2012 (9th Annual) Controversies in Dialysis Access (CiDA) and Simulation on Dialysis Access (SoDA) at the Palmer House, Chicago, IL

CiDA (and SoDA) are back, and in America's heartland. But what makes these two meetings unique and how will they be better than ever? The answer, in general, is that unlike any other dialysis access meeting, all dialysis access interests are equally represented at CiDA and SoDA. Neither meeting has any affiliation with an ESRD program, dialysis initiative, governing medical society, or university. Furthermore, CiDA and SoDA emulate the "best practice" of dialysis access, where success is not an isolated event in the operating room, the angio-suite, the nephrologist's office, or in the dialysis unit. This "best practice" is the result of a process summarized by the phrase "continuum of care," where patients move freely between 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 is the spirit of the 9th Annual CiDA meeting and its related SoDA session.

Though "continuum of care" in the practice of dialysis access sounds ideal, it is far from reality in 2012. As for inclusion of all professionals, we have much to learn from Doctors without Borders. When it comes to patient safety, we can once again look to the skies where the aviation industry has achieved an unprecedented safety record. When we consider "best practice," we must consider how to bridge the balkanization of medicine in America. Through CiDA and SoDA, we hope to move the dialysis access community a bit closer to seamless, safe, and effective care.

As for simulation of dialysis access, the SoDA half-day session features seven different experiences. There is a station called "The OR Cockpit" that is piloted by a commercial airline captain. During this experience, elements of aviation safety are juxtaposed with procedural dialysis access care. Other stations feature hands-on procedural simulation for vascular mapping, cannulation, central venous access, and catheter based intervention, as well as simulation of various situations where cognition and communication skills are assessed. Two examples of this type of situational simulation include PERCS (Program to Enhance Relational Communication Skills) and RCA (Root Cause Analysis).

CiDA will once again use a two-day format where didactic lectures, pro-con debates/discussions, and case presentations each account for about one third of the meeting, respectively. The biggest addition to the 9th Annual CiDA will be Live Cases on the second day, interspersed throughout the day's agenda. These cases will feature direct video feed and two-way audio discussion regarding techniques and judgment during surgical and catheter-based procedures. Through these live cases, CiDA attendees will experience the convergence of data-based medicine with the practical reality of real-time intra-procedural judgment. The crux of controversy in dialysis access lies at this convergence.

Beyond our sincere thanks to all of the professionals who attend CiDA and SoDA, we are deeply grateful to our sponsors and exhibitors for their generous support. New strategies and tools for dialysis access will be featured in the exhibit hall where a great deal of learning and professional interaction is guaranteed. Without the support of these sponsors the CiDA and SoDA meetings would not be possible.

Finally, we are indebted to the Journal of Vascular Access, through which we have again published the abstracts and meeting proceedings for both CiDA and SoDA. Every professional attendee should receive a copy of the Journal of Vascular Access SoDA-CiDA meeting issue. We hope you will agree that this is an extremely professional publication of the highest quality.

Finally, this year SoDA and CiDA are truly unique because it is the first time they are being held in the heartland of America. Although we want you to be present throughout the educational sessions, you must not miss the opportunity to see some of Chicago, considered by many to be the most "American" city in the US.

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The Simulation of Dialysis Access (SoDA) - Chicago IL, USA - October 10, 2012

Simulation of Dialysis Access (SoDA)

Surgical Simulation

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Procedural simulation continues a field in evolution. Education of medical students and residents has involved simulation of one level or another for many years. Knot tying is a good example of practicing a technical skill in preparation for participating in actual surgery. Suturing skills are often initiated on inanimate models as well. Advanced Trauma and Life Support (ATLS) is an intense simulation system to prepare surgeons and others to care for trauma victims using scenarios to coordinate teamwork and specific procedures, such as chest tube insertion and airway management.

Surgical simulation is being practiced for several endpoints including training, board certification, credentialing, maintenance of certification, and malpractice insurance premium discounts.

An enlightening article by Pandey et al (1), discovered that technical skill tested with standardized simulation did not correlate well with oral exam scores or reported surgical case logs in a group of candidates for European vascular surgery boards. Further, a follow up paper demonstrated that candidates self assessment of surgical skill was correlated poorly with the examiners' assessments (2). Surgical simulation in vascular surgery has been validated in a series of studies. Further validation of assessment of surgical skill by simulation was shown in a model of carotid endarterectomy demonstrating predictable differentiation of scores based on levels of previous training (3).

The European Board of Vascular Surgery has subsequently required demonstration with simulation of procedural skills for several years as part of board certification. In 2010, the American Board of Surgery, required Fundamentals of Laparoscopic Surgery (FLS) certification for initial board certification. The FLS certification process involves didactic and procedural training and ultimately an assessment module.

Credentialing at some facilities requires demonstration of technical skill by simulation, such as the endoscopy center at The Methodist Hospital in Houston. Carotid stenting also has been targeted with need for simulation prior to credentialing.

Maintenance of certification (MOC) has been enacted to try to ensure continued competence in multiple specialties by the American Board of Medical Specialties. Simulation plays a role in MOC for Anesthesia, Family Practice, and Interventional Cardiology. Although not specifically required, simulation fulfills requirements of ongoing education for these specialties.

Malpractice rates at various institutions including University of Kansas and and the Harvard system can both be reduced with participation in ongoing education and evaluation by simulation.

Clearly simulation is going to play a role in future surgical education, assessment of skils, and maintenance of ongoing skills. The potential benefit to patients, trainees, and practicing physicians is obvious. The real question will remain of how to best standardize and fund simulation in today's health economic environment to maximize its benefit and potential.

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Vascular Mapping for Hemodialysis Access: A Practical Algorithm

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Ultrasound (US) vessel mapping is an important element in constructing a successful vascular access for hemodialysis patients (1). Algorithms for US vascular mapping vary from detailed research protocols to more practical applications, ideally with the operating surgeon preforming the study or present for the examination (2). Below we describe a patient directed US vascular mapping protocol (Tab. I). Individual patient history and findings on physical examination are key elements in planning a successful vascular access and should be integrated with the US findings. Detailed descriptions of extremity vascular anatomy, and the technical application of US are presented elsewhere (3-5).

Surgical access options include over 20 possible surgical sites or procedures. The experienced clinician will quickly narrow these many possible access options scenarios to about 5 or 6 practical solutions. The surgeon's US examination narrows these choices to the most feasible opportunities, which are then presented and discussed with the patient. With this strategy there is rarely a procedure change made in the operating room.

The US examination starts with assessing the radial artery and the forearm cephalic vein. If neither has acceptable quality, the next level evaluated is the antecubital fossa. If the radial artery meets criteria and the cephalic vein is inadequate, the forearm basilic vein is assessed as a candidate for transposition with the distal radial artery as the inflow source. When no forearm options are possible, outflow into the upper arm is accessed. The presence and quality of the median cubital vein is determined, and its connection between the cephalic and the basilic vein systems in addition to the location of the v communicantes (deep communication vein), connecting the superficial venous system to the deep brachial veins is determined.

As the US probe is moved proximally along the medial aspect of the upper arm the presence of high arterial bifurcation is assessed, occurring in about 20% of cases. The larger (ulnar) artery is deeper than the more superficially located radial artery and should be used as inflow should the access be placed at this level. In case of two arteries, distal hand ischemia ("steal") may be avoided. The level of brachial artery bifurcation is noted along with the degree of arterial calcification.

The cephalic vein evaluation is continued from the antecubital fossa and followed along the upper arm to level of the shoulder. Record size and depth (less than 6 mm is recommended) to assess a needed cannulation length of at least 10-15 cm. Also, assess the distance between the cephalic vein and the brachial artery in order to plan the incision should a brachial-cephalic anastomosis be considered. The estimated size and the distances between the vascular structures and their anatomical relations at the fossa are important for planning any access surgery at the antecubital fossa. A hand drawn sketch of anatomy as a reminder or brief US mapping with site marking in the operating room is recommended.

Next the basilic vein is located above the elbow level. With great consistency the basilic vein branches 3-4 cm above the elbow joint. This branching is often useful as an end vein "patch" anastomosis to the brachial artery in cases of basilic vein transposition (6). The basilic vein often joins a brachial vein at any level along the upper arm. In such a case the brachial vein extension should be included in the transposition in order to achieve enough cannulation length of the transposed vein. This is especially important in the obese arm as vein length is "lost" coming out from the axilla and going back into the artery.

It is advisable to assess the risk for developing steal associated with a new dialysis access especially when using the distal brachial artery and in patients prone to ischemia (7). It can be done by the "Thumb Allen" test which involves measuring finger pressures while the radial and ulnar arteries are sequentially compressed. The authors use duplex color mode to assess the palmar arch vascular density.

Assess the subclavian vein as most patients have or have had dialysis catheter or pacemaker electric wires. The subclavian vein is assessed for cardiac pulsatility and respiratory phasicity to satisfy outflow needs. The loss of cardiac pulsatility and respiratory phasicity in the subclavian vein may represent a central vein stenosis; if in question a venogram of the central veins is indicated.

When no feasible upper extremity access sites are available, the lower extremity vessels are assessed for a possible saphenous or femoral vein transposition or a thigh lateral loop e-PTFE graft.

The decision of dialysis access mode, site and type is influenced by numerous factors including: Patient desire and comorbidity, life expectancy, ESRD stage and the decline of GFR over time, current mode of dialyzing, and the findings at US vascular mapping.

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TABLE I - SUMMARY GUIDELINES FOR TECHNOLOGIST PERFORMING AND REPORTING

I. Upper Extremity Vascular Mapping

Purpose: Determine size and patency of the veins and arteries of the upper extremities for dialysis access vascular suitability.

Patient Preparation

- Patient should be reclining with the arm extended to the side. A cold environment should be avoided.
- A tourniquet is used as indicated.
- Position the patient in supine position with slight head elevation to evaluate IJV and subclavian vein.

Technique

- Equipment gain and display settings is optimized while imaging vessels with respect to depth, dynamic range, and focal zones
- Color-flow Doppler images with proper color scale is used to demonstrate areas of high flow and color aliasing
- Spectral Doppler gains are set to allow a spectral window and optimized to reduce artifact
- Areas of stenosis or obstruction will include spectral Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction
- Sites of intervention will include spectral Doppler waveforms and velocity measurements from the proximal, mid, and distal sites
- Calcifications/Plaque are assessed and characterized
- An angle of 60 degrees or less is used to measure velocities
- Doppler angle must be parallel to the vessel wall
- Obtain AP measurements of the cephalic vein and basilic vein with a tourniquet
- The tourniquet is placed at the shoulder level; do not use in case of a working access or arm swelling
- Obtain skin depth measurements at all levels of the cephalic vein
- Document the level of (high) bifurcation of the brachial artery into the radial and ulnar vessels and their diameter at the antecubital fossa
- Document areas of vessel wall thickening, thrombus, or branches

Documentation

- **Arteries**
  - AP measurement of radial artery at wrist
  - Velocity/flow volume measurement of radial and ulnar arteries if stenosis is present
  - AP measurement of brachial artery at the antecubital fossa
  - Velocity/flow volume measurement of the brachial artery if stenosis is present
  - Longitudinal images with and without color

- **Cephalic Vein: AP measurements and skin depth**
  - Wrist
  - Mid Forearm
  - Proximal Forearm
  - Antecubital Fossa to include the median cephalic, median cubital, and deep communicating veins,
  - Mid Upper Arm
  - Upper Arm at the axilla

- **Basilic Vein: AP measurements**
  - Antecubital Fossa
  - Mid Upper Arm
  - Upper Arm at the axilla
  - Basilic /brachial vein confluence – if below the axilla
  - Forearm and upper basilic vein confluence

- **Neck veins**
  - Transverse with and without compression
  - Longitudinal with color and spectral Doppler

- **Subclavian Vein**
  - Longitudinal image at confluence
  - Spectral Doppler at innominate
  - Longitudinal mid subclavian with color and spectral Doppler
  - Longitudinal subclavian/cephalic confluence (lateral subclavian vein)

II. Evaluation of established hemo-access

Patient Preparation

- Patient recommended position is supine with arm relaxed and extended out to the side.
- Thigh dialysis accesses are examined in supine position.

Technique Considerations

- Equipment gain and display settings will be optimized while imaging vessels with respect to depth, dynamic range, and focal zones
- Color-flow Doppler images with proper color scale to demonstrate areas of high flow and color aliasing
- Spectral Doppler gains is set to allow a spectral window and optimized to reduce artifact
- Areas of suspected stenosis or obstruction will include spectral Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction
- Sites of intervention will include spectral Doppler waveforms and velocity measurements from the proximal, mid, and distal sites
- Plaque should be assessed and characterized
- An angle of 60 degrees or less is used to measure velocities
- Doppler angle must be parallel to the vessel wall
- Obtain 3 flow volume samples inflow and outflow; this should be taken at a site that is considered normal without stenosis or dilatation. A minimum of 3 waveforms must be included in measurement, open the sample gate to include the entire vessel, and set the mean trace above the baseline.
- Document the inflow artery, the outflow vein, and location of the fistula
- Document any fluid collections, and/or accessory branch/branches AP measurement and distance from the anastomosis
- Document the type of graft present i.e., loop or straight and the location of the graft
- If concerned for central vein stenosis or DVT, evaluate all central veins

Documentation

Native Vein Evaluation

- **Gray Scale and Color Flow Imaging**
  - Fistula anastomosis
  - Anastomosis diameter (grayscale only)
  - Diameter of the access vein (grayscale only)
  - Skin depth measurement
  - Diameter of the inflow artery (grayscale only)
  - Longitudinal image of the access vein
  - Longitudinal image of the inflow artery
  - Volume Flow in ml/min of brachial artery
- **Doppler Images: Peak Systolic Velocities**
  - Arterial and venous access anastomosis
  - Inflow artery, about 5cm from the anastomosis
  - Outflow fistula vein, about 5 cm from the anastomosis
  - Any area where stenosis is present
- **Volume Flow Measurements:**
- **Obtain 3 samples**
  - Inflow (usually the brachial) artery, at least 5 cm from the anastomosis
  - Outflow vein, about 5 cm from the anastomosis

Dialysis Graft Evaluation

- **Gray Scale and Color Flow Imaging**
  - Arterial anastomosis
  - Arterial anastomosis diameter (grayscale only)
  - Venous anastomosis
  - Venous anastomosis diameter (grayscale only)
  - Longitudinal image of the inflow side
  - Longitudinal image of the outflow side
- **Doppler Images: Peak Systolic Velocities**
  - Inflow artery
  - Arterial anastomosis
  - Arterial side, about 2 cm from the anastomosis
  - Mid graft
  - Venous side, about 2 cm from the anastomosis
  - Venous anastomosis
  - Outflow vein distal to the graft
- **Volume Flow Measurements: Obtain 3 samples**
  - Inflow artery (usually brachial artery)
  - Arterial side about 2 cm from the anastomosis
  - Venous side – 2 cm from the anastomosis

The OR Cockpit. Aviation Principles Applied to Dialysis Access

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In contrast to healthcare commercial North American aviation is enjoying an unprecedented safety record (1), much credited to implementing a program called CRM (Crew resource management) or HF (Human Factor). On any given day at airline training facilities around the world, airline crews undergo extensive and at times exhausting training in airplane simulators to hone their skills. The training runs the gamut from minor emergencies to catastrophic failures of major systems (engines, fuel, hydraulic, etc.) all designed to improve safety, performance, and team dynamics. How well crew preform as a team can be the crucial difference in achieving a successful outcome not only in the simulator but in actual flight.

Training and learning in the field of access for dialysis, including peritoneal and hemodialysis and access, is well suited for the use of simulators, simulated case learning, and root cause analysis of adverse outcomes and team training (2). Simulators range over a wide spectrum from simple suture learning devices, inexpensive systems for venous puncture simulation, such as a turkey breast or leg with a pressurized tunneled rubber or graft conduit, to sophisticated computer designed simulators to teach interventional procedures such as vascular access angiogram, balloon angioplasty and stent placing. Team training capitalizes on the principles used in aviation. The objectives of team training are summarized in Table I.

Lessons from the Flight Deck. For CRM training to be effective in the healthcare a culture paradigm, shift must take place (3). In addition to knowledge and skill training team members must learn and incorporate a culture of respect (4,5). This includes learning new skills to improve communications, managing errors and developing a variety of systems that contribute to safety. Areas focus on identifying links in the error chain, learning how to advocate by communicating "uphill" and recognizing the value of briefings, debriefings and the use of specially designed checklists for dialysis access procedures (6,7). Stress, poor communication, the failure to identify and correct errors and a culture of blame, lead to undesired and poor outcomes in the healthcare industry (3,4) Aviation addressed these same issues several decades ago, realizing that human factors account for 70% of all aviation incidents and accidents.

Simulation in the future should become the mainstay for training of all dialysis team members and access systems before being applied to patients. The penetration of simulation techniques into medicine varies across specialties and applications. It clearly means much more than just a surgical tool. The dialysis access training curriculum includes evaluation, testing and training of dialysis access delivery to stimulate realistic technological progress,

involving all team members in the ESRD system with focus on the system interfacing with the individual. The future impact of dialysis access simulation is yet to be determined.

Summary. Simulation for Dialysis Access (SoDA) capitalizes on principles and hard learnt lesson from the aviation industry. Although we recognize differences between the two industries, there are many similar principles that have saved lives in aviation. We can do the same for ESRD patients.

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TABLE I - POTENTIAL BENEFITS OF CRM TRAINING APPLICABLE TO DIALYSIS ACCESS TEAM TRAINING

- Improving communication and leadership skills among all team members.
- Integrating checklists and error traps into everyday practice, reducing the risk of error.
- Promoting a culture supporting professional development.
- Improving employee performance and staff retention.
- Assisting to make facilities safer, more efficient and nicer places to work.

Fig. 1 - *This cockpit from the B787 (The Dreamliner) is the largest commercial airliner recently placed in regular commercial traffic. It's cockpit is highly automated and largely managed by computerized commands.*

The Interventional Simulator

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Today, many of the larger vascular CME meetings offer some sort of procedural simulator, either as part of the meeting or more likely through their industry partners. Procedural simulators are fun and interactive, somewhat like video games for the older, professional set. The point of simulation is to provide training and mentoring in a realistic procedural recreation. A good interventional simulator can be designed to render realistic anatomy and physiology, avoid the use of patients or animals, obviate the need for X-rays, contrast agents, disposable implantable devices and catheters, hospital credentials, and medical licensure. Furthermore, the proctor (or mentor) or interventionalist can stop the simulated procedural experience and reset the situation. This permits repeated training and experience for the operator with efficient use of time and resources.

Building a "hands-on" AV access intervention simulator starts with the aim of recreating all aspects of fluoro-guided intervention. The AV circuit must be designed as a 3-dimensional model within which all dynamic real-time procedures are simulated. Within this three dimensional anatomic model, "live" simulated fluoroscopy, roadmapping, and imaging will conform to the anatomy during real-time performance of the procedure. In the best of all simulators, the visual components throughout the simulation experiment will align within space, and can be viewed from any orientation. This permits the operator unlimited opportunities to understand the anatomy and select treatment options throughout the simulation experience.

