Hemodialysis Reliable Outflow (HeRO) device almost certainly precludes future ipsilateral access placement. The HeRO device is a combination of an inflow PTFE graft and an outflow catheter that is inserted into the right atrium, allowing for central venous occlusions to be bypassed. In the past 4 years, several clinical studies of the HeRO device have been conducted, yielding results that compare favorably to that of ordinary grafts. Although the primary patency of the HeRO graft-catheter is relatively low (33-36% at 12 months), its thrombosis, bacteremia rates, and 12-month secondary patency are comparable to that of arteriovenous grafts (70-78% vs. 48-88%, respectively) (5-8).

Although this is a relatively small patient cohort, the results of our approach are promising. Fistulas have a superior durability, lower infection rate, and lower rate of interventions than both HeRO devices and grafts (8). Therefore, if such central venous occlusions are amenable to endovascular techniques, attempts should be made to establish a patent access circuit and create a native vein fistula.

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Place the AV Access and Worry About the Obstruction if it's a Problem

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The incidence of CVD amongst renal patients has been estimated between 25 and 40% in the literature. There is a strong association with the placement of central venous catheters reaching a very high 50% for those who have had a subclavian catheter inserted in their past medical history.

The risk factors are now well identified: multiple insertions of large catheters with long dwell times specifically on the left hand side and with a very high risk if inserted via the subclavian route rather than the internal jugular vein.

The vast majority of central venous obstruction (CVD) or stenoses are asymptomatic in patients who do not have a surgically created vascular access on the same side. It becomes symptomatic in only 50% of the patients once the access is up and running and in use. Although it is estimated that between 25 and 40% of patients who have had a centrally inserted catheter will develop CVD, it is very unlikely that any preemp-

tive patient would present such a feature.
It is clearly demonstrated that CVD patients when becoming symptomatic, require a proactive attitude. That could be surveillance and monitoring as long as the symptoms are not too debilitating and dialysis is adequate or angioplasty, stenting or surgery in the other presentations. It is clear that even if symptomatic not all patients will require a rescue or a change of vascular access. There is no means at the moment to predict which patient will become very symptomatic in case of CVD, venograms or ultrasound scans although quite good to visualize the collateral circulation fail to establish whether it will be sufficient to avoid any symptoms and their consequences on dialysis adequacy.
When a patient is referred for their fistula formation, even if they have been dialyzed through a catheter it does therefore not seem logical to multiply tests to establish whether the central veins are patent or not.
When a good clinical examination allows siting a good vein and artery what is then the point asking for further ultrasound scan or venogram? We advocate to operate on the patient and it is only in case of symptoms of CVD that we recommend to explore central venous patency further.
If a well conducted clinical examination was poor then an ultrasound scan should help precising the anatomy and could for no extra cost precise central veins patency.
We do not feel that there is any clinical or economical justification to always check on the central veins prior to performing a vascular access for hemodialyis.

The Swollen Arm (Due to Central Venous Obstruction on the Same Side as a Functional AV Access Circuit): What We Know and don't Know

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We know that …
1. Central venous obstruction in hemodialysis patients is largely due to use of central venous devices such as temporary and permanent hemodialysis catheters, PICC lines, pacemakers, and vascular access devices such as tunneled central lines and mediports (1). The 2009 United States Renal Data Survey reports that central venous catheter prevalence in dialysis patients was approximately 28%, and more than 80% of patients have a central catheter during initiation of hemodialysis (2). There are also extrinsic causes of central vein obstruction such as Paget-Schroetter Syndrome (subclavian vein) and extrinsic compression of the left brachiocephalic vein (3).
2. Central venous obstruction can be silent or can lead to debilitating edema of the arm, chest/breast, neck, or face. Silent central venous obstruction should rarely be treated (4).
3. Treatment of symptomatic central venous obstructions is imperfect, with about 20-30% of angioplasty procedures failing to adequately treat the obstruction (5, 6). When successful, angioplasty has poor primary 1-year patency in the range of 15-30%, and 1-year cumulative patency of approximately 50% (1, 5-7).
4. Stents improve the technical outcome following angioplasty, but have poor primary patency, with many reports citing one year primary patency with a reported range of 14-73%, and a cumulative patency around 50% (1). Most data is of marginal quality, typically single center and retrospective. Most symptomatic central venous obstruction will require repeated intervention to alleviate symptoms (1, 5-7).
5. Balloon expandable stents should not be used routinely to treat central venous obstruction due to the potential for deformation (crush) and migration, especially in the subclavian veins and left brachiocephalic vein (8, 9).