Simulation of AV access intervention would not be complete without recreating the "touch and feel" of the procedure. This sense of what it feels like during a simulated procedure is the science of "haptics." To achieve realistic haptics during AV access intervention, the electromechanical components of the simulator must be programmed to offer varying degrees of resistance as wires, catheters, and devices are passed, balloons inflated, and stent-grafts deployed. For example, a catheter may visually pass through tortuous anatomy, and because there is friction between the catheter and multiple sites of point contact around the tortuous vessels, there should be the "feel" of increased resistance by the operator who is advancing the catheter. Another example would be the resistive forces encountered during deployment of a stent-graft from a coaxial catheter delivery system. During the initial deployment, the coaxial resistive forces are very high, but as the device is mostly deployed, these forces abate. Recreation of accurate haptics during AV access interventional procedures is a very important component of the simulation experience.

Throughout the experience, the simulator's computer captures data regarding many different steps of the intervention. Review of these "metrics" is very useful for the operator, since the "experience" because they can show areas of deficiency or competence.

An AV access interventional simulation experience should evaluate the operator's technical ability as well as judgment. For example, the operator may accurately place and inflate an angioplasty balloon, but if the balloon is too large, the operator has made an judgment error. Alternatively, if the balloon is sized correctly but positioned poorly, it is a technical error.

Beyond assessing an individual operator, a procedural simulator can be used to compare different operators. Perhaps surgeons have a high level of competence deploying stent-grafts but frequently select the wrong length, while interventional radiologists select the stent graft length reliably but mal-deploy these devices more frequently. Different specialists may come to AV access intervention with different training and skill sets. Through a consistent simulation experience, these differences may be revealed. The hope is that with recognition of systemic differences, further training, tailored to the "type" of physician or their experience or skill level, can be offered.

Finally, new physicians are hired into practice based upon their training, letters of reference, and experience. But it isn't possible to see how a recruited physician performs actual procedures unless they've trained within the practice that they will be joining. Perhaps simulators can be used as a tool to determine AV access interventional competence (or other procedural competence) as part of the hiring process. Though this may seem futuristic or even intrusive, the reliance upon letters of reference and case logs is, at best, imperfect. Seeing how a proceduralist performs during an intervention may become the standard for entrance into a job where that procedure is an important part of clinical practice.

Pediatric Organ Donation After Circulatory Death: An Innovative Educational Initiative

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The landscape of healthcare is rife with challenging conversations for which practitioners often describe being unprepared, untrained and poorly equipped (1, 2). On any given day, practitioners are drawn into conversations to convey serious diagnoses, navigate complex treatment decisions, confront treatment failures, acknowledge adverse medical outcomes, and orchestrate conflict-laden situations. Over the course of his or her career, the average physician conducts thousands of healthcare conversations (3). Practitioners often spend more time communicating with patients and families about the technical procedures, treatments and surgeries for which they trained than in carrying out the interventions themselves.

Organ Donation after Circulatory Death: The inherent nature of organ donation after circulatory death (DCD) and the controversies surrounding the practice generate communicative demands and challenges, even under the best of circumstances (4-8). Family-staff conversations focused on pediatric DCD are quite naturally emotionally charged, time sensitive, and complex. Although some families spontaneously initiate discussion about organ donation, most families need the topic to be broached by trusted practitioners in a timely manner with the utmost sensitivity and professionalism (9). There can be differences of opinion among practitioners regarding patient eligibility for DCD and delays in outreach to families given the intensive care trajectory for children. Trust and working relationships between hospital-based practitioners and organ procurement organization (OPO) professionals are of paramount importance and require careful attention and ongoing communication.

At Boston Children's Hospital, an interdisciplinary committee labored for two years to create and approve a pediatric DCD protocol. Focus groups were convened to better understand practitioners' perspectives and to address their concerns (10). Educational efforts were undertaken to inform cardiovascular and critical care staff members of the DCD protocol. However, the abundant ethical complexities, the scope of the educational challenge, and the relative rarity of DCD soon revealed the need for just-in-time educational materials. The hospital leadership requested the Institute for Professionalism & Ethical Practice (IPEP), based at Boston Children's Hospital, to partner with the New England Organ Bank (NEOB) in this effort, ultimately creating an innovative, simulation-based educational film.

Innovative Educational Initiative: The purpose of the film was to sensitize and educate hospital-based practitioners about the underlying ethical issues and the continuum of family-staff conversations that unfold as part of the DCD process. The film begins with a brief overview of the two pathways to organ donation (brain death and circulatory death) and an introduction to the simulated case scenario and intended use of the film. As shown in Table I, the film's DVD menu includes several nodal conversations and debriefings, including the team preparing to talk with the family about DCD (Module One), the family declining consideration of DCD (Module Two), a series of conversations leading to organ procurement (Module Three), and DCD donation not leading to organ procurement (Module Four). The film utilized professional actors to depict family members, a full body mannequin to represent the pediatric patient, and an interprofessional team of clinicians from the hospital and NEOB to function in their typical roles. Disciplines represented in the film include physicians, nurses, social workers and chaplains. In keeping with the pedagogical approach of the Institute's Program to Enhance Relational and Communication Skills (PERCS), the film conversations were not scripted but rather represented "moments of real practice" that could be used as a springboard for reflection, discussion and interprofessional learning (11-13).

Case Scenario: The case scenario presented in the film is that of Danielle Bartlett and her family. Danielle is a seven-year-old previously healthy girl who suffers a near drowning incident at the family's pool during a barbeque party. On Day 4 her neurological examination is consistent with brain death except that she develops shallow respirations at 40 breaths per minute about two minutes into the apnea test. The pediatric intensivist explains the poor neurological prognosis, and the family decides that withdrawal of life support treatment is in Danielle's best interest and the best course of action.

Ethical Complexities, Realistic Concerns and Questions: The actors were coached to embed ethical complexities, raise realistic concerns and ask questions typical of family members considering organ donation. These included concerns about Danielle's care and perception of pain, the motivation behind organ donation, whether donation could be guaranteed if pursued, worry that the family would feel rushed or pressured to consent, and whether the family could change their mind. The following questions and concerns posed by the actor-parents provide a flavor of the film conversations:

TABLE I - DONATION AFTER CIRCULATORY DEATH DVD MENU

• Module One Preparation for talking with the family
• Module Two Family declines consideration of organ donation
• Module Three DCD donation leading to organ procurement – Family agrees to consider organ donation – Family agrees to attempt organ donation – Clinicians plan the logistics of DCD process – Meeting before transport to the OR – Withdrawal of life-support in the OR – Discussion with family after successful procurement
• Module Four DCD donation that does not lead to organ procurement

"You really think that withdrawing the ventilator is the best thing to do, what you would recommend, right? You're not rushing this just to get her organs, are you?"
"These are the last moments we will have with her while she is alive. I want to be able to hold her and be with her. I don't want anyone rushing us."
"Why can't we do all of this here in the ICU where we know everyone and feel comfortable? Why does this need to be done in the operating room?"
"What if we change our minds at the last minute and just can't say good-bye and let her go? We'll try to be strong, but what if we just can't do it? What happens then?"
"If we agree to do this, will anything be done to her that will be painful? How will you make sure she's comfortable?"
"I'm worried that if it looks like she isn't going to die within the 60 minute time frame, somebody might overdose her just to get her organs. I read about a case just like this in California."
"We really hope that she can donate her organs. If she doesn't die in the 60 minute window, this will be just one more loss and disappointment for us. Is there anything you can do to make sure she can donate? We will give you whatever legal permission you need."
"You're going to wait 5 minutes before you take out her organs. Is that long enough? Are you sure she will really be dead? Are you absolutely sure that she won't feel any pain?"

Experience and Lessons Learned: The film has been well received by hospital-based practitioners and has generated significant interest amongst clinical educators. Similarly, Organ Procurement Organizations have expressed interest in the film for purposes of orienting their staff members and illustrating the perspectives of hospital-based practitioners. The film demonstrates the important need for mutual trust and respect between hospital-based practitioners and OPO professionals. The respectful introduction of the OPO personnel to the family by familiar trusted clinical staff not only prepares family members but also confers trust and confidence to the OPO. Hospital-based staff members are particularly curious and eager to be "a fly on the wall" and view the conversation in which the OPO representative explains DCD to the actor-parents. To illustrate the range of family responses, the film includes situations where the actor-parents both agree and decline the option of organ donation. The scene in which the withdrawal of life support treatment is enacted in the operating room has been particularly well regarded, offering a rare glimpse into this part of the DCD process. The two outcomes are likewise depicted, in which the patient is able and not able to donate organs.
Within our own institution, the film has helped to demystify the process of organ donation and to promote mutual understanding between hospital and OPO cultures. By making available simulated, realistic examples of clinical conversations, we have provided an educational tool to access and unpack practitioners' reluctance, skepticism, worries and moral uncertainties about DCD.

It is our hope that the film promotes the goal of providing seamless, high-quality care to DCD candidates and their families through effective collaboration between hospital-based practitioners and organ procurement professionals.

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Using Simulation Root Cause Analysis to Evaluate Dialysis Complications

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Root cause analysis (RCA) is used by high-risk industries to evaluate the causes underlying accidents or adverse, unexpected outcomes. The application of RCA in healthcare is relatively recent, and although mandated in the United States for certain indications, the efficacy of the current technique has never been validated.

We have developed a method of incorporating simulation into the technique of RCA to assess the root cause(s) of adverse outcomes in healthcare. One benefit of simulation-based RCA is that it can more effectively assess the function of complex healthcare systems, identifying deficiencies that contribute to adverse outcomes. The care of patients with renal disease (ESRD) requiring dialysis access is highly complex, involving multiple healthcare providers and locations, and involves a substantial degree of risk, with potentially devastating consequences if care is not optimal.

The method and application of simulation-based RCA for evaluating complications arising in the care of the ESRD patient is described in the paper. Once fully implemented and tested, using simulation-based RCA as a method for evaluating adverse outcomes, will improve the understanding of underlying system deficiencies, and the development of comprehensive and testable solutions that include education to optimize patient care, thereby providing improvements in patient safety and cost-effective delivery of care.

Introduction: Root cause analysis (RCA) is a process used by many high-risk industries to evaluate accidents and unexpected outcomes. RCA can be done using several methods including interviews, retrospective review of data, and simulation. Use of the traditional RCA method of data review has been successful in decreasing falls in the outpatient hemodialysis setting (1). Simulation is a powerful tool that has some advantages over the traditional method including lessening recall and investigator bias.

Recently, the authors of this paper developed a method for performing RCA of adverse surgical outcomes using the medium of simulation (2, 3). Closed case files from a major malpractice insurance company (The Doctors Company, Napa CA) were utilized to re-create situations that led to adverse surgical outcomes with the greatest degree of verisimilitude possible at the Tulane Center for Advanced Medical Simulation and Team Training. Selected cases depicting non-technical errors were scripted and combined with necessary props and an actor -- a medical student – who portrayed the patient in an appropriate environment. Residents and attending physicians participated as test subjects in the cases, reacting to the simulations, as they deemed appropriate. The same process was then used to simulate the circumstances leading to an adverse surgical outcome reported in-house; placement of a percutaneous nephrostomy tube, complicated by a missed post-operative hemorrhage (3).

Our research has demonstrated several benefits of incorporating simulation into the evaluation of adverse medical outcomes. Some of these advantages include: comprehensive testing of hypothesized root cause(s), determining the flow of events with greater accuracy, and the ability to include multiple members of the healthcare team, including the patient, in the RCA process.

In this manuscript we describe how the technique can be applied to complications and adverse outcomes arising during the care of the dialysis patient, especially as it relates to dialysis access.

Methods: The technique we developed for simulation RCA mirrors the techniques used by high-risk industries such as aviation and transportation. The preparation and execution process for simulation-based RCA is divided into five phases: initial review, in-depth review, simulation development, simulation performance, and analysis. The *initial review phase* includes gathering relevant records and creating a summary of the adverse event. The *in-depth review phase* is more labor intensive, and consists of focused interviews with participants to gain additional insight into the circumstances surrounding the adverse outcome or complication. During this phase the simulation RCA team needs to establish a detailed timeline that places all events and circumstances in their proper order.

Simulation development is the process through which the RCA investigative team assembles and creates the script, props, and environment to allow the simulation to accurately represent the occurrence. The script provides background information for the simulation test subjects and confederates. The script also allows for compression of time; for example if a lab test is ordered, the results are given immediately instead of waiting the actual length of time it would take. It is important to note that confederates need to be provided enough information to make the simulation-based RCA accurate, but do not actually need to be aware of the ultimate outcome of the real case. The props include a deidentified medical record and the medical equipment required for patient care. The environment should include a fairly realistic representation of the actual location(s) where the patient care took place.

Simulation Performance is where the test subjects are placed into a simulation of the adverse event. The simulation is observed from a distance by the RCA team, and is recorded for review at a later time. The essential benefit of simulation-based RCA is that it allows for evaluation of a recreated event in the true order in which things occurred. This allows the simulation RCA team to evaluate the decision-making of the test subjects in a manner that most closely resembles the actual event(s). At the end of the simulation a *debriefing* is done to aid in determining why the test subject made their decisions. Typically the simulation is repeated 5 to 7 times, each time with a different test subject (or subjects).

During the *Analysis Phase* the simulation RCA team reviews and tabulates the results of the simulations and debriefings. Key information includes: (1) was the adverse event replicated, and if so what percent of the time, (2) what were key elements of the situation and environment that influenced the decision-making of the test subjects, and (3) what did the test subjects (and confederates) believe was missing that could have made the outcome different?

Application of Simulation RCA to Dialysis Access: Traditional evaluation of adverse healthcare outcomes tends to be limited to one location and often one healthcare provider identified as "responsible". The care

of the end-stage renal disease (ESRD) patient is complex and involves multiple healthcare locations and providers. This creates a system in which there are many places where errors can be introduced. In addition, because the decisions and actions of care providers at different locations can have a significant impact on other locations and providers, evaluating dialysis access complications in a traditional manner is exceptionally difficult. Simulation-based RCA can be applied to the evaluation of dialysis access adverse outcomes in an effort to determine the most important underlying causes of error, and the inter-related effects of decisions and actions made by a range of people and occurring at various locations. Importantly, simulation-based RCA includes the patient's actions in the evaluation.

Using our system of simulation-based RCA, an adverse outcome such as repeated sticking of an access in the same location resulting in aneurysm and thrombosis could be evaluated. In this example, details of the patient history would be collected and reviewed. Ideally anatomic details, including a picture of the actual access would be obtained and correlated with imaging studies and operative records. The simulation RCA team would visit the sites of care delivery noting the environmental factors, and interview the key healthcare personnel. A timeline would be created.

Next the simulation would be created. Given current state of simulation technology we cannot accurately reproduce the technical aspects of a surgical procedure. However, pre-operative, intra-operative, and post-operative decisions and communication can be reproduced when they are felt to have impacted the outcome. We can use simulation props to reproduce some aspects of a particular dialysis access if known. For example, if an access was very short or too deep, this can be reproduced using models that allow for assessing cannulation.

In this dialysis access example, simulation could include reproducing events in the dialysis access center and at other points of care such as the surgeon's office, and interventional radiology, as appropriate. In each simulation, the RCA investigative team would note those factors that contributed to the adverse outcome. The simulation(s) would be repeated 5 to 7 times using appropriate test subjects. In complex care delivery situations like dialysis access patients, evaluation of communication between different people providing patient care is important. The simulations are constructed so that the ability, accuracy, and timeliness of the test subjects to communicate critical aspects of the patient's care are accessed. At the end of each simulation debriefing allows the simulation RCA team to question the test subjects and confederates about their experiences during the simulation (for example was it realistic?). Debriefing also allows the team to question the simulation test subjects about their patient care decisions, any deficiencies they experienced that impaired their ability to deliver optimal care, and what queues they used during the simulation to make their decisions about care.

During the analysis phase, the team ranks the factors contributing to the adverse outcome in terms of frequency and importance. The team would pay special attention to any test subject actions or decisions that would be predicted to have *prevented* the adverse outcome.

Discussion: RCA has been used successfully for decades in high-risk industries such as aviation and nuclear power as a tool for retrospective analysis to uncover latent errors (4, 5). RCA was first introduced to the medical community in the mid-1990s by the US Department of Veterans Affairs (VA) and the Joint Commission; the Joint Commission now requires that organizations perform an RCA for every sentinel event, and VA facilities submit RCA reports for serious adverse reports to the National Center for Patient Safety (6). RCA as defined by the Joint Commission is a process for identifying the basic or causal factor/factors underlying variation in performance, including the occurrence or possible occurrence of a *sentinel event*. In 2008, Wu et al. noted a void in the peer-reviewed literature regarding evaluations of the effectiveness and cost of RCA compared with other tools to mitigate hazards (7).

In our research to date, the results for all cases demonstrated root causes different than those identified by traditional methods – most often systems deficiencies, as opposed to errors solely attributable to individuals (2,3). In the care of the ESRD patient and especially with respect to dialysis access, an optimal system is of paramount importance to provide the safest, most effective care. To optimize the patient care related to dialysis access, coordination across multiple providers and locations is necessary. Unfortunately, the patient is often shifted between care providers and locations only in reaction to problems or complications. Ideally, a system of care related to dialysis access would be prospective, and designed to minimize the potential for error in the first place, and to anticipate complications before they result in a significant adverse outcome. Given limitations of our current care delivery system, often there is little effective communication between care providers and locations of care, further compounding the potential for error and sub-optimal outcomes.

When an adverse outcome is evaluated by simulation RCA, the investigative team can determine the time course of decisions and events and their respective impact on medical decision-making. This is a signifi-

cant improvement upon purely retrospective RCA because, by using simulation, the reasons that patient care decisions are made *when they are made* is revealed. This is an important advantage of simulation RCA because the decisions made by the people involved in the original event must have made sense to them at the time, otherwise they would have made different choices (8). Incorporating simulation into the evaluation of adverse outcomes provides insight into what aspects of the patient, the environment, communication, situational awareness, and education led to the decisions about patient care that were made. The results of simulation-based RCA for dialysis access allow the investigative team to suggest changes in the system of care delivery. These changes can then be tested using simulation to determine if they will indeed be effective in achieving the expected improvements. This is an improvement over current methods, where traditionally new healthcare protocols and system changes are implemented (with good intention) but are never tested for effectiveness or unintended consequences before being applied in the patient care setting.

Finally, when the results of simulation-based RCA are fully analyzed, deficiencies in education are defined. Unlike any other existing method, simulation RCA can accurately reveal educational needs essential to improving the outcomes of healthcare delivery. Using simulation RCA we have identified educational needs in diverse but inter-related areas of knowledge such as basic medical science including anatomy, pathophysiology of disease, and communication. Interestingly, simulation-based RCA demonstrates the importance of educating healthcare teams together, including administrators. Optimal care of the ESRD patient and of dialysis access requires a coordinated multidisciplinary approach. The cost of adverse outcomes to the ESRD patient, and to the system that pays for care, is substantial.

Using simulation-based RCA as a method for evaluating adverse outcomes, determining the underlying system deficiencies, and developing comprehensive and testable solutions that include education has the potential optimize patient care, thereby providing improvements in patient safety and cost-effective delivery of care.

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Controversies in Dialysis Access (CiDA)

Timing of Dialysis Access: When Does the ESRD Patient Need to Initiate Dialysis?

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Over the past decade, there has been a trend towards initiation of dialysis at progressively higher levels of estimated glomerular filtration rate (eGFR). In 1996 19% of individuals starting maintenance dialysis had an eGFR above 10 ml/min/1.73m^2 at the start of dialysis, but by 2009 this percentage had grown to 53.8%. Furthermore, by 2009 20% of patients were initiating dialysis with an eGFR above 15 ml/min/1.73m^2. Guidelines from professional societies are widely seen as promoting this strategy. For example, in 2006 the National Kidney Foundation Kidney Disease Quality Outcomes Initiative (KDOQI) suggested that when the eGFR fell below 15 ml/min/1.73m^2 the 'nephrologist should evaluate the benefits, risks and disadvantages of beginning kidney replacement therapy.' In addition, certain signs and symptoms might justify the initiation of dialysis when the eGFR was above 15 ml/min/1.73m^2.

Despite this trend toward early commencement of dialysis, a number of studies have challenged whether or not there is a benefit to early initiation and in fact have raised the possibility that early start of dialysis is associated with worse outcomes. Since 2001, 11 observational studies have examined the issue of comorbidity-adjusted survival versus the estimated glomerular filtration rate at dialysis initiation. All but two of these studies found a comorbidity-adjusted survival disadvantage of early dialysis initiation.

The only randomized controlled trial that examined mortality and time of dialysis initiation, the IDEAL study, found no difference in survival between early or late initiation of dialysis. In this study, 828 patients with progressive CKD and an estimated GFR between 10 and 15 mL/min per 1.73 m^2 were randomly assigned to dialysis initiation when the estimated GFR was either 10 to 14 mL/min per 1.73 m^2 or 5 to 7 mL/min per 1.73 m^2. The median time to the initiation of dialysis was 1.8 and 7.4 months in the early and late start groups, respectively. At a median follow up period of 3.6 years, the two groups had no significant difference in survival as well as no difference in cardiovascular events, infections, or dialysis complications.

Among patients with progressive chronic kidney disease dialysis initiation should be based upon clinical factors rather than the estimated GFR alone. These patients require close follow up, early nephrology referral, and adequate advance dialysis planning (including the presence of a functioning peritoneal or vascular access and referral for transplantation). The clinician must be vigilant for the presence of symptoms and/or signs of uremia and patients should also be fully informed of any symptoms of uremia to be able to contact their physicians appropriately.

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Peritoneal Dialysis: Why It's the Best Dialysis, and What is Being Done to Increase Its Acceptance

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Peritoneal dialysis (PD) is a home-based renal replacement therapy that has been used continuously for close to fifty years. PD used to be more prevalent in the United States and Canada than it is currently. In Canada, about 20% of dialysis patients use this technique; in the United States it is less than 10%. The fall-off in popularity over the years has many explanations.

These include the growth and industrialization of hemodialysis facilities, the suboptimal exposure of nephrologists-in-training to patients using PD, and little exposure of surgeons-in-training to techniques to enhance the placement of functioning PD catheters. In addition, the dialysis population in the last decades has aged inexorably and become more fragile. This population may be more reluctant to undertake self-dialysis, or, their doctors may be reluctant to suggest home-based dialysis. Finally, although this is difficult to prove, the wholesale adoption of urea-based kinetics as a marker of adequacy of dialysis serves to disadvantage PD, since weekly total Kt/V urea in PD is reliably less than that of conventional hemodialysis. No form of dialysis is inherently superior to another. Different modalities may serve different patients, or even be appropriate for the same patient at different times over their career with endstage renal disease. Furthermore, analogous to "cat people" and "dog people", patients inherently often gravitate to one modality and have a distaste for the other. Nonetheless, the poor prevalence of peritoneal dialysis in the United States suggests that Americans are either very different from dialysis patients in the rest of the world, or that the systemic factors discussed above play a significant role.

Peritoneal dialysis has many advantages over conventional center hemodialysis. Firstly it is a home-based modality. In most instances the patient takes partial or full responsibility for carrying out the therapy. The home-based modalities are associated with an increase in quality of life parameters. Although PD can be complicated by infection of the dialysis fluid, leading to peritonitis, the incidence of this complication has decreased dramatically over the last several decades. In our program the incidence is approximately 1 episode every 48 months, and most of these resolve with antibiotic therapy. This stands in contrast to hemodialysis, particularly when performed through a tunnelled venous catheter, where the incidence of infectious complications are higher and results in bacteremia, a life-threatening complication in itself, with the possibility of metastatic abscess. PD is also continuous therapy and therefore avoids the intermittency inherent in center thrice-weekly hemodialysis. The continuous therapy is more physiologic and avoids episodes of acute volume overload and hyperkalemia encountered after the weekend in intermittent hemodialysis patients. Finally, since the publication of the National Cooperative Dialysis Study and the formulation of Kt/V urea as a metric for measuring adequacy of dialysis therapy, it has become clear that urea kinetics do not adequately capture adequate dialysis, particularly for PD. Therefore the notion that PD is inferior therapy because of weekly lower average Kt/V urea has no basis in fact. This is supported by the well-conducted studies in both hemodialysis and PD that do not demonstrate an association between higher Kt/V urea and improved survival.

An increase in the use of PD for renal replacement will be contingent on a new generation of nephrologists without preconceived notions of this dialysis as second-best treatment. This worldview will depend on letting go of urea kinetics as a measure of adequacy, a comfort with the therapy itself and its complications, training surgeons/nephrologists/radiologists how to put in catheters that work, and an appreciation by nephrologists for the benefits of this therapy. The North American Chapter of the International Society of Peritoneal Dialysis is working toward these goals, and has put a curriculum for the management of PD on the internet (http://ispd.org/NAC/education/pd-curriculum/). CMS has put in place financial incentives to increase the use of PD, and this should go some way in encouraging nephrologists to re-consider the value of this low-tech but surprisingly successful therapy.

Fluoroscopic and Peritoneoscopic Guided PD Catheter Placement: Patient Selection and Outcomes

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The fluoroscopic and peritoneoscopic techniques are well established methods of peritoneal dialysis (PD) catheter placement. The fluoroscopic method uses the supplies and equipment available in a vascular access center: C-arm, ultrasound, puncture needles, guide wires and dilators whereas the peritoneoscopic method requires a rigid peritoneoscope and a trocar-sheath-dilator assembly (1). Both methods do not need cardiac or anesthesia clearance because they are done under local anesthesia and conscious sedation, administered by the physicians and nurses in the interventional suite. Since these techniques are simple and straightforward, end-stage renal disease patients with multiple co-morbid conditions can receive peritoneal dialysis catheters in a timely fashion. These PD placement methods are most suited for emergent start (in days) and urgent start (in weeks) dialysis, when patients present with the complications of ESRD (uremia, volume overload etc.) and do not have a functioning vascular access. In such instances, tunneled central venous catheters are avoided altogether and PD is selected as the initial dialysis modality. The patient who has a PD catheter has many distinct advantages when compared to the patient with a central venous catheter (CVC): a significantly lower incidence of bacterial sepsis and therefore better survival, preservation of veins for vascular access construction, avoidance of central vein stenosis, better blood pressure and fluid control, better preservation of residual renal function, higher hemoglobin levels with less use of EPO, better outcomes after renal transplantation, less risk of acquiring a blood borne virus, a more flexible lifestyle and better patient satisfaction.

There is also a significant cost savings coupled with similar reimbursement for nephrologists taking care of hemodialysis patients but with less effort (only one clinic visit each month) and a physician training fee at the start of PD.
These percutaneous techniques have excellent success rates with minimal complications. Whereas the peritoneoscopic method allows the operator to visualize the peritoneal cavity prior to catheter placement, injection of contrast through the puncture needle ensures entry into the peritoneal space in the fluoroscopic method. Comparison of percutaneous methods with surgical and laparoscopic techniques shows similar rates of technical success. The laparoscopic method has the advantage of visualizing the abdominal cavity and surgically removing adhesions and omentum. It is therefore most suitable for patients who have had prior abdominal surgery, abdominal hernias or in those with a migrated PD catheter.
Nephrologists who have mastered the percutaneous methods can educate their patients in the nephrology clinic and then proceed with PD catheter placement in their Interventional Nephrology Centers (one stop shop) (2). In addition, they can quickly start PD in patients who show up with the complications of ESRD but do not have a vascular access. Since they can place the PD catheter there are minimal scheduling conflicts. Efficient and early placement of PD catheters by nephrologists is a great CVC avoidance strategy. It has also been shown that when nephrologists place PD catheters the PD programs automatically grow (3).

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Surgically Placed PD Catheters: Laparoscopic or Open Techniques

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Background: Renal-Replacement Therapy RRT options include hemodialysis (HD), Peritoneal Dialysis (PD) and renal transplant. While renal transplant remains the RRT of choice, the proportion of ESRD patients receiving renal transplant has not changed in the past decade. With increasing number of ESRD patients requiring dialysis, one would expect a proportionate growth of all dialysis modalities. To the contrary, while utilization of HD has progressively increased, there has been a steady decline in PD usage (1). PD is associated with patient survival advantages when compared to HD in the first years on dialysis (2-9). PD delivers a more steady-state treatment avoiding fluctuations in plasma volume and solutes and is generally better tolerated by the patients with cardiovascular compromise. PD provides a flexible schedule, thus allowing patients to work, travel and participate in daytime activities. As PD does not involve needle-sticks patient anxiety is mitigated, arteriovenous access sites for future HD is preserved and the risk of acquiring blood-borne infections are minimized. Additionally, residual renal function (RRF) is better preserved on PD than HD (7-13) and is beneficial to patients who receive a kidney transplant (7, 14-16). Despite advantages, the number of patients in the US on PD remains low (17) at 8.8% of the total US dialysis population. Elsewhere in the world, such as the United Kingdom, New Zealand and Mexico, PD is utilized in up to 80% of cases. Peritoneal catheters can be placed with open or laparoscopic technique. This overview summarize the pros and cons with these operative techniques. More detailed operative description of these techniques are reported elsewhere (15,16)
Preoperative Evaluation: Preoperative evaluation begins with a thorough history and physical examination. To perform PD adequate vision and manual dexterity is required, since most PD is performed at home by the patient. Patients with significant handicap may perform PD with dedicated assistance available. The extent and nature of previous abdominal surgery/operations, past episodes of peritonitis, repeat diverticulitis or pelvic inflammatory disease are associated with increased risk for failure, but do not represent absolute contraindications to PD placement. Prior open non-inflammatory abdominal operations does not preclude PD placement (17,18). In cases where the surgeon suspects intra-abdominal adhesions will preclude PD catheter placement, it is advised to have a backup plan for HD access placement in the same operating setting. Although PD is the dialysis mode of first choice, the patient should be offered a native vein arterial-venous fistula (AVF) in the same operating setting, assuming suitable vascular anatomy. This AVF will then have time to mature and serve as "life insurance" and backup dialysis should PD be temporarily stopped or fail. Ideally, the PD catheter is placed 3-4 weeks prior to the anticipated initiation of dialysis to avoid complications related to hemodialysis catheters.

Operative Planning

Location of catheter and marking of the skin. Preoperative planning is essential as 21% of technique failures within the first year are due to catheter related mechanical problems (19). Non-infectious PD catheter related complications are strongly associated with catheter failure (17). The curled portion of the peritoneal dialysis catheter is located in the true pelvis, allowing for proper dialysate instillation and removal/ exchanges. The exit site must be easily accessible, visible for the patient, away from the beltline, skin folds and scars. The subcutaneous tunnel should be fashioned to avoid catheter stresses and kinks. Preoperative planning should also take into consideration the location of the superior border of the pubic symphysis, the umbilicus, the level of the anterior superior iliac spines, and skin folds (18).-With the patient in the upright and supine positions, the incision, the intended subcutaneous tract and exit site of the catheter are marked (Fig. 1a, 1b). This is especially important in obese patients, as a pannus will change position on standing. In a virgin abdomen, the left side is chosen because the right iliac fossa is the preferred site for a first kidney transplant (Fig 1a, 1b). Also, as opposed to the right side, the downward intestinal peristalsis of the left colon is thought to maintain proper catheter orientation in the pelvis.

The obese patient. PD catheters in obese patients work surprisingly well, however requires special considerations. Seventy-percent of the US population is overweight and in recent years the authors have been placing an increasing number of catheters in overweight individuals. Choosing the exit site in the upper abdomen or on the upper chest using a presternal extension segment is an option in obese individuals (19).

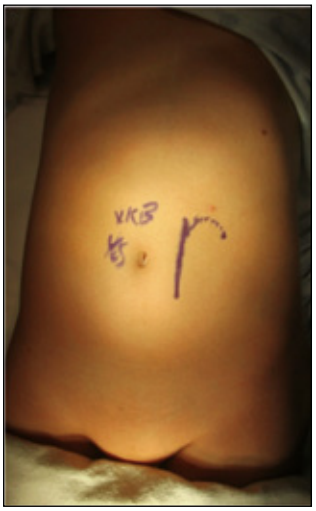

Fig. 1 - *Skin markings for the placement of a peritoneal dialysis catheter in the open technique. Note the locations of the planned incision, the subcutaneous tunnel and exit site.*

Choice of catheter. Peritoneal dialysis catheters come in a variety of configurations with one or two Dacron cuffs (Fig. 2a-2h). With single cuff configurations, the Dacron cuff is placed at the posterior rectus fascia; with double cuff configurations, the second or outer cuff is placed in the subcutaneous space 1.5 – 2.0 cm from the skin exit site. The subcutaneous cuff provides an additional barrier from bacterial migration along the catheter preventing tunnel tract infections and peritonitis (20). The intra-peritoneal and extra-peritoneal PD catheter designs vary greatly (Fig. 2). The intraperitoneal segments can be straight, coiled, or weighted (so called, self-locating tips, [26]). Catheters with a coiled intraperitoneal segment provide greater bulk and more side-holes for fluid passage and therefore increased likelihood of success (22-26). The straight intraperitoneal tip is also thought to produce more pain with instillation of fluid secondary to a "jet" effect.

Fig. 2 - *The different commercially available types of peritoneal dialysis catheters*

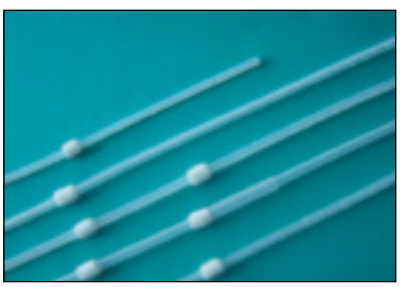

Fig. 2a - *Straight Tenckhoff peritoneal dialysis catheters, in single and double cuff configurations*

Fig. 2b - *Coiled Tenckhoff peritoneal dialysis catheters, in single and double cuff configurations.*

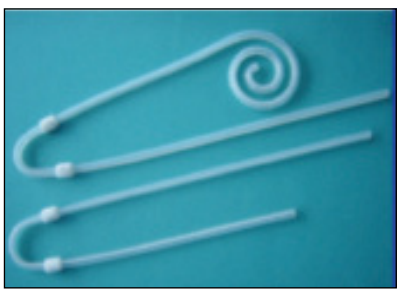

Fig. 2c - *Swan neck peritoneal dialysis catheters, with straight and coiled intraperitoneal segments.*

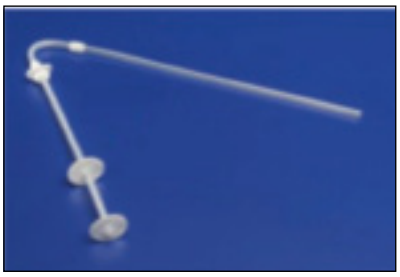

Fig. 2d - *Swan neck Toronto Western Hospital peritoneal dialysis catheter.*

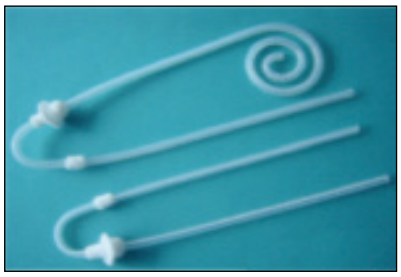

Fig. 2e - *Swan neck Missouri peritoneal dialysis catheter with a straight intra-peritoneal segment.*

Fig. 2f - *Swan neck presternal peritoneal dialysis catheter with coiled intra-peritoneal segment.*

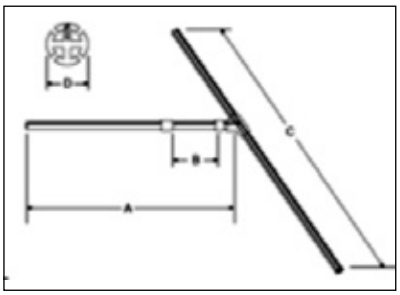

Fig. 2g - *T-fluted Ash Advantage peritoneal dialysis catheter. A is the transabdominal tube length, B the distance between cuffs, C is the overall intraperitoneal length and D is the flute diameter.*

Fig. 2h - *The "self-locating" Di Paolo peritoneal dialysis catheter. Note the weighted tip at the end of the intraperitoneal segment.*

Surgical Technique

OPEN VERSUS LAPAROSCOPIC TECHNIQUE. Choice in surgical approach partly depends on the comfort level of the operating surgeon. PD catheters are typically inserted using an ***open*** approach or the ***laparoscopic*** technique. (The blind Seldinger technique, using fluoroscopic guidance, and placement under peritoneoscopic visualization (22) a technique the authors strongly discouraged for increased risk of inadvertent visceral injury). The pros and cons open and laparoscopic techniques of PD catheter placement are discussed here.

PROS AND CONS. Advantages and disadvantages exist for both methods. The open approach is associated with shorter operating time and can be performed under spinal or local anesthesia, although general anesthesia is preferred. Laparoscopic placement, with the insufflations of carbon dioxide into the peritoneal cavity, requires general anesthesia, and may preclude some patients from undergoing placement using this approach. Laparoscopic placement is associated with longer operating times, (23-28), but allows for direct visualization of the secure placement of the tip of the catheter in the pelvis (26) The laparoscopic approach also allows for additional procedures, such as repair of umbilical hernias, lysis of adhesions and omentopexy (29). The open approach is more cost-effective, as only basic equipment is required for the procedure (24).