We don't know …

1. If central vein obstruction should be treated before or after creation of AV access on that side.
2. If symptoms will improve, worsen, or remain the same over time if left alone.
3. If there is a symptomatic difference or treatment patency difference for stenosis versus occlusion.
4. If subclavian vein obstructions are worse than brachiocephalic ones, or if combined lesions are worse.
5. When central vein obstruction in hemodialysis patients is partly or completely due to Paget-Schroetter

Syndrome or left brachiocephalic vein extrinsic venous compression.
6. How to measure the role of AV access flow on arm swelling and when to reduce flow versus treat the obstruction.
7. How to measure the effectiveness of collaterals.
8. Which central vein PTA procedures will fail early and require stenting.
9. If stents grafts offer a more durable solution than bare metal stents.
10. What to do with stenoses related to endovenous subclavian pacemaker/ICD leads when PTA fails.
11. When to use a graft-catheter (HeRO) rather than primarily treat the obstruction.

Percutaneous Techniques for Reconstruction of the Occluded Central Vein

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"To stent or not to stent?" Is that really the only question?
The most difficult portion of the procedure with a central vein occlusion is not the question of whether or not stent placement is needed; it is really, "how do I get across the lesion." We have all had the patients in our practice who become the "venous cripples" or those that have no other sites for access since all of their veins are occluded. This is not only the patient with the upper arm fistula/graft presenting with arm swelling, but it also includes those patients who have no other access options and receive dialysis via a catheter, often times a femoral catheter. Becoming technically competent at crossing chronic occlusions is one of the most important aspects of caring for these patients.
Very frequently, the lesion is not a complete occlusion, but rather a high-grade stenosis. These lesions that have a "beaked" appearance with a small lumen of vein connecting the segments are crossed and treated with a high degree of success in most centers. Although controversy exists, most feel these high grade stenoses are best initially treated with angioplasty alone, reserving stent placement for those that fail angioplasty or those with early recurrence of lesions (< 3 months), or in those rare cases of rupture. Clinically significant rupture or perforation of the central veins is uncommon. Small wire perforations when trying to cross occlusions happen frequently. Once a wire perforation occurs, it is very difficult to find another path to cross the lesion. Terminating the procedure and then trying again on another day, is a very useful approach. Care must be taken when a wire perforation is suspected to not perform a vigorous injection of contrast at the site, as this can contribute to the development of a mediastinal hematoma. One must also be very aware of the extent of the pericardial reflection along the superior vena cava. A wire perforation within the superior vena cava can rapidly cause pericardial tamponade.
Multiple access sites are very helpful with difficult chronic occlusions. If the lesion is on a curve, such as the junction of the right subclavian and innominate vein, access from the right internal jugular vein and/or femoral vein is very helpful. If the graft or fistula drains via the cephalic vein, and the lesion is in the subclavian, access from the brachial or basilic vein is helpful since it keeps the lesion more directly in line to facilitate wire and catheter pushability. Sharp recanalization is another technique that can be used for difficult occlusions. Once two access sites have been established and the catheters can be lined up in at least 2 different views, a needle can be passed from one site, puncturing through the occlusion, allowing a wire to be passed and retrieved from the other access site. Often times, if the occluded segment is straight, this can be accomplished with the stiff end of a wire, performing a short thrust to puncture at the site of occlusion. Once again, all of these techniques are made more difficult if the occlusion spans a curved segment.
After the occlusion has been crossed with a wire, placement of a stiff wire to facilitate further passage of balloons is very helpful. Placement of a long sheath is also helpful and the sheath and dilator can be used to help dilate particularly difficult lesions. For very tight occlusions in which the sheath will not pass, initial dilatation with a small caliber balloon can be helpful with sequential dilatation to a final diameter of 10-12 mm. Remember, prolonged inflation within the superior vena cava may be poorly tolerated by some patients, possible due to increased intracranial venous pressure. The patient may complain of headache and other discomfort, which should prompt releasing the pressure in the balloon.

Once the lesion has been crossed and treated with angioplasty, then the question becomes to stent or not. Indications for stent placement include greater than 30% residual stenosis, recurrence of the lesion in less that 3 months or rupture. There are no randomized controlled studies comparing PTA alone to stent placement in central vein occlusions. Data on bare metal stents show very high technical success rates with 3-month primary patency rates from 63-100% and cumulative patency rates 72-100%. At 12 months, these fall to 14-73% and 31-91%, for primary and cumulative patency rates. There is no data at this time that supports the superiority of the routine use of stents over PTA.

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Surgical Techniques of Central Vein Reconstruction

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Surgical reconstruction of central veins is reserved for patients who fail less invasive means of relieving venous outflow obstruction. The concept is not new (1) and the popularity of these procedures has largely waned due to effectiveness of endovascular techniques and the HERO™ device.

The algorithm we employ depends on whether the patient has a functioning access with central venous occlusion and venous hypertension or has need for access creation. For patients with venous hypertension, failure of less invasive means leads directly to central venous reconstruction. Need for access creation is more complicated and depends on whether the patient has a good fistula option or not. If we anticipate that a good fistula can be created, then that is usually done at the same time as a central venous bypass. If the option is limited to a graft, we typically will not do that in concert with a central venous bypass but would instead consider the options of an all arterial access or an arterial to atrium graft.

Central venous bypasses follow the same surgical principles as other bypasses. Good vessel selection as inflow and outflow is crucial with good conduit in between. We have performed many different types of bypasses, but find that an axillary vein to right atrium bypass is the most straightforward and satisfying. An infraclavicular incision is created for the axillary vein dissection and an anterior thoracotomy is utilized for the right atrium. A 12 mm ringed PTFE graft provides the best fit in most patients.

Brachial to atrial grafts are performed in a similar fashion. The atrium is exposed with an anterior thoracotomy and the brachial artery with standard techniques. We prefer an 8 mm ringed PTFE graft and create a taper at the arterial anastomosis to reduce the likelihood of both clotting and steal.

Because of the magnitude of these procedures, caution is recommended. Careful review of venograms and other access options is crucial along with a frank discussion of the procedural risks with the patient. Like other surgical procedures, careful patient selection, careful planning, and careful execution can lead to successful outcomes.

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The Emperor's New Clothes? Are the Effects of Catheter Coatings and Surface Treatments Visible?

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The substantial morbidity associated with catheter-related infection and thrombosis continues to limit the use of tunneled catheters as long-term vascular access for hemodialysis. However, recent developments in catheter surface coatings may decrease the incidence of these complications and thereby improve the acceptance of central venous catheters as a suitable long-term vascular access.

The pathogenesis of catheter-related infections is complex, multifactorial, and continues to be a topic of intense research. Catheter infections are the result of a sequence of events that begins with contamination of the catheter surfaces, followed by bacterial colonization, and the subsequent development of a biofilm layer (1). The initiating event can be caused by bacterial skin flora that gain access to the external surface of the catheter at the time of insertion or by bacteria that migrate from the skin surface onto the catheter once it is in position. Alternatively, the internal surfaces of a catheter can become contaminated with bacteria by frequent manipulation of the catheter hub or by hematogenous spread from another source. With knowledge of these mechanisms for bacterial contamination, it is imperative that bioactive surface coatings be applied to both the internal and external surfaces of a long-term (tunneled) hemodialysis catheter.

Antimicrobial Surface Coatings

Antimicrobial surface coatings inhibit bacterial attachment and thereby prevent biofilm formation and catheter-associated infection (1). Antimicrobial surface coatings have been available on short-term central venous catheters for more than ten years and these devices have been well-tested in the critical care environment. Numerous studies have demonstrated the cost-effectiveness of antimicrobial coated catheters for short-term applications and the Centers for Disease Control recommends there use in selected patients (2).

The duration of intravascular catheter placement is another important determinant for catheter-related infection (3). Colonization of the external surface of a catheter is the most common source of infection during the first ten days after catheter placement. Colonization of the internal (luminal) surfaces of the catheter, likely due to contamination of the hub, predominates after 30 days of catheter placement. Unfortunately, the first generation of antimicrobial coated catheters was effective for only 7-10 days; the chemical coating leached into the blood or surrounding tissues, decreasing the local concentration of the agent, thereby diminishing its antimicrobial activity. Newer generation antimicrobial surface coatings have demonstrated sustained bioactivity for up to 30 days duration.