Laparoscopy is the best technique to rescue problem catheters (29). Studies comparing the rates of complications with open vs. laparoscopic PD placement have been mixed (28) and one method of placement cannot be recommended over another as the PD catheter surgical technique approach is influenced by the patient's medical risk, the operating surgeon's training, and institutional resources.

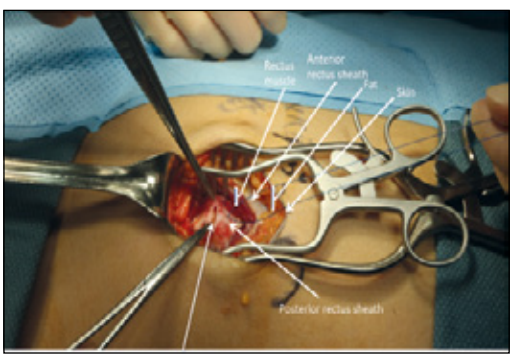

Fig. 3 - *The abdominal wall anatomy.*

Operative Techniques

OPEN PARAMEDIAN APPROACH. Although open PD catheter placement can be performed under local anesthesia, for patient comfort, general anesthesia is preferred. Preoperative antibiotics, such a first generation cephalosporin (e.g. Cefazolin) are administered prior to skin incision. Patients with penicillin or cephalosporin allergies should receive either clindamycin or Vancomycin as alternatives.

The skin incision is placed 2-3 cm on either side of the um-

bilicus, with the left being the preferred side (Fig. 1). The abdominal wall anatomy is shown in Figure 4. The anterior rectus muscle fascia is divided longitudinally. Muscle sparing technique is used to expose the posterior rectus fascia. Using fine scissors, the posterior rectus fascia and peritoneum are opened for a length of 3 mm (Fig. 4). Caution is advised to avoid inadvertent small bowel injury during entry. A 2-0 Prolene purse-string suture is placed around the fascial-peritoneal defect. The suture is placed so the tie will be located cephalad to the cuff; this suture will be also be used to secure the inner Dacron cuff to the posterior rectus fascia. This purse-string suture allows for a watertight seal around the catheter (Fig. 4).The intra-abdominal catheter placement is facilitated by the use of a stiffening stylet (Fig. 5). The catheter must first be flushed with saline in order for the stylet to slide freely on the catheter. The tip of the stylet must not pass outside the tip of the catheter, to minimize the risk of visceral injuries during insertion (Fig. 6a, 6b). Once inside the abdomen, the stylet is retracted to release the curled end the catheter now directed downward along the anterior abdominal wall. Force must not be used. If resistance occurs, redirection of the catheter is attempted until the pelvis is reached. At this point, the stylet is removed with one hand securing the PD catheter at the exit site. Once fully inserted the purse string suture is tied snugly around the catheter. The inner Dacron cuff is then secured to the posterior aspect of the posterior rectus fascia with suture (Fig. 9). A second purse string suture is not required. Next, the catheter is tunneled through the rectus muscle and (Fig. 10) and pulled through the anterior rectus fascia (Fig. 11). This step secures the cranio-caudad direction of the catheter making malpositioning unlikely.

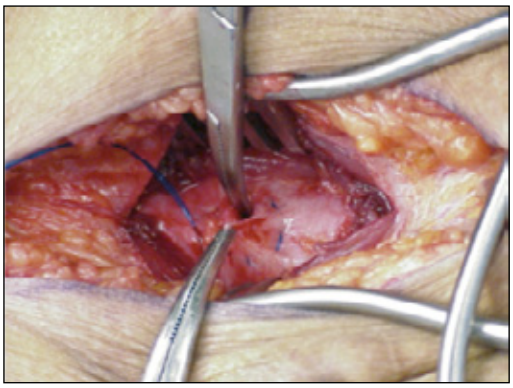

Fig. 4 - *Several bites (6-8) purse-string sutures are placed about 5 mm around the small peritoneal opening.*

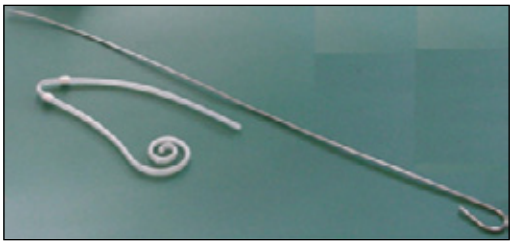

Fig. 5 - *Catheter and stylet.*

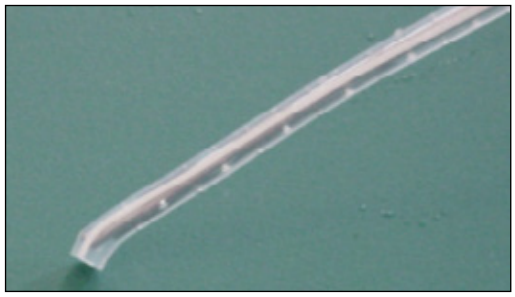

Fig. 6a - *This is the ideal position of the stylet as it is inserted through the small peritoneal incision minimizing the risk of injuries to visceral structures.*

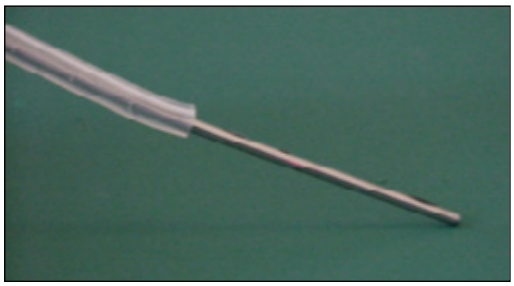

Fig. 6b - *The catheter with the stylet protruding is dangerous and lends to injuries.*

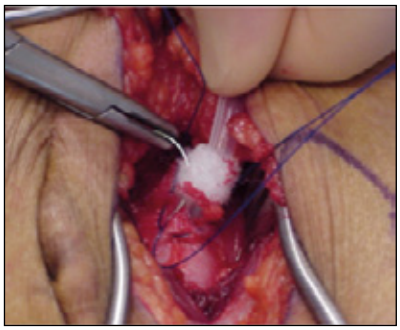

Fig. 7 - *This image details the placement of suture to secure the inner Dacron cuff. Care should be taken not to inadvertently penetrate the catheter.*

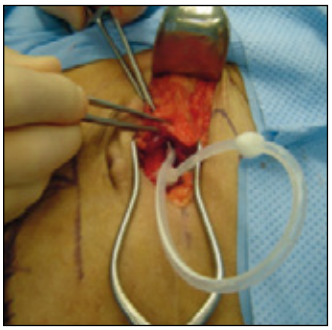

Fig. 8 - *The catheter is tunneled through the rectus muscle and pulled through the anterior rectus fascia.*

The sharp curved subcutaneous Faller tunneler is used to create a smooth, curved subcutaneous tract as the catheter exits through the skin (Figs. 10, 11). The tunneler is the same diameter as the catheter tubing, making the skin exit site snug (Fig. 12). A snug exit site minimizes irritation from catheter sliding and minimizes the risk of infection. The external Dacron cuff is placed 1.5-2.0 cm from the exit site.

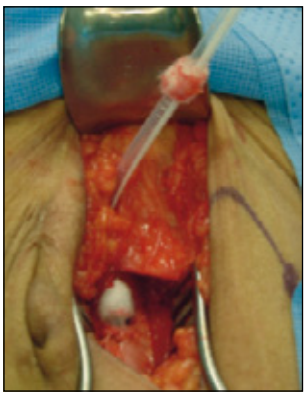

Fig. 9 - *The inner Dacron cuff rests sutured to the posterior rectus muscle fascia. The catheter is aligned in a cranio-caduad direction keeping the coiled portion of the straight down towards the pelvis.*

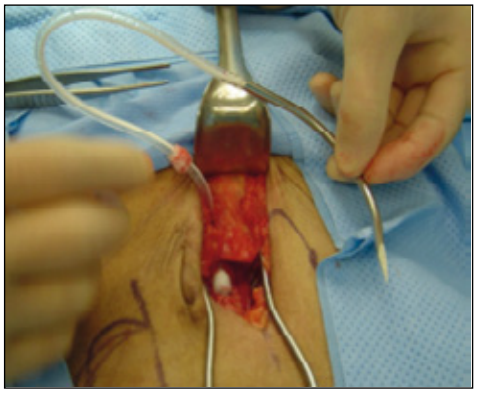

Fig. 10 - *The inner cuff is aligned in a cranio-caudad direction. The subcutaneous sharp (Faller) tunneler has now been attached to the catheter.*

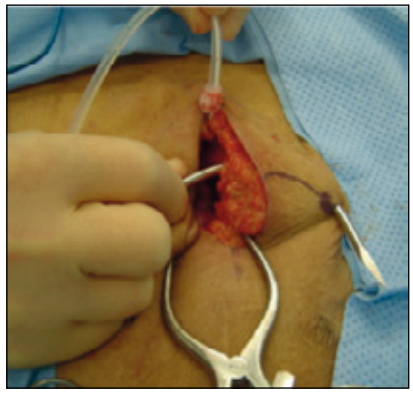

Fig. 11 - *The sharp Faller tunneler has penetrated the skin at the predetermined and marked site. The external cuff ideally will be located 2.0-2.5 cm from the skin surface*

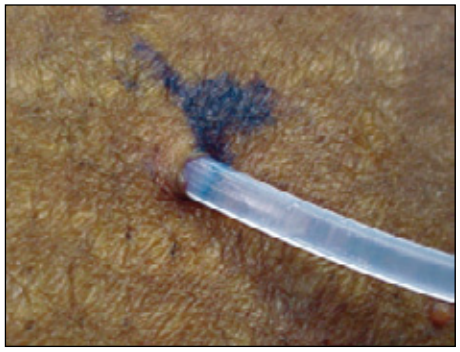

Fig. 12 - *This close-up image of the catheter skin exit site shows the importance of using the correctly sized and fitted tunneling device*

The tunneler should exit the skin at a 30-45 degree angle in order to optimize catheter alignment to the skin and comfort for the patient. The author strongly advises against the technique of using a skin incision at the exit site and retrograde insertion of a hemostat to catch the PD catheter and pulling through the skin. This technique induces bleeding, is traumatic to the skin and is prone to complications (mainly infection). The larger skin exit defects (and bleeding) with this technique may require stitching at the skin exit site, which further increases the infection risks and external Dacron cuff migration. Stitches must not be placed at the exit site; sutures here cause trauma, tension and promote infection at the exit site. The anterior fascia is closed in a running fashion with a 2-0-prolene suture. The skin is closed with an inverted 4-0 polydioxane or polygalactin subcuticular suture and covered with 1/2" Steri-strips ™ and a sterile dressing.

LAPAROSCOPIC TECHNIQUE. Although the laparoscopic placement of the PD catheter can be performed under local anesthesia and sedation, general anesthesia with endotracheal intubation is safer and preferred for patient comfort. Prophylactic antibiotics are given in the operating room before skin incision as in the open procedure. For first time catheters with no previous abdominal surgeries, a single camera port and the 22 g peel away catheter sheath are needed. Incidental minor surgical procedures such as small umbilical hernia repairs and omentopexy can also be accomplished with a single port. More complicated and extensive repairs will require additional ports. The site for Veress needle insufflation should be 1-2 inches below the costal margin in the mid-clavicular line on the ipsilateral side as catheter placement (Fig 13a, b). Once pneumo-peritoneum is established, the Veress needle is exchanged for the camera port. A 5 mm port is placed into the abdomen under direct vision with the camera inside the device. If the patient has had prior abdominal operations, or there are concerns for significant adhesions, open Hasson placement in the supraumbilical midline may be utilized to establish pneumoperitoneum and gain access to the abdominal cavity. After surveying the abdomen for injury and incidental pathology, the 0 degree camera is changed to the 30-degree lens for improved visualization during the PD catheter insertion steps. The desired level of catheter insertion is determined as a location away from the epigastric vessels, or about 3 cm lateral to the midline and 1-2 cm above the level of the umbilicus (Fig. 13b). A 5-7 mm transverse incision is made at the selected catheter insertion site.

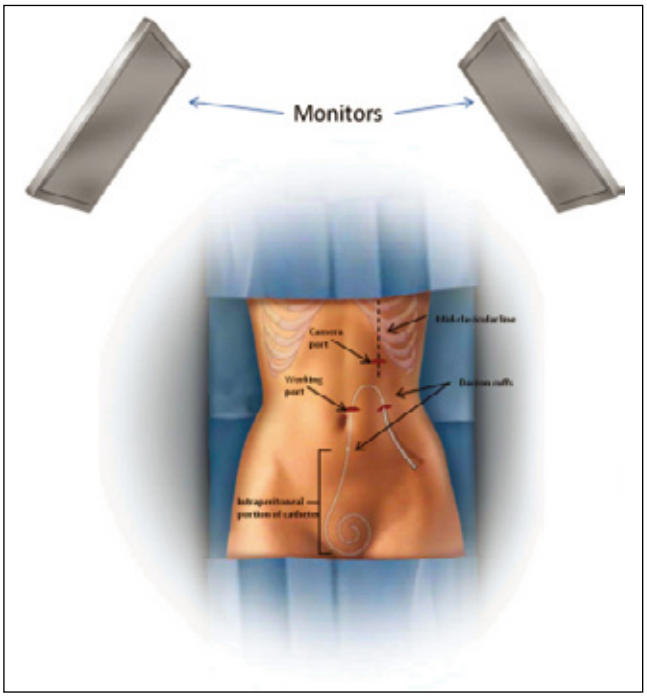

Fig. 13 - *Port locations and final position of the peritoneal dialysis catheter after laparoscopic placement*

A slightly larger skin incision is helpful when pulling the catheter with the external cuff to the skin exit site. An 18 gauge needle is inserted through the incision site directed at 45 degrees caudad. As the needle is advanced along and between the peritoneum and the posterior rectus fascia for about 3-4 cm, local anesthetic (e.g. bupivacaine 0.25%) is injected along the tract and between the peritoneum and the fascia to create a sub-peritoneal tunnel as well as to achieve postoperative pain control. The needle is then used to penetrate the peritoneum about 4-5 cm below the level of umbilicus and about 3-cm lateral to the midline in a downward direction.

The syringe is removed and a 0.35" DIA 50 cm guide-wire is inserted. With adequate wire length inside the peritoneal cavity the needle is also removed leaving only the guide wire in place. The catheter tract is created using only the stiff dilator inserted over the guide-wire with the peel away sheath off. This facilitates the second pass with the complete peel away set. While keeping the wire in place, the dilator is removed and the dilator is inserted into the 22Fr peel away sheath.

The complete set (dilator and peel away sheath), is now re-inserted over the guidewire into the abdomen under direct laparoscopic visualization. When the peel away sheath is visualized in the abdominal cavity the inner dilator is removed. The PD catheter is prepared on the back table by inserting the stylet into the PD catheter. The double-cuffed 62 cm long PD catheter with stylet is now inserted into the peel away sheath and under direct vision, the PD catheter is advanced until the tip of the guidewire is seen exiting the sheath inside the abdomen. At this point, the guide is retracted as the catheter is advanced, and the catheter will regain its "pigtail" configuration, which is to be located in the deep pelvis. The catheter is advanced until the inner Dacron cuff is seen. The guide is now completely removed, as is the peel away sheath. The inner Dacron cuff is pulled back to sit at the posterior rectus muscle fascia or in the rectus muscle. The degree of pull-back is determined based on length needed to place the external cuff at 1.5-2.0 cm from the skin exit site. Next, the curved sharp tunneler is attached to the catheter and penetrated from a first upward then downward curvilinear fashion, out through the skin. This subcutaneous tract step is identical to that in the open procedure. The superficial cuff is placed 1.5-2.0 cm from the skin.

Before the camera is removed, the proper position of the curled portion of catheter in the pelvis is confirmed. Should there be some blood in the abdomen irrigation through the PD catheter under direct camera vision is performed. After the camera is removed, pneumo-peritoneum is released prior to removal of the 5 mm cannula. Port sites are closed with one or two inverted sutures.

CLOSURE AND POSTOPERATIVE CARE. Regardless of technique, it is recommended to leave 40-60 ml of saline in the abdomen. The newly placed catheter is flushed and aspirated gently with saline, or better, allowed to drain by gravity, ruling out catheter obstruction. Three ml of heparin (concentration 1000 units/ml) are injected into the catheter to avoid catheter obstruction from small blood clots or fibrin. The catheter exit site is covered with 2x2 inch gauze wrapped around the catheter to keep the site dry. Dressing changes should be performed in a sterile fashion until wound healing is complete. If immediate PD use is required, low volume exchanges can be initi-

ated within 24-48 hours, but it is generally recommended that dialysis be delayed for approximately 2-4 weeks depending on urgency and postoperative course.

CATHETER REMOVAL. PD catheters require removal for various reasons, such after a successful renal transplant or after technical malfunctions. First during prepping a hemostat clamp is placed on the catheter next to the skin and the external catheter with the transfer set removed. Using the prior incision used for open placement, the catheter is dissected circumferentially free and sharply divided. The catheter is then followed down to the rectus muscle and its posterior fascia. The deep cuff is exposed by dividing the rectus muscle and fascia and the peritoneal defect becomes visible. Placement of a 2-0 polypropylene suture at the edge of the defect, before the cuff is completely free, will prevent losing the deep defect. After the catheter is pulled out the defect is closed. This suture is also hemostatic as bleeding can occur into the abdomen. Exercise care so as not to splash infected peritoneal fluid during removal of the intra-peritoneal segment of the catheter. Cultures are sent as indicated. Depending on location, the external cuff is excised from inside and sharply divided distal to the cuff which frees the external portion of the catheter. The skin exit site may require some skin excision or debridement and one inverted suture to close.

Complications. Catheter related complications (leaks, peritonitis, obstruction, or hernias) may occur in up to 70% of cases over the lifetime of the PD catheter and described elsewhere. (15,16).

Summary. Peritoneal dialysis remains an underutilized modality for renal replacement, despite ample evidence of improved survival and quality of life when compared to hemodialysis. Careful patient selection and planning by the surgeon as part of a multidisciplinary team caring for the ESRD patient can lead to long-term success with peritoneal dialysis. One year actuarial catheter survivals of 80% should be expected by International Society for Peritoneal Dialysis standards (30). Catheter survival rates as high as 91% at 3-years can be accomplished with proper patient management (17-19).

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Why are Catheters Still the Predominant Initial HD Access in the US and What Effectively Reduces Their Use?

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The percentage of incident dialysis patients using central venous catheters (CVC) has changed little from July 2003 (the beginning of the Fistula First program) at 72.1% to April 2012 at 72.3%. Of some encouragement is that the percentage of incident dialysis patients with a maturing arteriovenous fistula (AVF) has increased from 24.7% to 39.0% over the same period. The implication is that more patients are being referred for AVF placement prior to the onset of end-stage renal disease (ESRD) but not with sufficient lead time to allow for AVF maturation. The barriers to timely AVF placement prior to onset of ESRD are numerous. Patient-related factors include denial of the inevitability of ESRD, inadequate education regarding the importance of CVC avoidance, fear of surgery, distrust of the medical establishment, and the number of appointments that may be necessary to complete venous mapping, surgical evaluation, surgical placement of an AVF, and surgical follow-up. Education sessions to address these issues for Stage 4 CKD patients are reimbursed by Medicare, but this appears to have had little impact since there has been very little standardization of education models or research into which models are most effective.