Antithrombotic Surface Coatings

There is a causal relationship between thrombosis and infection; it is believed that the presence of pericatheter thrombus will predispose a catheter to subsequent infection (4). Antithrombotic surface coatings have been shown to decrease the deposition of plasma proteins and platelets onto the surface of intravascular devices and thereby inhibit the early stages of catheter-related infection. In addition, antithrombotic surface coatings may prevent catheter occlusion due to intraluminal thrombus formation.

Jain et al. performed a retrospective review to compare the outcomes of 89 patients with heparin coated tunneled hemodialysis catheters to 86 patients with non-coated tunneled hemodialysis catheters (5). These investigators reported a decreased rate of catheter-related bacteremia in patients who had the heparin coated catheters (34% vs. 60%) but the rate of catheter malfunction was similar. In this study the cumulative catheter survival for the two study groups was also similar. Clark et al performed a similar retrospective study comparing the outcomes of 50 patients with heparin coated tunneled hemodialysis catheters to 38 patients with non-coated tunneled hemodialysis catheters (6). These investigators reported no differences in the rates of catheter-related infection, catheter function, or catheter patency between these two groups. The rate of infection for heparin-coated catheters was 0.08 per 100 catheter days and for non-coated catheters was 0.14 per 100 catheter days ($p = 0.23$).

In summary, antimicrobial surface coatings have proven to decrease the incidence of catheter-related infection in the critical care environment but the long-term effectiveness of these antimicrobial coatings have not yet been demonstrated. There is a paucity of clinical information regarding the value of antithrombotic surface coatings on central venous catheters and the available data is discordant. It's evident that a multicenter, prospective clinical trial with enrollment of a large number of patients (>500) will be necessary to determine the benefits of these new surface technologies.

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The Controversies in Catheter Coatings. Do Biologically Active Catheters Represent an Advance? WE ARE STILL NOT SURE

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Infection remains a major problem in hemodialysis patients treated with central venous catheters (1), determining significant complications (sepsis, osteomielylitis, death, need for catheter exchange). Numerous strategies have been employed to reduce the occurrence of infection and improve longterm outcomes, with varying degrees of success. One approach is coating the external surface of catheters with antimicrobic substances (antibiotics, antisepics), rendering them biologically active. Heparin coating has also been tested.

Silver coating. In a landmark study (2) published in 1998, probably the first randomized study in the field, Trerotola and collaborators aimed at determining whether silver-coated tunneled hemodialysis catheters reduce infection. 91 patients were randomly assigned to a treatment (silver-coated catheter; n = 47) or control (identical catheter without silver coating; n = 44) arm. With a mean catheter duration of 92 days, infection occurred in 11 patients (five in the treatment group, six in the control group). In addition, silver-coated catheters in two (4%) patients were removed due to reaction to the coating. Therefore, they concluded that silver coating does not confer a benefit against clinical infection or colonization. Despite results of the previous study, catheters whose external surface is coated with silver using physical vapor deposition processes are still on the market.

Some experimental and some non randomized clinical studies investigating the effects of silver-coated dialysis catheters concluded that silver coatings can reduce bacterial colonization and occurrence of infection associated with these devices (3). However, often positive results were obtained in short term studies, while for long-term tunneled dialysis catheters the Trerotola RCT produced the best (negative) evidence available.

Bismuth coating. In a recent randomized, prospective, double-blinded trial (4) investigating the clinical value of bismuth-coated non-tunneled dialysis catheters in patients in need of temporary short-term vascular access, surface modification with bismuth film reduced bacterial colonization, but not infection rates. In addition, catheters were tested for only 15-20 days, thus giving little information on long-term outcomes. Moreover, bismuth has potential toxic effects such as cytotoxicity or neurotoxicity that may only be observed after treating a larger population.

Antibiotic coating. Given their high activity against Staphylococci, which are the leading cause of catheter-related bloodstream infections in hemodialysis patients, the efficacy of minocycline-rifampin-coated hemodialysis catheters in preventing catheter-related infections was tested in a randomized controlled trial in patients requiring hemodialysis for acute renal failure (5). This study demonstrated that coated catheters were less likely to be associated with infection, but mean catheter duration was very short, only 8 days.

Heparin Coating. Central venous catheter thrombosis and infection are often associated. In particular, the intraluminal thrombus may act as a nidus for the catheter biofilm, thereby increasing the risk of bacteremia. Notably, two short-term randomized clinical trials in hospitalized patients not on dialysis with nontunneled

central vein catheters found a lower risk of catheter-related bacteremia in patients with heparin coated catheters (6, 7). Thus, heparin coating of catheters may potentially reduce thrombosis and infection in tunneled dialysis catheters as well. This hypothesis was tested in a recent retrospective study (8), investigating the outcomes of 175 tunneled dialysis catheters placed in the internal jugular vein, including 89 heparin-coated catheters and 86 noncoated catheters. Heparin coating significantly decreased the frequency of catheter-related bacteremia (34 versus 60%) but it did not reduce the frequency of catheter malfunction. Thus, it is difficult to understand the mechanisms of the putative beneficial effects of heparin, if it is not related to a reduction in thrombosis rates. A randomized clinical trial is required to confirm this potential benefit of heparin coated dialysis catheters.

Conclusion. In the adult intensive care unit setting, there is evidence for short-term antimicrobial-coated central venous catheters in lowering rates of catheter-related bloodstream infections. A systematic review (9) of 34 clinical studies showed that externally impregnated chlorhexidine/silver sulfadiazine catheters reduce risk of infection relative to uncoated catheters (RR, 0.66; 95% CI: 0.47-0.93). Minocycline and rifampicin-coated catheters are significantly more effective relative to chlorhexidine/silver sulfadiazine catheters (RR, 0.12; 95% CI: 0.02-0.67). The new generation chlorhexidine/silver sulfadiazine catheters and silver, platinum, and carbon-coated catheters showed non-significant reductions in risk of infection compared with uncoated catheters.

However, in the hemodialysis setting, things may be quite different, especially for long-term, tunneled catheters (Tab. I). In a recent systematic review of antimicrobials for the prevention of haemodialysis catheter-related infections (10), antimicrobial coating of catheters or catheter components did not result in a significant reduction in the risk of catheter related bacteremia (three trials, 322 patients, RR 0.81, 95% CI 0.31–2.08), or exit site infection (two trials, 192 patients, RR 0.36, 95% CI 0.06–2.22) and catheter loss due to all complications (three trials, 322 patients, RR 1.29, 95% CI 0.87–1.91).

So, why we are still not sure that catheter coating is beneficial in dialysis? There are many factors that suggest caution: positive studies are all short term; studies in dialysis did not show clinically relevant advantages of coated catheters; we do not know if side effects of coatings are relevant (they might be, as suggested by Trerotola et al (x1998); infection rates are different in different Countries and even in different units within the same Country, and therefore coated catheters may be beneficial only in units with higher infection rates. We need more evidence in dialysis patients before switching to coated long-term tunnelled catheters.

TABLE I - TESTED SURFACE COATINGS IN CENTRAL VENOUS CATHETERS FOR HEMODIALYSIS

Author	Year, Journal	Type of HD CVC	Patients	Length	Coating	Outcome
Trerotola S	1998, Radiology	Tunneled	91	92 days	Silver	no effect
Schindler R	2010, NDT	Non-tunneled	77	15-18 days	Bismuth	lower bacterial colonization
Chatzinikolaou I	2003, Am J Med	Non-tunneled	130	8 days	Minocycline and rifampin	reduced infection
Jain G	2009, Clin JASN	Tunneled	175	150-170 days	Heparin	reduced bacteremia

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National Standards for Suspected Catheter Infection and Catheter Revision