Physician-related factors include late patient referrals to the nephrologist by primary care physicians due to the lack of clear-cut referral triggers, fear of losing the patient to the nephrologist, and underestimation of the degree of renal impairment by using serum creatinine level rather than GFR. Even if the patient is referred in a timely manner, the nephrologist may see AVF placement as a "defeat" and postpone it excessively. Many nephrology practices do not have the resources to shepherd the patient through the process of surgical referral, AVF placement and follow-up. Vascular access coordinators in nephrology practices are vital in this respect, but they are often distracted by troubleshooting of existing permanent vascular access among prevalent HD patients. The

30-20-10 mnemonic may have some impact in standardizing referral triggers: GFR 30 = referral to nephrologist; GFR 20 = referral to surgeon; GFR 10 = consideration of renal replacement therapy.
Healthcare system barrier are considerable, including fragmentation of care, payment gaps, and lost opportunities to identify and refer patients with CKD. Integrated healthcare systems such as Kaiser and the Dept. of Veterans Affairs have much higher incident AVF rates than fee-for-service systems. Most surgeons will not place AVFs in uninsured patients, who have to wait until 3 months after the onset of HD to quality for Medicare. Hospital systems have the opportunity to identify patients with CKD when they assess renal function prior to a CT scan or MRI with contrast. Patients with GFR <30 should be automatically referred to a nephrologist and possibly for AVF placement. Better vein preservation strategies at the hospital system level (including avoidance of PICC lines) will allow for healthier vessels at the time of surgical evaluation for AVF placement. Medicare payment policies should be changed to reimburse AVF placement during a hospitalization for a medical DRG and retroactive Medicare eligibility for uninsured patients to the time of AVF placement. An improved data collection and reporting system will allow for alignment of payment incentives among all stakeholders, including nephrologists, surgeons, and hospital systems.

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FFBI: Old News or New Hope?

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The Fistula First Breakthrough Initiative (FFBI, Fistula First) was established in 2003, to increase autogenous arterio-venous fistula (AVF) use in our hemodialysis patients. Additional goals included optimizing access management and catheter reduction. Based on the early success of the FFBI, the Initiative was given "breakthrough" status, whereby the Initiative was extended to provide further increase in AVF use as well as quality improvement in the area of hemodialysis access. At the inception of the FFBI in 2003, AVFs in use was 32%, compared to 60% at the end of 2011. Further, during the same period, the prevalence of total tunneled cuffed catheters (CVC) dropped from a high of 28% to 21%, and CVCs in use for greater than 90 days dropped from 21% to 16%. Related to these significant improvements, there were marked quality improvements in all areas of hemodialysis access. However, with these improved outcomes also came associated problems and challenges, which needed to be addressed. The major problem, especially as the envelope was pushed in complex AVF construction, was the non-maturing AVF. Further, in the future, as young surgeons go through a lengthy learning curve to develop the necessary skills and judgment necessary for successful AVF construction and use, there will be a higher early failure and non-maturation rate. In addition to this problem, other areas that will need to be addressed in the future are:

-- continued efforts by the FFBI and ESRD Networks, to assist poor performing professionals and centers, to increase AVF use and reduce Catheter use.
-- evaluation of outcomes and implementation of strategies necessary to achieve success
-- education and training of our young surgeons / access teaching centers (Access University)
-- a focus on Monitoring/Physical exam of the access and access extremity
-- efforts to include HD access on agendas of major scientific meetings
-- randomized. controlled trials to identify the outcomes and suitability of various procedures
-- criteria that should be used to better evaluate the suitability of patients for an AVF.

Vascular Evaluation and Decisions for Access in Diabetic Patients: Anything Different?

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Patients with diabetes mellitus frequently have vascular complications. This suggests that vascular access outcomes may be inferior in diabetic dialysis patients than in non-diabetic patients. However, the analysis is more complex, because diabetes is associated with other demographic features and co-morbidities, such as female sex, black race, older age, obesity, coronary artery disease, and peripheral vascular disease, which are independently associated with worse vascular outcomes. Thus, it is necessary to determine whether diabetes is associated with worse vascular outcomes after statistical adjustment for these variables.

A large observational study evaluated the association of AV fistula use in 1824 HEMO Study patients with various parameters (1). On univariate analysis, diabetes was significantly associated with a lower rate of fistula use (odds ratio 0.50, $p<0.001$). In other words, diabetic dialysis patients were only half as likely to dialyze with a fistula than non-diabetic patients. However, when multivariable logistic regression was performed, only 5 factors were independently associated with a lower likelihood of fistula use: female sex, black race, older age, obesity, and peripheral vascular disease. In other words, diabetes was not an *independent* predictor of fistula use; rather, it was a marker for other characteristics that were associated with lower fistula use.

Similarly, a large, prospective study evaluated the association of various clinical factors with fistula non-maturation in 422 hemodialysis patients receiving a new fistula (2). On univariate analysis, diabetes was associated with a higher likelihood of fistula non-maturation (hazard ratio 1.77). However, on multivariable logistic regression, only 4 variables were independently associated with a higher likelihood of fistula non-maturation: older age, black race, coronary artery disease, and peripheral vascular disease. One again, diabetes was not an independent predictor of fistula non-maturation; rather it was a marker for other demographic or clinical variables that were associated with fistula non-maturation. Likewise, in another prospective study of 205 patients receiving a new fistula, diabetes was not an independent predictor of fistula non-maturation (3).

Other studies have evaluated the association of diabetes with AV graft outcomes. A single-center study evaluated the association between graft survival and various clinical variables in a cohort of 256 patients receiving a new graft (4). Diabetes was not significantly associated with either unassisted or cumulative graft survival. Subsequently, a multi-center prospective study (Dialysis Access Consortium) evaluated the association between unassisted graft survival and various clinical factors in 354 patients receiving a new graft (5). On multivariable logistic regression, there was no significant association between diabetes and graft survival (hazard ratio 1.09, $p=0.5$).

In summary, diabetes is not an independent predictor of fistula use, fistula non-maturation, unassisted graft survival or cumulative graft survival. Therefore, the clinical evaluation and decision process regarding vascular access should be identical in diabetic and non-diabetic patients.

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AVF Timing: Should Pre-emptive AVF's Be Created in High Risk Patients?

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Arteriovenous fistulas (AVF) are the preferred hemodialysis vascular access due to their low complication rate (1) once they are able to provide reliable, prescribed dialysis. Therefore, timely AVF creation before dialysis initiation is considered optimal care for patients expected to start dialysis. However, in North America, 80% of patients continue to initiate hemodialysis with a central venous catheter (2, 3) and <15% with an AVF. The reasons are complex and highlighted when considering "should a preemptive AVF be placed in a high risk patient?"

The immediate response is to wonder what "high risk" is referring to - high risk for AVF failure? Fistula failure rates have recently ranged 20-60% (4-6). Even with preoperative mapping, overall AVF non-use or abandonment has been reported as high as 50-60% within the first year (5-7). Lok at el. previously developed and validated a clinical risk score based on four variables (age≥65, coronary artery disease, peripheral vascular disease, ethnicity) to predict the likelihood that an AVF would "fail to mature" (FTM). The FTM risk categories and associated risks of failure were: low: <2.0 (24%); Moderate: 2.0 to 3.0 (34%); High: 3.1 to 7.9 (50%); very high:>=8.0 (69%). Should a patient with a high FTM risk of >50% have an AVF placed? Intuitively, if there is sufficient time prior to dialysis initiation, then, the answer is "yes". Presumably, even if the AVF fails, there might be time to either salvage the AVF or create a new one. However, how do we know when a patient will need to initiate dialysis?

There are major limitations to using eGFR alone to predict risk of ESRD, need for dialysis initiation and timing of AVF placement (8). This is exemplified when fixed eGFR cut-points are applied to patients of different ages. For example, older patients tend to have slower GFR declines and lower incidences of ESRD compared with younger patients at similar levels of eGFR. A cut-off eGFR indicating the time for "pre-emptive" fistula creation might result in a high number of unnecessary AVF procedures in an older patient (9). Further, elderly patients are at "higher risk" of mortality than initiating dialysis. Thus, should "high risk" refer to the risk of death before starting dialysis? If so, should patients at high risk of death have pre-emptive fistula creation? In a new, preliminary analysis of 261 patients, we found a striking association between the FTM risk score (risk of fistula failure) and risk of mortality:

	Unadjusted HR (95% CI) for mortality
Low (ref)	1.00
Moderate	2.53 (0.55-11.6)
High	4.13 (0.90-19.1)
Very high	7.83 (1.03-59.4)
P-value for Trend	0.01

This association is not surprising as a higher FTM score is associated with advanced age and greater comorbidity (cardiac and peripheral vascular disease). Together these findings raise a very clinically relevant question for fragile elderly patients burdened with significant comorbidity. Should such patients undergo AVF creation where the risks of both FTM and death are high? This question needs to be explored in a rigorous manner where the same patients can be evaluated for these two competing outcomes at specified timeframes from the time of AVF creation. Until then, we should pause when considering preemptive AVF creation in patients at high risk of both AVF failure and mortality, and whether this course of action is the most appropriate one to optimize their care.

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For ESRD Patients, An AVF Should Always Be Considered First

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It has been well established that the autogenous AVF (AVF) is superior to other access types in all categories: patency, complications, interventions needed, mortality and costs."Fistula First" is a moniker for the Fistula First Breakthrough Initiative (FFBI), whose objective is that all patients should be evaluated and considered for an AVF first, utilizing best practices, including vessel mapping. The AVF goal set by the FFBI Work Group was 66%, which is conservative based on the experience in other developed countries as well as many centers in the U.S. An increasing number of centers throughout the U.S. have already achieved this goal, and higher, proving that the 66% target is feasible and reasonable. These centers report a reduction in catheter use as well as morbidity and costs and missed dialysis treatments, as a result of their high AVF rates. This 66% target also takes into account the many patients who are not going to be considered suitable candidates for an AVF. The intent of "Fistula First" is to increase the prevalence of *functioning* AVFs in *suitable* patients. "*Fistula First" does not mean that all patients should have an AVF at all costs.* It means that all patients should be *evaluated and considered for an AVF first,* utilizing best practices, including vessel mapping. Many patients, following evaluation/consideration, will not be deemed to be suitable for an AVF. These patients may be better suited for an A-V graft, a tunneled cuffed central venous catheter, or PD. If the intent were to expect AVFs in all patients, the goal would have been set much higher. Based on the success of the FFBI, the AVF prevalence goal of 66% is being increased to 67%, which is certainly conservative, based on the recent experience in the U.S. as well other developed countries.

A Native Vein AVF, When Possible, Is not Always in the Patient's Best Interest

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Planning is of paramount importance for the crucial and timely selection of the optimal renal replacement modality for the individual patient with end stage renal disease (ESRD) to sustain and prolong life. Controversy surrounds the algorithms of proper planning, placement and management of dialysis access including selection of the dialysis modality hemodialysis (HD) vs. peritoneal dialysis (PD), type of HD access, and when and by whom to place the access. Confounding factors, including the socio-economic diversity of the ESRD population, only partly explain the dialysis access conundrum. The rapidly developing and competing technologies, the

wide spectrum of professional experience, personal bias create forces that make the dialysis access multivariate and complex (1, 2)

The different dialysis modalities and access types must not be seen as competitive, but rather complementary, where the outcome strategy is the effective utilization of several RRT treatment options over the patient's lifetime. In contrast to this statement Individuals, institutions, governments, and specialty societies direct and subliminally influence the selection of dialysis modality. The most visible and widespread effort in this regard has been the CMS Fistula First National Vascular Access Improvement Initiative (3). Similarly, the International Society for Peritoneal Dialysis (ISPD) is stressing the underutilization of the PD modality (4). Rather than emphasizing the doctrine of one modality fitting all, selecting the most optimal access for each patient, at all times, is ethically and morally the better model.

Native vein vs. Graft. Generally, outcomes *of* native veins AVFs are reported superior to those of grafts (5). The PD modality is usually not considered in these assessments. Using the principles outlined in this abstract patient selection or suitability for a certain modality and access types becomes the decision making algorithm philosophy. As a consequence outcome is maximized for each modality and each type of access. This is true for the PD modality (6) and for grafts (7), with markedly improved outcomes compared to when a specific modality such as grafts (8) or native veins (9) is favored.

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Thigh Access: Options, Outcomes and Controversies

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Once hemodialysis patients have exhausted all options for a permanent vascular access (fistula or graft) in both upper extremities, subsequent options are to place a permanent access in the thigh or to maintain the patient indefinitely with a tunneled hemodialysis catheter. If the decision is made to place a thigh graft, one should first obtain vascular mapping studies to ensure that suitable vessels are available. In addition, it is important to screen clinically for evidence of peripheral vascular disease, to avoid the possibility of inducing lower extremity ischemia when the graft is created. If there is a clinical suspicion of PVD, additional vascular studies may need to be performed.

A number of small retrospective cases series have reported outcomes of thigh grafts without providing a control group of patients with upper extremity grafts. Several studies have compared the outcomes of thigh grafts to those placed in the upper extremity. The largest published series compared the outcomes of 409 AV grafts placed during 3.5 years at a single large medical center, of which 63 (~15%) were placed in the thigh and 346 in the upper extremity grafts (1). A technical failure (defined as inability to complete the surgery or failure within 24

hours of surgery) occurred more frequently in thigh grafts as compared with upper extremity grafts (12.7 vs 5.8%, p=0.046). The higher technical failure rate was likely due to severely calcified femoral arteries (2). However, there was no difference between thigh grafts and upper extremity grafts in terms of unassisted graft survival (median, 3.9 vs 3.5 months, p=0.55), assisted graft survival (5.7 vs 5.5 months, p=0.94), or cumulative graft survival (14.8 vs 20.8 months, p=0.62). The frequency of angioplasty, thrombectomy and surgical revisions was similar in the two groups. However, graft loss due to infection tended to be more common with thigh grafts (11.1 vs 5.2%, p=0.07).

A second single-center study compared the outcomes of 103 thigh grafts, 116 upper extremity grafts and 49 upper extremity fistulas (3). The primary failure rate (access never suitable for dialysis) was 3% for thigh grafts, 13% for upper extremity grafts and 61% for fistulas. After excluding primary failures, the 3-year cumulative survival was 53% for thigh grafts, 14% for upper extremity grafts, and 32% for fistulas. Thigh grafts had a lower thrombosis rate than upper extremity grafts (0.54 vs 1.46 per year), but a similar frequency of infection.

Finally, a recent abstract described the long-term outcomes of 209 thigh grafts placed over 8.5 years at a single medical center (4). Cumulative graft survival was 43% at 3 years and 38% at 6 years. Infection-free graft survival was 70% at 3 years and 61% at 6 years.

In summary, thigh grafts have excellent long-term survival and should be considered a viable option in patients who are not candidates for an upper extremity graft. They do have a higher risk of infection, but this risk is far lower than that obtained with tunneled dialysis catheters.

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Those Little Yellow Things that are Sold to Keep Catheters from Clotting and Getting Infected

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Dialysis-catheters are the primary mode of access for newly initiated dialysis patients in the United States, and between 15 and 20% of prevalent dialysis patients are catheter-dependent for clinical reasons or patient choice. Catheter-associated bacteremia (CAB) and catheter dysfunction (CD) are the primary causes for loss of the catheter due to its exchange or removal, catheter half-life has been described as from 2 to 5 months (1, 2). Reduction in frequency of CAB and CD will reduce patient morbidity and mortality, as well as lead to significant cost savings from reduced hospitalization and procedure rates.

Catheter-hub devices such as the BD q-Syte, the Swan-Lock or the TEGO have been FDA-approved as needle-free access devices for the administration of fluids or withdrawal of fluids from a patient and therefore passively aiding in the reduction of needlestick injuries. TEGO devices are now marketed as 7-days dialysis tunneled catheter hub devices which 1) allow for use of normal saline instead of heparin as fill solution without increase in thrombosis of the catheter lumens, and 2) decrease the catheter infection rate as direct contact with the catheter hubs is reduced.

Available data on the use of hub devices with dialysis catheters reveal that all of them increase arterial and venous pressures, albeit to varying degrees (3). Dialysis tunneled catheters by design have two compartments in the venous and arterial lumen: one between hub and safety clamp, and a second between safety clamp and catheter tip. Loss of fill solution from the second compartment is determined by the difference in specific gravity between fill solution and blood (4), as well as motion of the tunneled catheter inside the patients and in relation to gravity. Based on these circumstances neutral displacement connectors would not be expected

to have any effect on the catheter compartment beyond the clamp and clinical observations show blood in catheter lumens up to the clamp in catheters using such devices. The apparent equivalency of normal saline locks with use of TEGO devices compared to traditional heparin locks with regard to catheter dysfunction (5) raises the question if heparin locks are necessary at all for the majority of tunneled catheter. In terms of infection, if catheter hubs and the dialysis tubing are clean, no bacteria should be introduced into the circuit. The manufacturer's recommendation for use list three separate cleaning steps for the TEGO device, and its bright yellow color makes adherent debris more visible than, the red or darker blue of un-covered catheter hubs. However, an ongoing randomized controlled study using TEGO devices has thus far not found a significant difference in infection rates (6).

In summary, equivalent catheter dysfunction rates with use of normal saline instead of heparin as catheter lock solution are unlikely to be related to the use of a catheter hub device. A potential effect on catheter infections is more likely due to altered human behavior than a technical design feature of catheter hub devices other than their bright color.

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Terms and Definitions – Do They Matter and Can We Agree?

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Vascular access is increasingly recognized as a subspecialty clinical practice. Many hospitals now have a dedicated vascular access team, in the U.S. there are more than 200 outpatient vascular access centers, and there is one national journal and one international journal focused on vascular access, two national vascular access associations, and a national certificate for vascular access competency (1). An increasing number of State Boards of Nursing are recognizing vascular access as a nursing subspecialty and broadening the scope of local nursing practices.

Vascular access specialists work in nursing homes, operating rooms, chemotherapy infusion centers, angiography suites, critical care units, hemodialysis centers, emergency rooms, inpatient apheresis, and home infusion therapy. A vascular access specialist may be a registered nurse, a nurse practitioner, a physician's assistant, a respiratory therapist, an interventional radiologist,

an interventional nephrologist, a critical care specialist, an anesthesiologist, or a surgeon of any type. Regardless of their background or work setting, most vascular access specialists perform the same procedures using the same techniques (ultrasound + Seldinger) and use the same CPT codes.

Many national organizations in nursing, surgery, medicine and radiology have published guidelines, recommendations and standards of practice related to vascular access practices, procedures, and publications. Some of these documents were created independently and others were created collaboratively with consensus of multiple national organizations (2). Some guidelines and recommendations are based upon consensus opinion and others are based upon research and data analysis. A few of these documents were written without knowledge of nearly identical preexisting documents written by other national organizations. A recent editorial

in the journal *Anesthesiology* highlighted issues and problems related to the inequality of nationally recognized patient care policies (3). Butterworth and Rathmell argue for evidence-based policies that should "arise only from relevant medical specialty societies" (3).

Ideally, the national guidelines, recommendations, standards of practice, and government policies related to vascular access should be uniformly recognized by all vascular access specialists, the government, the health insurance industry, and the legal system (4). Standardized terms and definitions allow better comparisons of medical information and research over time. It is in everyone's best interest for there to be much greater sharing, collaboration, consensus, and agreement among shareholder societies and organizations (5).

A necessary first step in this process is to establish uniform terms and definitions for all vascular access applications and for all types of vascular access procedures (6). Existing terms and definitions used in documents from the American Boards of Surgery, Radiology, Medicine, and Nursing should become the de facto national nomenclature for vascular access procedures. Of similar importance, terms and definitions used in documents from governmental agencies, such as the Centers for Disease Control (CDC) and the Centers for Medicare & Medicaid Services (CMS) should be incorporated into the vascular access lexicon.

A uniform, well-recognized nomenclature is needed to improve many aspects of vascular access. It is a necessary first step for unification of national guidelines, recommendations, and standards of practice.

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It's an RCT, It Must Be True

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The efficacy of a new intervention is most readily accepted if the results are from a randomized controlled trial (RCT). It is generally accepted that in this time of evidence based medicine that an RCT, when appropriately designed, conducted, and reported provides the best possible basis for making clinical decisions. However, they can yield misleading and erroneous results if certain basic methodological principles are not followed. Unfortunately, some studies published with an RCT label are lacking in methodological rigor (1-3). One of the most frequent errors that occur in published RCTs relates to sample size. Many studies are simply under powered. The purpose of an RCT is to determine statistical significance. Generally, a result is considered to be statistically significant if the observed difference between groups could have occurred by chance alone less than one time in 20 (5%). This is the same as the false-positive rate (Type I error or α. This generally expressed as a probability value ($P < 0.05$). Power refers to the probability of finding a difference in treatment effect between the intervention groups when a difference really exists. It is equal to 1 – the false negative rate (Type II error or β. Generally the goal is to achieve an 80% to detect a 50% difference.

In a systematic review of RCTs published in 3 major medical journals (JAMA, New Eng J Med, Lancet), Moher, et al (4) reviewed 102 studies. Only 36% had an 80% power to detect a 50% difference. An additional 16% had an 80% chance of detecting a 25% difference. Of the RTCs reviewed, 68% failed to report sample size calculations. Since investigators submit Underpowered RCTs and reviewers overlook their inadequacies, it is left to the reader to determine if what is being presented as the highest level of medical evidence is actually biased as a result of being underpowered.

Although the calculation of sample size required to attain the desired power for a study involves a complex

formula, there are two simple methods that can be used to arrive at a good approximation (2): 1) 50:50 rule and 2) the width of the confidence interva (CI)l.
50:50 rule – This states that for studies with a dichotomous outcome (+ or -), 50 events are needed in the control group for an 80% chance of a 50% difference (2). It is important to note that this is the number of events not number of cases. For example, if the thrombosis rate in a cohort is known to be 0.25 per patient-year, then it requires 200 cases for each arm of the study. If the rate is 0.5, then only 100 cases for each arm would be required.
Width of CI - If the CI is very wide, then there is little certainty that the study result is a good estimate and the study is likely to have been too small. If the CI is not stated, it can be calculated from the standard error of the mean (CI is equal to $\pm$ 1.96 X SE). The smaller the SE, the closer the CI limits. For example, a study was done comparing angioplasty to no angioplasty. More infection was seen in the angioplasty group and the conclusion was that this treatment predisposed to infection. The hazard ratio was 6.13 and the CI 1.14–33.10, $P = 0.04$. Looking at the CI suggests that their conclusion is biased by being underpowered.
Even in reports where the number of cases needed to obtained the desired power and the mechanism by which this number was derived is described, one frequently sees instances in which the drop-out rate is high and the number of cases that complete the study makes it underpowered. It must be kept in mind that power calculations for a study that is looking at outcomes over a period of time are based upon the number of cases that complete the study, not those that simply start.
RCTs are the gold standard for evidence based medicine, but An RCT requires more than just a label. Methodological rigor should be considered minimum criteria for publication. Until it is, readers beware.

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AV Access Surveillance and Monitoring: What's Expected and How It's Really Being Done in the US?

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Monitoring and surveillance are complementary processes for detecting vascular access dysfunction. The goal is to detect clinically significant stenosis that if untreated will result in thrombosis. Treatment of stenosis and preventing its recurrence should prolong the life of the vascular access. Monitoring comprises awareness of clinical indicators of vascular access dysfunction and the physical examination of the access, whereas, surveillance involves periodic evaluation of the vascular access using special instrumentation. The positive predictive value of a properly performed physical examination by skilled dialysis personnel is as high as 70-80% (1). Measuring intra-access blood pressure and access blood flow are two common methods of vascular access surveillance (2, 3). Doppler ultrasound as a surveillance method has the advantage of combining blood flow measurement with direct visualization of access stenosis (3). Monitoring and surveillance should start from the surgical construction of the vascular access and continue throughout the life of the access. Monitoring plays an important role in the CKD patients whereas surveillance complements monitoring in HD patients. Monitoring is difficult to practice in HD patients who are typically examined during HD when needles are within the vascular access. Surveillance is limited by the need for equipment and trained personnel. In addition, all randomized trials to date have not shown a significant benefit of surveillance in the prevention of access thrombosis (4). Hemodynamic variability during hemodialysis causes marked changes in access blood flows and pressures. Therefore, changes in surveillance measures should be repeatedly confirmed before interventional referrals are

made. A combination of clinical indicators, physical examination and trend analysis of surveillance data may be the best way to detect vascular access dysfunction.

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AV Access Flow Measurements – When Are They Abnormal and What Should Be Done?

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Periodic measurement of the rate of intraaccess blood flow can be used as a surveillance method for early detection of vascular stenoses associated with hemodialysis grafts and fistulas (1). Since the mid-1990's the ultrasound dilution technique has been a popular method for measuring the rate of blood flow in PTFE grafts, autogenous fistulas and hemodialysis catheters (2). There are many publications reporting rates of intraaccess blood flow measured using the ultrasound dilution technique. This uniformity of measurement has improved our ability to compare the results of different research studies. There are now other reliable methods for measuring the rate of blood flow and some new hemodialysis machines have integrated blood flow measurement modules to improve the frequency of blood flow measurements.

It is important to understand that rates of blood flow measured using ultrasound dilution or another qualitative technique will not directly correlate with rates of blood flow measured using Doppler ultrasound (3). There are several studies that confirm this lack of correlation between ultrasound dilution and Doppler ultrasound (4).

The rate of intraaccess blood flow can be used as a criterion to define a dysfunctional vascular access. Guideline 4.4.3 of 2006 K/DOQI recommends referral for fistulography if the rate of blood flow is <600ml/min in a prosthetic graft or <500ml/min in an autogenous fistula (5). These criteria have been incorporated into national policies pertaining to hemodialysis vascular access including Medicare/Medicaid and other national health care insurance providers.

But there is a growing body of evidence that calls into question the reliability and usefulness of using blood flow measurements for vascular access surveillance (6). It has been shown that day-to-day variations in the patient's blood pressure can affect the rate of blood flow and thereby confound trend analysis and decrease the specificity of the method for detection of stenoses (7).

In 2001 a catheter-based system became available that could easily measure the rate of blood flow during diagnostic angiography and subsequent interventional procedures. This 6 French catheter system uses ultrasound dilution for measurement of blood flow so values obtained in the angiography suite are directly comparable to those obtained in the hemodialysis treatment center using standard ultrasound dilution equipment (8). An early report by Brian Murray suggested that a post-angioplasty blood flow rate >1000ml/min in a PTFE graft was predictive of a good result (9). However, a recent study found no correlation between the post-angioplasty rate of blood flow and graft patency (10).

This presentation will present perspectives on the usefulness of using intraprocedural blood flow measurements; 1) to assess the functionality of a hemodialysis graft or fistula, and 2) to assess the success of an interventional procedure.

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Hyperkalemia in the Pre-operative Patient

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Potassium homeostasis is generally well maintained in patients with advanced chronic kidney disease until the glomerular filtration rate falls below 10-15 ml/min. Loss of nephron mass is counterbalanced by an adaptive increase in the secretory rate of K^+ in remaining nephrons such that fractional excretion of K^+ is increased. With more severe reductions in the GFR hyperkalemia becomes a common electrolyte disorder. Prompt recognition, patient risk stratification, and administration of appropriate treatment are essential in preventing the serious complications of this common electrolyte disturbance.

The therapeutic approach to hyperkalemia generally is based on the absolute value of serum potassium concentration and specific electrocardiographic (ECG) changes. ECG changes reflective of cell membrane depolarization cannot serve as a reliable indicator of hyperkalemia severity because up to 60% of patients with a serum potassium level >6.0 mEq/L present without ECG abnormalities. Moreover, severe ECG disturbances, such as ventricular fibrillation, occasionally may occur without antecedent T-wave peaking or QRS prolongation. In patients with typical hyperkalemic ECG findings, emergent therapy should be initiated without waiting for biochemical confirmation. Therapy also should be initiated in patients with a serum potassium level >5.5 mEq/L, even in the absence of ECG changes, because of the significant risk of rapid development of such changes. The recommended sequence of interventions starts with measures to stabilize the myocardium, followed by therapies to shift potassium into the cells, and finally, definitive treatment to remove potassium from the body.

Calcium administration is an emergent treatment modality directed at restoration of the transmembrane electrical gradient of the cardiac myocytes. Insulin treats hyperkalemia by activating skeletal muscle Na^+-K^+-ATPase, thereby leading to intracellular potassium shift. β_2-adrenergic agonists induce intracellular potassium movement by upregulating Na^+-K^+-ATPase activity in skeletal muscle by a cellular pathway distinct from that caused by insulin. Thus, the potassium-lowering effects of insulin and β_2-adrenergic agonists are additive.

Sodium bicarbonate is not effective for the treatment of acute hyperkalemia, although it may be useful in a subset of patients with significant metabolic acidosis. Sodium polystyrene sulfonate resin given orally or rectally binds potassium secreted into the colon; however, its hypokalemic effect and timing are variable and can take up to 10 hours. Oral sodium polystyrene sulfonate often is supplemented by a cathartic, such as sorbitol, to avoid the resin-induced constipation. Complications of the resin include volume overload and intestinal necrosis when administered with sorbitol in the settings of decreased intestinal motility. Dialysis is the definitive therapy in patients with end-stage renal disease, severe CKD, and acute kidney injury or if there is a comorbid condition, such as digitalis toxicity or rhabdomyolysis.

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The Safe and Effective Use of Carbon Dioxide in Fistulography

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As an imaging agent, carbon dioxide (CO2) was first introduced to the practice of radiology in 1914 to evaluate the retroperitoneum, visualize the kidneys, and discover possible tumors. Later in the 1950s, CO2 was used in the venous system to diagnose pericardial effusions. Today, with the development of high-resolution digital subtraction radiography, stacking software, tilt tables, c-arms, and reliable delivery systems and with significant research in regard to the metabolism and physical properties of CO2 by Hawkins and Cho, CO2 is now used in countless interventional procedures and produces nearly comparable imaging to iodinated contrast medium. Iodinated contrast medium has been the gold standard for radiographic imaging since its discovery. While it is easy to use, it can often cause contrast induced nephropathy or the development of contrast allergy. An alternative contrast agent is gadolinium. Although expensive, gadolinium provides excellent image quality, but in 2008, it was found to have a direct causal relationship with nephrogenic systemic fibrosis (NSF). The risk of NSF is greatest in acute renal injury (AKI), chronic kidney disease stage 5 (CKD), and end stage renal disease (ESRD). Thus, the use of gadolinium in patients requiring vascular access intervention would not be recommended.

CO2 has proven to be an excellent radiographic imaging agent. It is inexpensive, found to be safe for intravascular injections, has a low viscosity, and is highly soluble. In addition, CO2 does not mix with blood, but instead, replaces it, and there is no limit to the volume of CO2 that can be injected, provided the operator allows one to two minutes between injections. It is important to emphasize that these individual injections should be less than 100cc per dose. In addition, because of CO2's rapid dissolution and elimination from the lungs, great care needs to be given to patients who suffer from significant chronic obstructive pulmonary disease.

There are absolute contraindications to the use of CO2 in the vascular tree. Neurotoxicity, which can result when CO2 is injected into the cerebral circulation, may be manifested by seizures, altered mental status, loss of consciousness and possible death. Thus, extreme caution needs to be given when injecting CO2 into a fistula or shunt because an explosive delivery of CO2 could cause reflux of CO2 into the feeding artery and subsequently into the subclavian artery. The coronary circulation should never be exposed to CO2. The known clinical signs of gas embolism in the coronary arteries include bradycardia, hypotension and an abnormal EKG. A relative contraindication to the use of CO2 is its use in conjunction with nitrous oxide anesthesia. Nitrous oxide has been found to diffuse into the CO2 bubble and can increase its volume six times. Additional relative contraindications are pulmonary gas embolism or possible systemic gas embolism secondary to a patent foramen ovale.

Studies have been performed by Sullivan et al. evaluating the usefulness of CO2 as a contrast agent in the assessment of upper extremity veins and by Hahn et al. assessing the efficacy of CO2 gas for the image-guided placement of peripherally-inserted central venous catheters. Both studies found favorable results with image quality and effectiveness when using CO2 as their contrast agent. Heye and Maleux conducted a study comparing iodinated contrast medium to CO2 in the assessment of upper-limb and central vein patency and stenosis. They demonstrated that CO2 venography had a sensitivity of 97%, specificity of 85% and an accuracy of 95% when compared to iodinated contrast medium.

When administering CO2, the delivery system should consist of a hand-held syringe and a closed plastic IV bag system. Neither the bag, nor the syringe and delivery tubing should be connected to the CO2 canister. Care needs to be taken so that saline does not mix with CO2 to form carbonic acid which can cause pain upon injection.

In summary, carbon dioxide is a safe, effective and inexpensive diagnostic alternative to iodinated contrast medium in the evaluation of the anatomy and the pathology in the pre and current dialysis patient and in the renal transplanted patient .

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12 Month Interim Results from a Multicenter, Prospective, Randomized, Concurrently-controlled Post-approval Study of the Flair® Endovascular Stent Graft (RENOVA)

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The pivotal study of the Flair® stent-graft compared outcomes with PTA alone versus PTA with an ePTFE covered Flair® stent-graft for primary treatment of stenosis at the venous anastomosis of hemodialysis access grafts . There was significantly improved 6 month treatment area primary patency (51% vs. 23%, P<0.001) and access circuit primary patency (ACPP) (38% vs. 20%, P=0.008) in the Flair® group versus PTA alone. Based upon that positive outcome the Flair® stent graft was approved by the FDA for treatment of stenosis at the venous anastomosis of hemodialysis access grafts. The RENOVA study was performed as a post-approval trial to evaluate long-term safety and efficacy of the Flair® stent-graft, extending the post-intervention observation period to 24 months. The RENOVA protocol was modeled closely upon the Flair® trial, with an important exception: The Flair® trial stipulated protocol angiography studies of the graft at 2 and 6 months; no protocol angiography was performed in the RENOVA trial with all imaging and intervention based upon clinical and functional criteria.

Patients included in the RENOVA study had a patent upper extremity graft with ≥ 50% stenosis at the venous anastomosis associated with hemodynamic, functional, or clinical abnormalities. The target lesion length was ≤ 70mm. Infected grafts and those that had undergone thrombectomy within 7 days prior to the index procedure were excluded. Eligible patients were randomized to either treatment with PTA alone or PTA with placement of a Flair® stent-graft. Subjects were followed-up at 30 days, 6, 12, and 24 months post-index procedure, recording all adverse events and access interventions. The primary outcome measure was ACPP.

Between January 2009 and November 2010, 28 study sites in the U.S. enrolled 270 patients. 132 patients received treatment with PTA alone and 138 patients received treatment with PTA and a Flair® stent-graft. There were no significant differences in patient demographics or baseline criteria between the PTA and Flair® cohorts (including patient age, gender, years on dialysis, graft age, location, size, prior treatments, and presence of remote lesions). ACPP at 12 months for the PTA group was 10.3% (95% CI, 0.049-0.157) compared with 24.1% (95% CI, 0.167-0.316) for the Flair® group (p=0.005). The incidence of all adverse events was similar.

Early results of the RENOVA trial demonstrate a large and statistically significant difference in 12 month ACPP favoring the Flair® stent graft. This was similar to the differences in patencies reported in the Flair® trial at 6 months. The clinical implications of these findings remain to be fully elucidated. Secondary graft patency data collection and analyses are incomplete and post-hoc analyses will be performed to examine other outcome measures including treatment area patency rates and modes of access failure.

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Stent-grafts for Salvage of PTA: Outcome in 106 Patients

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Introduction: Loss of permanent arteriovenous (AV) access function is a frequent and recurrent problem for hemodialysis patients, often related to the development of stenosis with or without secondary thrombosis (1, 2). Percutaneous transluminal angioplasty (PTA) has been widely adopted to treat AV access stenosis (3, 4) but residual stenosis, venous rupture and early recurrence of stenosis at the treatment site reduce technical success as well as post-PTA patency (5). Furthermore, on occasion, hemodialysis pseudoaneurysms develop that may require treatment. In our practices, we have used a number of techniques to manage AV access PTA failures, PTA-related complications, and pseudoaneurysms, including the use of either a self-expanding bare metal stent or a stent graft (SG). SG's are used commonly in many practices, though an understanding of technical and clinical outcomes after using these permanent implants is limited. To better understand use of SG's in AV access intervention, we retrospectively reviewed the technical outcomes and 180-day clinical patency when SG's were used after PTA for maintaining or restoring access flow.

Methods: Our most extensive experience has been with the Fluency Plus SG. We identified all cases where this SG was used to salvage angioplasty (PTA) technical failures and complications in AV accesses over two years. 106 patients were treated with 138 SG's. Indications for SG use were residual stenosis post-PTA (n=81), post-PTA extravasation (n=22), early recurrent stenosis (n=14), pseudoaneurysms (n=4), and "other" (n=4). Data were retrospectively analyzed for complications and outcomes.

Results: Clinical success, with residual stenosis <30% and successful first post-procedure hemodialysis treatment, was achieved in 104 of 106 patients (98%). Technical complications were few, with peri-procedure AVG re-thrombosis (2), intra-procedural SG dislodgment (1), venospasm (2), and contrast-related hives (1). One patient returned at 2 months with both an infected AVG as well as an infected SG in the outflow vein.