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Standard - A technical standard is an established norm or requirement. It is usually a formal document that establishes uniform … technical criteria, methods, processes and practices. In contrast, a custom, convention, which becomes generally accepted and dominant is often called a *de facto* standard.
Standards can also be developed by groups such as trade unions, and … associations. Standards organizations often have more diverse input and usually develop voluntary standards: these might become mandatory if adopted by a government, business contract, etc. (Wikipedia)
There has been a recent impetus for developing national standards for central venous catheter related infections. This is based on the observation that the use of central venous catheters may cause as many as 80,000 bloodstream-related infections and 28,000 deaths in ICU patients annually in the US at an estimated cost of $2.3 billion. Subsequently, the Centers for Disease Control and Prevention (CDC) issued guidelines on the prevention of catheter-related bloodstream infections in 2002. These observations lead the Institute for Healthcare Improvement development of the "Central line bundle" of best evidence-based practices, which is a group of interventions for patients with intravascular central catheters. When the "central line bundle" of practices is implemented, it results in fewer central venous catheter related deaths (1).
The implementation of the "central line bundle" in 103 Michigan ICUs demonstrated a significant reduction (66%) in the rate of catheter-related bloodstream infections. These results suggested that the incidence of catheter-related bloodstream infections and their associated mortality and health care costs can be reduced in the ICU setting if implemented on a national basis. The end result has been that as of October 1, 2008, CMS no longer reimburses hospitals for the extra care required to treat hospital acquired catheter-related bloodstream infections (1, 2). This has the effect of establishing a national standard.
Since the publication of the first KDOQI Vascular access guidelines in 1997, several national and international organizations have published guideline re-commendations or "standards" for the management of catheter infection and to a lesser extent for the management of catheter dysfunction. KDOQI published an update of the vascular access guidelines in 2006 (3). Although more terse and less specific, the European Guidelines published in 2007 closely mirror the KDOQI vascular access guidelines. (4) The Infectious Disease of America (IDSA) updated their guidelines in 2009, however, the primary focus of these guidelines is on non-dialysis catheters; the guidelines do not specifically address how the general recommendations apply to hemodialysis catheters (5). In order to address this issue, the European Renal Best Practice group, which is the new organization of the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA), amended the IDSA guidelines to specifically focus on hemodialysis catheters. Vanholder et al. have recently summarized these guidelines (6).

A review of these different guidelines reveals enormous congruency. Although guidelines have not yet become "standards" within the Nephrology or Infectious Disease communities, there has been significant progress toward a consensus approach. Given the CMS mandate for hospital acquired catheter related infections and the high cost of catheter related infections with hemodialysis catheters, a similar mandate is likely.

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Is Heparin the Best Solution? Other Options for "Locking" Catheters

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The use of central venous catheters (CVCs) as permanent vascular access in hemodialysis patients is progressively growing in most Countries (1), despite the risks associated with CVC use in this patient population, compared to native AV access. Specifically, catheter use rose 1.5- to 3-fold among prevalent hemodialysis patients in many Countries from 1996 to 2007, even among non-diabetic patients. The percentage of patients dialyzing with a CVC 90 days after the start of dialysis has remained constant at about 50%.

CVCs carry an important risk for infections and inadequate dialysis due to flow problems, often associated with thrombosis. The locking solution of the CVC has been traditionally an anticoagulant, most commonly concentrated unfractionated heparin at 5000 IU/ml. However, in the past years many reports suggested the use of alternative anticoagulants (citrate) and/or antimicrobial locks (2). Due to a wide range of possible approaches, the American Society of Diagnostic and Interventional Nephrology (ASDIN) prepared a position paper on this issue (2). Based on available evidence, it appears that heparin 1000 U/ ml, or 4% sodium citrate are suitable choices for lock solution to maintain patency of tunnelled central venous catheters for dialysis. Risks from systemic anticoagulation are lower with heparin 1000 U/ ml and 4% sodium citrate, compared with higher concentrations of heparin (5000 and 10,000 U/ ml), which should be reserved for patients who have evidence of catheter occlusion or thrombosis when heparin is used
at 1000 U/ ml. Importantly, when heparin is used for catheter lock, the injected volume should not exceed the internal volume of the catheter (3) and even with the correct volume catheter lock solutions may exit from side holes at the catheter tip (4).

In Canada, observational studies found that 4% sodium citrate is as effective but more cost-efficient than concentrated heparin (5, 6). Specifically, a retrospective analysis (5) compared the outcomes of the year prior and after the conversion from heparin 10,000 U/ml locking to 4% sodium citrate. The rate of flow-related catheter exchange was not different during the two periods. Falsely elevated INR values were eliminated with citrate and the rate of rt-PA treatments was similar during the two periods. The number of bacteremias was similar during the two periods (0.77 vs 0.94 per 1000 catheter days). There was an 85% reduction in the costs associated with catheter-locking therapy during the citrate period. The results of this observational study led many dialysis unit to convert from concentrated heparin to 4% sodium citrate. Hendrickx et al (7). in a a small randomized study involving 19 patients, which compared heparin vs 4% sodium citrate in single lumen CVCVs, found different results, with

the citrate group having a higher incidence of CVC thrombosis.

At higher concentrations, sodium citrate has not only anticoagulant but also antibacterial properties. Trisodium citrate 30% has been shown in a randomized control trial to be an effective antimicrobial catheter locking solution, able to significantly reduce CVC-related bacteraemia in hemodialysis patients (8). Subsequently, similar results were found with 46.7% trisodium citrate, described as a safe, convenient and highly effective CVC locking solution, leading to significant reduction in CRB largely by preventing staphylococcal bloodstream infections (9). However, these data could not be reproduced by others in a randomized controlled trial of 46.7% trisodium citrate versus heparin in 232 patients (10), maybe because of a much lower baseline CVC related infection rate. CVC-related bacteremia did not differ in the 2 groups, with an incidence of 0.7 events/1,000 catheter-days. CVC thrombosis defined by the use of a urokinase lock was significantly more common in the citrate group, with an incidence of 8 versus 4.3/1,000 catheter-days. In addition, a greater incidence of adverse events was also reported in the same study, which has been related to overspill of concentrated citrate from the catheter tip (10). Concerns on the safety of concentrated citrate lock solutions have been expressed (11) after the FDA issued a specific warning in 2000 after a fatal accident, due to inappropriate over-injection, and the product was withdrawn from the market in the U.S.A.

In a population with a significantly higher baseline infection rate, Allon (12) demonstrated a positive effect of a lock solution containing taurolidine and citrate. Bacteremia-free survival at 90 days was higher among patients who received taurolidine-citrate than among control patients who received heparin (94% vs. 47%), but unassisted catheter patency (without tissue plasminogen activator instillation) was lower among patients who received taurolidine-citrate than among control patients (32% vs. 76%), thus indicating that the reduction of CVC-related bacteremia is associated with an increased requirement for thrombolytic interventions to maintain catheter patency.

Balestrino et (13) al used a concentrated (60%) ethanol based CVC lock solution, reporting interesting results on the eradication of bacteria embedded in the catheter biofilm, with a superior antimicrobial activity compared to a control group treated with 46.7% trisodium citrate.

Many studies have addressed the use of antibiotics mixed with anticoagulants. Labriola et al (14) summarized the results of prospective randomized studies in a meta-analysis. She concluded that the use of antimicrobial lock solutions reduces by about a factor 3

the risk of CVC-related bacteraemia in hemodialysis patients. However, they pointed out that the limited follow-up of the studies does not exclude the onset of adverse events or bacterial resistance with longer use of antimicrobial lock solutions.

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A Hybrid Graft/Catheter Device – Are We Smarter Now that We Have Used it for 2 Years?

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In May 2008, the FDA approved the use of a new device for hemoaccess. This device, now known as the HeRo device is composed of standard ePTFE graft attached to a silicone outflow component that reduces the need for a venous anastomosis. This device is primarily used in patients with central vein stenosis and those patients with history of multiple failed access grafts.

We have reported on the largest single center series using this device and the lessons learned. We have been able to learn from our mistakes and look at data in hopes to improve patency rates and outcomes. Optimization of use of this new device is paramount to its success.

From 2002 to 2006 there was a 58% increase in the number of patients with end-stage renal disease (ESRD) who depend on tunneled dialysis catheters (TDC) for hemodialysis (HD). This is in the face of recommendations from the National Kidney Foundation Kidney Dialysis Outcome Quality Initiative (KDOQI) for the preferential creation of autogenous dialysis access for these patients. This is a problem because TDC's are associated with increased infection and bacteremia rates which is one of the main causes of morbidity and a preventable cause of death in hemodialysis patients. As a result of this increasing frequency of TDC usage, over 40% of patients presenting for dialysis access have central vein obstruction which affect the long-term patency of further distal access sites. Moreover, TDC's are associated with poorer dialysis flow rates with less effective dialysis and frequent malfunctions compared to arteriovenous fistula and grafts.

A new device to circumvent these issues, the Hemodialysis Reliable Outflow (HeRO) Vascular Access Device, has been approved by the United States Food and Drug Administration (FDA) for the use in ESRD patients who have exhausted all other peripheral vascular access options. Two previous multicenter clinical trials have demonstrated that the device can be implanted with high technical success, low morbidity, and with patency, intervention, and bacteremia rates that were better than TDCs and comparable to conventional HD grafts. To date, there have been no reports on how to reduce complication rates or improve patency of this device. The purpose of this study is to determine factors which improve patency, reduce infection, and ultimately improve performance of the HeRO device.