At 180 days, post-intervention primary patency (PIPP) was 47% and post-intervention secondary patency (PISP) was 79% for all AV access circuits (AVF's and AVG's). PIPP was 62% for autogenous fistulae (AVF's) and 35% for prosthetic grafts (AVG's); p = 0.010. The 180 day PIPP for 9-10 mm diameter SG's was 63% versus 38% for 6-8 mm diameter; p =0.012. Implants that did not cross the elbow had a 180-day PIPP of 47% compared to 25% across the elbow; p =0.032.

Discussion: The Fluency Plus stent graft afforded overall primary and secondary patency rates similar to retrospective reports of primary uncomplicated PTA. In certain subgroups the 180 day PIPP exceeded the K-DOQI threshold of 50% following PTA. For example, patients who received 9-10mm stent grafts had 180 day PIPP of 63%.

The AVF group that received a SG had better patency than the AVG group. While the explanation may be due to the often cited superior patency of a working AVF compared to an AVG (6-8), we wondered if diameter of the implanted stent graft biased the results. For example, if there were many more 9-10mm devices used in the AVF group then improved PIPP for AVF's may simply be related to using larger diameter devices. But we found no difference in mean diameters of the implanted stent grafts (8.30mm AVF; 8.35mm AVG).

Thrombosis at initial presentation is probably the best explanation for the observed patency difference between AVF's and AVG's. Thrombosis has an adverse impact upon secondary patency of an AV access circuit when compared to secondary patency of a stenosed but flowing access (9). In our series 20 of 58 AVG's (35%) were thrombosed at presentation whereas thrombosis was present in only 4 of 43 AVF's (9%). Therefore, the higher percentage of thrombosed AVG may have reduced overall 180-day PIPP for AVG's and favored AVF's.

Primary patency of stent grafts placed at the elbow was poor. We believe that this location exposes the device and its adjacent venous segments to repeated trauma through repeated flexion which may induce restenosis or mechanical narrowing due to device deformation or fracture. While this theory has not been tested, our data suggests that use of the stent graft at the elbow should be avoided.

Conclusion: The FLUENCY Plus Stent Graft was effective for maintenance of hemodialysis access circuit patency and was comparable or better than historical outcomes for successful and uncomplicated PTA. Factors that favored improved patency included larger diameter devices, use in AVFs, and avoiding placement across the elbow joint.

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Stent Grafts in AV Access: Is There Madness to the Method?

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There has been an explosion of stent (S) and stent-graft (SG) use in AV access in the US and elsewhere over the past several years. While many practices, including ours, consistently use these devices in less than 5% of all HD interventions, it is now common to see publications reporting S/SG use in a much higher percent of interventions (1). Indeed, I am aware of some practices which have over 50% S/SG use in HD interventions (privileged communication, 2011). Compared with PTA, in the US a stent graft costs ten times as much; a stent five times as much. Thus, the costs of AV access maintenance are likely exploding, unless it can be shown that these devices reduce reintervention by the same degree. Unfortunately, that is not the case: the only randomized controlled trial (RCT) to show benefit of SG in HD access over PTA alone showed AT BEST a doubling of patency, thus making the devices not even close to cost-effective (2). Further, that study only evaluated the results of a single device at the AV anastomosis of grafts, and no RCT has studied stent grafts versus PTA in any other location, whether in grafts or fistulae. There continue to be a moderate number of retrospective studies (with all of their associated limitations) showing glowing results of SG in particular in HD applications; over 80% primary patency at over 2 years was reported for one device in a small study (3). A more recent publication provides an interesting and insightful counterpoint to that study, a retrospective review of a similar patient population and a slightly different device yielded 47% primary patency at 180 days; similar to results reported for PTA in studies of like design (4). This broad variation in reported results sharply underscores the need for RCT in this area and should cause anyone using S/SG in double digit numbers to pause and reflect.

Further madness has occurred with the proliferation of stent-graft use in cannulation zones, either to treat cannulation site lesions (CSL, a term preferable to pseudoaneurysm for multiple reasons) or true aneurysms in fistulae. Not only does the evidence not support this practice compared to surgical revision, there is ample

evidence of poor patency (5-7), increased infection (1) and device breakdown sometimes with skin penetration (7, 8) to give any sane practitioner pause when considering this option. While these devices may have a temporizing role in acutely bleeding patients to salvage an access, the ready availability of durable immediately puncturable graft material (thus not requiring a temporary catheter) makes surgical repair the preferred option at present. These is no question this is a ready area for a RCT, however no manufacturer at present is willing to stand behind their SG device as "puncturable" and placement tin cannulation zones is contraindicated.

The terminal arch of the cephalic vein is another area of current insanity. A RCT comparing S to SG in the terminal arch of the cephalic vein (9) showed fairly convincing evidence of superiority of the covered device in this location. However, since no RCT of SG or S versus **PTA** in this location has been performed, there is not a shred of evidence that either is preferable to PTA, a nuance apparently lost on many practitioners considering that we see a huge number of SG/S placed in the terminal arch in our geographic area, often as part of a "full metal jacket" and often with disastrous results. SG/S in this location can extend into the subclavian vein and eliminate subsequent alternative accesses in the same arm (this disastrous complication is illustrated nicely in the paper by Shemesh et al) and even when the device is well positioned, the resulting alteration of flow can result in stenosis of the axillary vein, with identical problems for future ipsilateral access. Further, and perhaps most importantly, PTA provides a durable result in this location in most patients.

Finally, it is sheer madness to place a SG in frustration when repeated access failure occurs. While this has not been clearly fleshed out in the literature as of yet, it will almost certainly eventually be: in these patients there are likely multiple reasons for repeated failure which can include hypercoagulable states, latent access infection, or other factors which no mechanical device will fix. In our practice, after initial enthusiasm based on the initial RCT (2), we found little if any improvement in patency when using SG in this setting and have largely abandoned doing so.

Is there any sanity amidst the madness? I believe there is. The limited available evidence suggests that when we must place a S/SG device, it should be covered (2, 9) and we will see yet another SG-PTA RCT published later this year or early 2013, which will hopefully further inform our decision making. When balloon tamponade of PTA-induced rupture fails (it is successful 70% of the time), we now use a SG where we previously used a bare metal device (10). As noted above, a SG may be life- and access-saving in the event of a CSL. In selected patients with solitary lesions responding well to PTA initially, then yielding diminishing returns over time, I believe a SG can "reset the clock" and yield cost-effective patency; however the entire question of cost effectiveness of PTA versus S/SG has yet to be answered in any meaningful way. As noted above, our (we believe) judicious use of stent-grafts in this fashion results in approximately 4% S/SG use in a busy HD practice. Those whose SG/S use reaches into the double digits should question whether there is indeed madness in the method.

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The Hybrid AV Graft: Clinical Experience

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The Hybrid AV graft (WL Gore, Flagstaff AZ) is a heparin bonded ePTFE graft with a nitinol-reinforced stent section. Once deployed into the outflow vein, the stent portion of the graft results in a sutureless end-to-end anastomosis. Presumably, with the costs of the graft, its use is to be focused on complex patients, and not for routine application. It can be placed through an open incision or an over-the-wire, percutaneous technique. Theoretically, the "end-to-end" configuration with the stent portion improves the hemodynamic characteristics of the graft outflow, decreasing variation in wall sheer stress, and reducing subsequent internal hyperplasia. A porcine study (1) has demonstrated reduced stenosis and thrombosis associated with the Hybrid graft in comparison to an end-to-side anastomosis.
Examining the limited clinical data available, the outcomes look promising.
Ross (2) describes outcomes in 83 patients, with a mean follow-up of 245 days. Functional graft patency is reportedly 82% and 69% at 6 and 12 months respectively. Brandt et al. (3) reports the outcomes of 14 patients with the Hybrid graft placed over a 6 month time period. They observed 3 graft occlusions in the follow-up period (79% patency) only one of which was secondary to venous outflow abnormalities. Twenty-three successful cases have been reported by Anaya-Ayala (4). Nineteen patients had functional patency (2 had not used the graft). They have reported that 7 patients required additional procedures including stent graft extensions and PTA to improve venous outflow in the complex patients chosen for this procedure.
While this may not be a graft for everyday use, in well selected patients it may provide very good outcomes as an anatomic solution for difficult anatomy.

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Venous Window Device: Save Trial

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The SAVE trial was initiated to evaluate efficacy and safety of the Venous Window™ Needle Guide (VWNG) to salvage uncannulatable but otherwise functional arterial venous fistulas. Buttonhole cannulation technique is utilized through the small totally implanted titanium device. The Venous Window guide is surgically secured with fine vasculature suture to the anterior wall of the vein and positioned to allow palpation of the cannulation ridge for reliable buttonhole cannulation of the established AV fistula. The device comes in various heights from 4.0 to 10.0 mm tall and 7.0 or 9.0 mm in diameter. The study is a prospective multicenter single arm evaluation with the subject acting as their own control. AV fistulas 6.0 to 15.0 mm in depth that have had multiple attempts at failed cannulation or are simply unable to be palpated for cannulation are among the inclusion criteria. Patients with recent myocardial infarction or stroke are among those excluded. The study end-point is six months follow-up with reliable and successful cannulation avoiding adverse events. A total of 54 subjects are to be enrolled at up to 15 locations.
Results to date include 26 patients with 39 devices implanted for cannulation. There have been no devices

requiring removal due to dysfunction or infection. All patients qualified for cannulation have successfully had repeated cannulations within the study guidelines. Catheters have been removed in 9 of 24 patients. There have been no device related complications, infections, interventions, ulcerations or deaths after more than 2000 device days. It is anticipated that the device will offer a useful alternative to more major procedures for reliable and safe salvage of difficult AV fistulas.

Early Access Grafts

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In the last several years, there has been a major shift in the pattern of dialysis access in the United States as a result of the Kidney and Dialysis Outcomes Quality Initiative and the Fistula First Program. Fistulas now comprise more than 60% of prevalent accesses (1). In some communities, the prevalence of fistulas approaches 100%, but the rest of the country continues to have need for prosthetic grafts.

Graft technology has sought to make improvements in many aspects. Technologies have been developed to make grafts feel more like fistulas, alter the fluid mechanical forces to reduce intimal hyperplasia, drug coating to reduce thromboses, and alterations in the wall structure to allow early access.

Early access grafts have the potential to be used immediately after surgical placement rather than the typical 2-4 weeks allowed by most surgeons. Improved wall structure might as well improve the tolerance of grafts for needle puncture and reduce the incidence of pseudoaneurysms. Perigraft hematomas are also thought to predispose grafts to infection, so this as well might be improved with early access grafts. Some physicians employ early access grafts to reduce catheter use, which could improve rates of catheter sepsis which are clearly a major source of morbidity and mortality. Another potential benefit of immediate stick grafts is reduction or elimination of graft seromas.

The only approved early access graft is the Vectra™ graft from Bard. This graft is made of polyurethane, with distinct properties from most grafts marketed which are made of polytetrafluoroethylene (PTFE). This graft comes in 5 and 6 mm diameter sizes, between which we prefer the 5mm for its reduced tendency to king. In studies done Vectra has comparable patency rates to standard PTFE grafts (2).

Another graft commonly used as an early access graft but without specific Food and Drug Administration (FDA) approval for that indication is the Flixene™ graft from Atrium. This is a PTFE graft with a trilaminate structure which has eliminated seromas and proved to function well as an early access graft (3). Generally, this graft is thought to be able to be accessed within 72 hours of implantation.

Other grafts are currently under trial, including the Accuseal™ graft from W.L. Gore.

Some physicians have suggested that in many cases it is bruising and pain from tunneling that limits early access of grafts due to patient discomfort.

In the hands of most surgeons, grafts will continue to play a role in the care of access patients. Potential improvements offered by early access grafts may prove to be important advancements in graft technology that benefit patients requiring dialysis that are not candidates for fistulas.

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Safety of Conscious Sedation for Hemodialysis Access Surgeries in an Outpatient Setting

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Background: Patients on hemodialysis require a functioning vascular access, ideally an AV Fistula, to receive therapy. This patient population often has multiple co-morbidities which could present a barrier to dialysis access surgery. Reduction of barriers to AV access surgery may increase the incidence and prevalence of a reliable vascular access and further decrease the use of tunneled catheters for dialysis.
Methods: From September 1, 2011 through January 5, 2012, 170 consecutive outpatient dialysis access surgeries were done by 3 operators using conscious sedation and local anesthesia. These procedures were performed both on an Ambulatory Surgery Center and in a Vascular Access Center. The types of surgeries included 63 forearm AVF creations, 89 upper arm AVF creations, 5 AVG placements, 9 basilic vein transpositions, and 11 AVF superficialization/elevations.
Results: The patient ages ranged from 22.25 to 91.12 (63.80) years and the procedure time ranged from 14 to 224 (64.65) minutes. 58% of the patients were diabetic, 96% had pre-existing hypertension and 36% had established End-stage Renal Disease. Surgery was performed with local anesthesia (mixture of Lidocaine 2%, Bupivacaine 0.25% and Sodium Bicarbonate) without epinephrine. Most of the study population also received sedation with Midazolam 0.5 to 12 (3.42) mg and Fentanyl 0 to 450 (71.16) mg (N=119) or Morphine 1 to 10 (3.84) mg (n=34). No significant intraoperative complications due to sedation or local anesthetic occurred. One patient did experience intraoperative hypotension and bradycardia that was treated medically during the procedure and did not require any other change in the operative plan or termination of the surgery. In follow-up consisting of questionnaire and examination with ultrasound, no significant complaints or problems were elicited at 0 or 2 weeks post-operatively. Of note, 1 patient was on chronic Methadone therapy pre-operatively and tolerated the 79 minute case using 4 mg Midazolam, 100 mcg of Fentanyl and 18 ml local anesthetic and another patient using a transdermal Fentanyl Patch had no issues with pain or stress during a 100 minute procedure using 6 mg of Midazolam, 100 mcg Fentanyl and 13 ml of local anesthetic.
Conclusion: Most vascular access surgeries can be safely and comfortably performed using local anesthesia supplemented as necessary with sedation. Inability to tolerate general anesthesia or regional anesthetic block should not be a barrier to achieving an effective AV access for dialysis.

Central Venous Occlusion Anatomy and Etiology in the Dialysis Patient: Begging for Clarity

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Central venous stenosis or occlusion has been well reported as a cause of dialysis access failure. The source of this problem has been postulated by several authors, yet no clear consensus regarding its etiology has been reached. Many believe that central venous pathology in this population is the result of multiple catheterizations, scar formation and fibrosis of the central veins (1, 2). This often leads to clinically significant venous hypertension after placement of a dialysis access conduit and thus necessitates intervention on behalf of the venous outflow obstruction, perhaps exacerbating the already troublesome problem.
The anatomy of central venous occlusion is of critical importance in determining a feasible treatment strategy. Many lesions are amenable to percutaneous transluminal venous angioplasty; however, in some instances the anatomy of the central venous pathology prohibits adequate venous outflow decompression via this technique (3). This situation can render the upstream conduit at risk for failure if left untreated or necessitate more invasive treatment options including surgical bypass or extensive central venous reconstruction (4,5). Deciding which treatment algorithm best suits each individual patient requires a clearer understanding of the underlying anatomy and pathology.
Extrinsic compression of the central veins can also result in central venous occlusion. In these cases, removal

of the offending structure(s) followed by endovascular treatment of the central vein can alleviate the outflow obstruction. However, identifying this as the culprit can be a diagnostic challenge (6, 7).
Perhaps no single etiologic pathway leads to central venous occlusion, rather each individual patients prior "central venous history" is of paramount importance to understanding the anatomy and etiology of their central venous obstruction.

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An Honest Reappraisal of PTA and Stents for Central Venous Obstruction

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Prior to treating central venous occlusions, the interventionalist should ask what endpoint one is seeking to accomplish. Is the planned intervention for symptomatic relief, for access dysfunction, or for access placement? Additional clinical considerations include the overall access situation of the patient, characterization of symptoms, presence of a pacemaker, potential complications and durability of the intervention. Another point that interventionalists should consider is that central venous occlusions are rarely the cause for access thrombosis due to the fact that most of the patients develop collateral circulation. On the other hand, if the patient has a single access remaining, with poor flows, with no opportunity for transplantation, more aggressive measures can be considered.
When one considers angioplasty (PTA) and stents for central venous occlusion, it is important to distinguish stenosis from occlusion. All study outcomes are retrospective and many of them do not differentiate between stenosis and occlusion. Definitions of patency also vary greatly. Durability of interventions for CVO has technical success rates of 70-100%. Overall primary patency for endovascular interventions for central venous lesions in hemodialysis patients without pacemakers, including angioplasty and/ or stent insertion range from 14-67% at 12 months (1). For studies utilizing Wallstents, primary patency ranged from 42-84% at 6 months (1). In addition, multiple interventions (2-3 per year) are the rule rather than the exception. In-stent stenosis and frequent stent fractures are common with no approved therapy as yet for either problem. Fractures are particularly common at costo-clavicular junction and lead to aggressive and accelerated intimal hyperplasia. In pacemaker lead-related CVS/CVO in hemodialysis patients with ipsilateral access, endovascular interventions have a primary patency of 18-45% at 6 months (2-4).
Overall, PTA and stents for central venous occlusions have promising technical success rates but very poor primary patency. Initial interventions lead to a need for multiple repeat interventions to maintain patency. In addition, for complicated CVO's, the risks of recanalization are not insignificant and include patient mortality. Stent grafts have gained recent interest with up to 80% primary patency at one year observed in one retrospective study (5) but more evidence is required before a change in practice is justified. Perhaps, the best treatment for CVO remains no initial treatment. Two studies have demonstrated that early angioplasty of CVS leads to acceleration of symptoms and potential occlusion (6, 7).

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Surgical Decompression for Central Venous Obstruction

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Today, we have several approaches to address central venous obstruction even in the most challenging of patients. Yet, in a small subset of patients with this problem, surgical decompression is the only option to adequately address a chronic venous occlusion.

With the advancement of modern day interventional techniques, many patients with central venous obstruction have benefited from our ability to treat a variety of simple and complex central venous lesions (1). Some patients unfortunately present with lesions that are unable to be addressed with percutaneous techniques or are left with a suboptimal technical result. On occasion, attempts at treating complex lesions with balloon angioplasty and/or stent placement has led to rupture of the central veins or embolization of the stent during deployment (2). For this group of patients, surgical decompression via traditional open techniques or developing hybrid techniques may present a viable option.

In the dialysis patient, central venous obstruction presents a very challenging and often serious problem. In these patients, the longevity of any arteriovenous hemodialysis access is largely affected by the quality of venous outflow. Thus, all efforts to maintain a low resistance venous outflow bed should be made. When a central venous obstruction is present, venous hypertension can result in failure of an upstream arteriovenous access. Many central venous obstructions are identified and often addressed via advanced interventional techniques, however, when this is not possible or fails, an effort at surgical decompression may be considered.