This was a retrospective review of all HeRO device implantations by a single group from May 2008 to 2009. The criteria for device placement followed closely with FDA-approved guidelines, which included all patients older than 18 who were dependent on a TDC for hemodialysis or were currently undergoing dialysis through a poorly functioning arteriovenous fistula or graft. All patients had undergone previous vein mapping, venography, and/or upper extremity angiography and were found to have no other upper extremity arteriovenous access options. Patients were excluded from the study if there was known or suspected active infection, significant arterial insufficiency, ejection fraction 20%, systolic blood pressure > 200 mmHg, degenerative connective tissue disease, or known bleeding diathesis. The primary endpoints were infection rates, thrombotic complications, and patency. The study was designed to identify which factors which adversely affected the aforementioned outcomes. Secondary endpoints were morbidity and mortality. The study design and protocol was approved by the Institutional Review Board.

The definition of a HeRO device-related infection was the same as that used by the Centers for Disease

Control and Prevention for catheter-related bacteremia. This included the postoperative occurrence of at least one positive blood culture, one or more clinical manifestations of infection (e.g. fever, hypotension) and no other source of infection. Bacteremia data were calculated as a rate per 1000 HeRO days or catheter days as commonly used in the catheter literature. HeRO days were defined as the number of days from HeRO implantation to either removal, ligation, or death.

Statistical analyses were carried out using chi-square and student's t test and finally logistic regression analysis in order to determine which factors influenced patency rates, infection rates, and thrombotic complications.

A total of 42 procedures were performed yielding 40 successful implants (95%). One implant was removed after 6 hours due to upper extremity numbness and severe pain. A second procedure could not be done in a patient with refractory superior vena cava stenosis. After multiple attempts to angioplasty the stenoses, the procedure was aborted. The patient eventually required a thigh arteriovenous graft.

The mean age was 57.5 years and the study population was largely African American with almost half of patients with insulin-dependent diabetes. Over half were receiving dialysis through a femoral TDC prior to device implantation. In addition, the mean total number of dialysis catheters per patient was 7.2 prior to implantation. Sixty percent of patients had the device placed ipsilateral to the previous TDC. The device was also implanted over the wire through the same implantation site in almost a third of the population (32.5%).

A total of 8 HeRO device infections occurred over a mean follow-up of 8.9 months producing an overall device-related infection rate of 1.09 per 1000 catheter days. All infected devices were removed. Seven of these infections were in insulin-dependent diabetics (17.5% vs. 2.5%, p=0.007). The number of prior TDC's was very strong risk factor for device-related infections such that there were no infections in patients who received less than 5 previous TDC's (p=0.021). There was a trend toward increasing infection after placing the HeRO device at a site in an over-the-wire fashion through the previous TDC although this was not statistically significant (p=0.055).

There were a total of 21 thrombotic complications over 8.9 months of follow-up. Patients taking Plavix were less likely to develop device thrombosis such that there were no thrombotic complications in patients taking Plavix preoperatively (p=0.025). This protective affect was not seen in any other antiplatelet or anticoagulant medications. Again, only one patient who had less than 5 prior TDC developed a device thrombosis (p=0.005) illustrating the high risk of multiple TDCs on complications.

Overall primary patency was 42.5% over a mean 8.9 months. Secondary patency was 77%. Thirty day mortality was 13% no related to the procedure and one-year survival was 72.5%.

This study was designed to identify a subset of patients in an already high-risk population in which the HeRO device could be implanted with better patency, lower thrombotic complications, and decreased infection rates. All of the patients in the study were access-challenged with an average of over 7 TDCs per patient with over half of these in the femoral site. This is higher than other populations studied that were using the HeRO device. We have identified insulin-dependent diabetes mellitus as a risk factor in these high risk patients. In addition, prior TDC usage (≥ 5) also lead to increased infectious and thrombotic complications. Plavix was also the only medication providing a protective affect against device thrombosis.

In this high risk patient population, the HeRO device can be placed successfully with relatively low morbidity. Factors which may optimize performance of the HeRO device include the postoperative use of plavix, use of the device earlier in traditional dialysis access algorithms, and possibly the administration of broad spectrum antibiotics perioperatively.

These new algorithms are presently being used in our practice. We have seen a dramatic drop in the infection rate and an improvement in patency rates with adding Plavix to our regimine.

So, are we smarter now with 2 years experience. Of course we are! Are patients better off now with this device? The simple answer is YES!