Today, surgical decompression of central venous obstruction comprises a variety of techniques that include venovenous bypass and complex central venous reconstruction as well as newer hybrid techniques. Central venous reconstruction has been performed with variable success in patients with few remaining hemodialysis options, thus allowing salvage of a functioning conduit (3). In addition to traditional surgical options, newer devices can allow percutaneous "bypass" of central venous obstruction while still utilizing native arterial inflow and a subcutaneous conduit. Outcomes related to the use of these techniques are still being investigated (4). Moreover, not all lesions arise from endoluminal pathology. In the setting of costoclavicular compression of the subclavian vein, extrinsic bony compression is the source of the central stenosis. Percutaneous techniques play little role in correcting this problem prior to surgical correction of the extrinsic compression (5).

Surgical decompression of central venous obstruction plays an important role in those patients with challenging anatomy or failure of less invasive measures.

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Transvenous CIED Leads are Disastrous for CKD/ESRD Patients - Place Epicardial Leads

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Traditionally, the transvenous route has been the most frequently used pathway to insert cardiac rhythm device leads. However, this route of cardiac device placement can cause major problems in chronic hemodialysis patients including central venous stenosis due to the presentence of leads and cardiac device infection during episodes of dialysis access-related bacteremia. The occurrence of these complications in chronic hemodialysis patients has major implications. The development of stenosis not only produces symptoms but can also have a direct impact on decreasing dialysis dose by restricting blood flow. Because the leads of a transvenous cardiac device are directly exposed to blood, they are more vulnerable to contamination during episodes of bacteremia. Each episode of bacteremia carries a risk of associated mortality.

Central venous stenosis is a recurrent problem observed with the use of transvenous leads. This complication is not infrequent and has been reported to occur in up to 64% of the nonhemodialysis dependent patients. Because of the absence of a dialysis access in the extremity, only a minority of these patients developed symptoms. The situation is vastly different in end-stage renal disease patients receiving dialysis therapy with an arteriovenous access in the upper extremity. This population is particularly vulnerable to the development of edema of the face, neck, breast, shoulder, and the arm due to the development of central venous stenosis. The high rates of occurrence of symptoms of central venous stenosis in hemodialysis patients to a great degree is attributable to high flow of an arteriovenous access compared to patients with no access in the upper extremity. In addition, fibrous tissue covering the leads can compound the occlusive problem brought on by the presence of underlying stenosis. Finally, the development of binding sites or pedicles between the vein wall and the fibrous tissue covering the leads can restrict blood flow to the atrium. Over the past decade, the use of endovascular stents for the management of dialysis access dysfunction has dramatically increased. A recent retrospective study employed 17 bare metal stents/stent grafts in 15 patients over the CRD leads. The approach achieved primary patency at 6 and 12 months of 41.7% and 8.3%, respectively). However, avoiding this process with the use of epicardial leads would be a major plus.

Recent reports have found that moderate to severe renal disease (glomerular filtration rate of ≤60 ml/min per 1.73 m2) is the most potent risk factor for infection of a pacemaker. Infection is the second leading cause of death in end-stage renal disease patients. The annual percentage of mortality secondary to sepsis is approximately 100–300-fold higher in dialysis patients compared to the general population. The intravascular location of the CRD leads potentially makes the leads vulnerable to bacterial seeding with each dialysis session. Instead of navigating through the central veins and the tricuspid valve, the epicardial leads traverse through the subcutaneous tissue and get inserted into the epicardium. These leads are not directly exposed to blood flow and seem to be protected from blood steam infection. Lack of involvement of epicardial leads despite repeated episodes of catheter-related bacteremia observed in a recent study supports this contention.

Transvenous leads can cause central venous stenosis and are vulnerable to contamination during arteriovenous

graft or tunneled hemodialysis catheter-related bacteremia. Because these complications are not infrequent in hemodialysis patients an alternative pathway is warranted for cardiac rhythm device placement. Epicardial leads do not traverse through the central veins. They are not directly exposed to blood flow and do not cause central venous stenosis.

Transvenous CIED Leads May Not Be so Bad After All - Epicardial Leads Aren't the Answer

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Cardiovascular Implantable Electronic Device (CIED) leads are associated with central vein stenosis or occlusion that may compromise or preclude arteriovenous (AV) access for hemodialysis (HD) (1). This can result in significant morbidity, frequent percutaneous angioplasty (2), central venous stenting (3), or loss of access due to intractable venous hypertension (4). Compared with the general population, dialysis patients are at substantially greater risk for bacteremia which may result in CIED lead infection (5). The true extent and severity of problems related to transvenous CIED leads has not been well established. The preferred use of epicardial leads has been proposed as a means of avoiding complications of transvenous CIED leads (6). Epicardial leads may be similarly effective as transvenous leads for treatment of most cardiac rhythm disorders. However, there is likely greater morbidity and expense involved in placement epicardial leads.

Our impression over the last decade has been that many of our HD patients suffered complications or morbidity related to transvenous CIED leads. In order to determine the prevalence of this problem we conducted a survey of all 1236 prevalent chronic HD patients managed in our practice from Jan-Mar 2011. A CIED was present in 131 patients (10.6%), including ICDs in 72 (5.8%) and pacemakers in 59 (4.8%). All CIED leads were transvenous utilizing the subclavian or cephalic vein approach; none had epicardial leads. 113 patients had both a CIED and upper-extremity AV access. The CIED leads and access were contralateral in 69 patients (61.1%) and ipsilateral in 44 patients (38.9%). Ipsilateral cases were predominantly left-sided (42/44, 95%) reflecting the common preference for the left subclavian vein for CIED lead insertion and left (non-dominant) arm for AV access. Intervention rates were calculated per access-year (AY) for the access circuit in general and the central veins in particular. Access circuit intervention rates were 1.44/AY in the contralateral group and 1.53/AY in the ipsilateral group ($p=0.27$). Central venous intervention rates were 0.28/AY in the contralateral group and 0.59/AY in the ipsilateral group ($p<0.001$). No central venous interventions in the contralateral group central venous were required for CIED lead related stenosis. There were no instances of superior vena cava stenosis requiring intervention in either group.

Of the 44 patients with ipsilateral AV access and CIED included in this study, 30 had no clinically significant venous hypertension and required no central venous interventions. Seven had symptomatic venous hypertension that was managed with ≤2 interventions per year. Seven others required percutaneous interventions at more frequent intervals. Six patients in the contralateral group had abandoned previous AV access ipsilateral to an existing CIED due to intractable venous hypertension that failed percutaneous intervention.

Ideally we would protect all central veins that might be needed to support future AV access in either limb, due to the high likelihood of access failure over the lifetime of a dialysis patient. This problem is mitigated by the fact that dialysis patients with heart disease requiring a CIED have very poor survival; those with an ICD have 30-35% annual mortality and <20% 5-year survival (5). Therefore, the benefit of preserving central veins for future AV access may not justify the additional risks and expense of epicardial leads in all patients.

Infection is the other area where epicardial CIED leads are purported to confer advantages over transvenous leads (6). While all HD patients are at higher than average risk for infection, those dialyzing with a chronic venous catheter are at extraordinary risk, 8-10 times higher than those with AV access. This subgroup should be protected from the potentially lethal combination of venous HD catheter and transvenous CIED leads. Venous catheters can be avoided in patients with an existing CIED by delaying non-urgent initiation of dialysis and/or accelerating creation of a functional AV access. Conversely transvenous CIEDs can be avoided in patients with existing venous catheters by delaying non-urgent CIED implantation or utilizing wearable external defibrillators for patients at higher risk for sudden death. If the combination of a transvenous CIED and HD catheter cannot be avoided, then an accelerated timetable to eliminating the venous catheter should be pursued, including rapid

construction of functional AV access or use of peritoneal dialysis. When long-term venous catheter access cannot be avoided, and for patients at highest risk for infection, epicardial leads may indeed provide the best alternative. We conclude that transvenous CIED leads may not be such the disaster as we had originally assumed them to be. Planning and coordination between nephrologists, vascular access surgeons, and cardiac electrophysiologists has resulted in contralateral AV access and CIED in the majority of our patients. For those who require ipsilateral access and CIED, thorough pre-operative imaging of the central veins can assure that there is venous patency to support AV access flow. Most of our patients with ipsilateral AV access and CIED do not have symptomatic venous hypertension; many those who do become symptomatic can be managed effectively with periodic angioplasty. Relatively few patients develop intractable symptomatic venous hypertension leading to excessive interventions or loss of the access.

From a practical standpoint, there are significant obstacles to adopting epicardial leads as the preferred route for CIED leads. Practice patterns are deeply ingrained toward placement of transvenous leads by cardiac electrophysiologists. Some programs may not have CT surgeons who are well-versed in current epicardial lead procedures. Any widespread change in practice patterns would need to be driven by good current evidence demonstrating safety, efficacy, and cost-effectiveness of utilizing epicardial *versus* transvenous CIED leads in dialysis patients. It will be difficult to persuade practitioners or "the system" to embrace this change in the absence of such evidence. By the time this could be achieved, newer technologies such as the subcutaneous defibrillator are likely to emerge as better solutions (7).

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DHIS: Definitions, Causes, Measurements and Clinical Presentations

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Steal syndrome is an unusual but potentially morbid complication of AV access placement. The concept of steal syndrome has recently been broadened to encompass all distal ischemic events and has been termed distal hypoperfusion ischemic syndrome (DHIS) (1, 2). This occurs under three broad circumstances: 1) excess blood flow through the AV access, diverting flow from distal perfusion (steal); 2) excessive atherosclerotic changes causing occlusive changes proximal or distal to the access; and 3) inability of the arterial circuit to adapt to the increased demand from the AV access. It occurs in 1-8% of access procedures, and is more common in grafts, access in the upper arm, in diabetics and the elderly, as well as in extremities with previous access procedures (3, 5-7). Diagnosis of this syndrome is dependant upon history and physical exam, digital arterial pressures (indices) and waveforms, and angiography. Proximal arterial stenosis is a classic setup for development of ischemia and

needs to be addressed in all settings. In mild cases, observation may be appropriate. Multiple surgical options are described for reversing significant ischemia (4).
Unrecognized or untreated ischemia following AV access creation can be morbid. DHIS needs to be differentiated from ischemic monomelic neuropathy (8). If this syndrome is being considered, written documentation and appropriate testing is mandatory. Significant ischemia demands timely intervention to avoid loss of distal function or tissue.

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Dialysis Access Associated Steal Syndrome

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Dialysis Access Associated Steal Syndrome (DASS) requiring treatment will develop in 1-2% of radial artery AV fistulas and 10-15% of brachial artery inflow vascular access procedures. Patients with mild symptoms of numbness but without motor deficit, constant pain, ulceration or threatened tissue loss may be monitored without intervention. Noninvasive evaluations include arterial pressures, pulse volume recordings, finger pressures, digital brachial indices and pulse oximetry, and most importantly, access flow measurements. A patient with significant symptoms or physical findings should also undergo arteriography with fistulogram. The vascular access and distal arterial anatomy are evaluated for treatment options. In addition, proximal arterial stenosis may be discovered that is treatable by angioplasty. It is commonly felt that 10-20% of DASS patients will have such a proximal arterial lesion and their ischemic symptoms may be resolved with angioplasty.
For the majority of patients requiring intervention, treatment options may be based on vascular access flow while taking into consideration the presence or absence of peripheral vascular disease. Those patients with high-flow fistulas may often be successfully treated by 1) precision banding using real-time flow monitoring or 2) distillization of the anastomosis from brachial to radial artery. Those patients with DASS associated with a marginal or relatively low flow fistulas often require 1) proximalization of inflow to the axillary artery or a 2) DRIL procedure. Patients with a threatened hand may be best served with access ligation and possible excision of the venous outflow for translocation to another extremity. Minimizing the risk of DASS is an important component in dealing with this serious complication. Constructing AV fistulas based on the radial artery (proximal or distal) when possible is recommended. For patients felt to be at high risk for DASS development, creating a primary access based on axillary inflow may avoid distal ischemia. Peritoneal dialysis remains a consideration for those individuals at high risk of steal syndrome. Determining access flow volume and evaluating the presence and degree of peripheral vascular disease will allow preservation and maintenance of a safe vascular access in almost all patients.

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Management of Complications Associated with Excessive Hemodialysis Access Flow Using Dilator-assisted Banding

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Excessive hemodialysis access flow can cause ischemic steal syndrome and heart failure. Endoluminal balloon-guided banding is minimally invasive but requires fluoroscopic guidance (1-3). In our practice, we have developed a technique, called Dilator-assisted Banding (DAB), in which vascular dilators are used within the lumen of the vein so that banding can be performed with great precision, with or without fluoroscopic guidance (4). We have used dilators of 3.3, 4.0, and 4.7 mm in diameter to perform banding in a series of patients with ischemic steal syndrome. The mean age of the fistulae was approximately 1.5 years. Dilator-assisted banding was performed either without fluoroscopic guidance (during fistula vein superficialization and basilic vein transposition), or with fluoroscopy. Nearly all patients had complete resolution of ischemic symptoms and one reported marked improvement of ischemic symptoms. We feel that DAB represents an effective and economical flow-reduction alternative for managing ischemic steal syndrome. It may also be useful for managing other complications associated with excessive access flows. DAB has the advantage of being performed safely without fluoroscopic guidance.

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AVF Aneurysms

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The success of the Fistula First Breakthrough Initiative has had major impact on the dialysis community. There has been in a shift in our practice at The Methodist Hospital from dealing with graft complications to dealing with fistula complications. Steal continues to be a problem that is fortunately infrequent, but still quite troublesome. Synthetic graft complications of thrombosis, infection, and pseudoaneurysms no longer are the major troubles that dominate the access surgery schedule. Fistula complications of failure to mature, high flow, and aneurysmal degeneration now comprise a significant portion of the access surgery schedule.

The assigned topic is subtitled, "cause for concern or just ugly". There is no doubt that "ugly" or "disfiguring" are terms that are used frequently by dialysis patients and health care professionals to describe many of the dialysis access options. Catheters dangling outside the body, needle marks over grafts and fistulas, and even normal healthy accesses are rarely not noticeable. Fistulas with aneurysms can be quite disfiguring and clearly have a social impact for many patients (Fig. 1).

Beyond the appearance of fistula aneurysms, complications can include rupture, thrombosis, and pain. The most dramatic of these complications is rupture with potential for fatal exsanguination. An aneurysmal fistula with skin compromise in an ominous finding (Fig. 2). It is the fear of this potentially fatal complication that is most motivating to repair these lesions. The Kidney Dialysis Outcomes Initiatives (KDOQI) has published guidelines to establish indications for repair of pseudoaneurysms (1). The indications include loss of adequate length of access for cannulation, skin erosion or compromise, symptoms such as pain, or evidence of infection. The recommended therapy per those guidelines is surgery, but it is stated that "an endovascular stent option may exist."

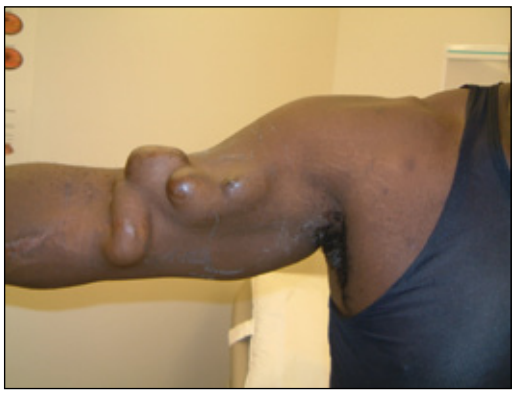

Fig. 1 - *Large high flow aneurysmal fistula.*

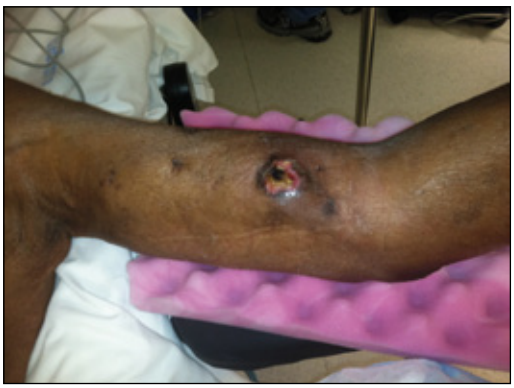

Fig. 2 - *Erosion over fistula aneurysm.*

We routinely use stent grafts for autogenous fistula aneurysm treatment in our practice as we find that surgical revision, mostly with aneurysmorrhapy has been quite satisfactory. A report by Woo et al, describes technical details of fistula aneurysmorrhapy and results with no significant problems with fistula recurrence at greater than one year with their technique (2). Her study and our unpublished findings are that brachicephalic fistulas tend to be the most common fistulas requiring repair. Frequently in the case of AVFs with 2 large aneurysms, we stage repairs to allow cannulation of the rest of the fistula while each area heals and thus avoid dialysis catheters.

In evaluation of fistula aneurysms, before commencing surgical repair, a consideration should be made about the etiology. It is critical to evaluate both for obstructive outflow lesions and high volume flow as these are both common issues in aneurysmal native AVFs. Flow reduction procedures and treatment of outflow lesions, such as the cephalic arch, are commonly required adjuncts for durable treatment of fistula aneurysms.

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Do Most Aneurysmal AVF's Have Associated Downstream Stenoses?

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Although AVFs are the preferred method of dialysis access, beyond stenoses, one of the more common complications to occur is venous aneurysm development, which can occur in up to 31% of fistulas (1). This can translate into AVF dysfunction in the form of flow disturbances, loss of access site, cosmetic problems, thrombosis, and rupture (2, 3). These venous aneurysms represent a dilatation of the outflow vein and involve all layers of the vessel wall. The term pseudoaneurysm is a misnomer and incorrect. It is a commonly held notion that AVF aneurysms are in part due to venous outflow obstruction; however, there is no published literature that investigates this association.

Furthermore, the definition of what constitutes a venous aneurysm of an autogenous fistula is somewhat elusive with no standard definition in place. In a recent surgical paper an aneurysm of the outflow vein was defined as a dilatation of more than three times the native vessel diameter. In addition, the authors also stated that no uniform definition could be found and additionally, the authors hypothesized that outflow stenosis was a potential cause of aneurysms with no prior surgical literature referencing this association (4).

In a single soon to be published retrospective study of 89 patients presenting with fistula dysfunction, 77.5% of patients had an associated venous outflow stenosis which was most commonly located in the outflow cephalic vein (56.8%), followed by the cephalic arch (20.0%), brachiocephalic vein (9.5%) and subclavian vein (6.3%). Outflow stenoses in AVFs with venous aneurysms were seen in 87% of brachiocephalic AVFs, 60% of radiocephalic AVFs and 80% of brachiobasilic AVFs. Brachiocephalic AVFs with venous aneurysms were significantly more likely to have an associated outflow stenosis than radiocephalic AVFs with venous aneurysms ($p=0.007$). AVFs with outflow stenosis were on average 1502 days old while AVFs without outflow stenosis were on average 2351 days old, which was a statistically significant difference ($p=0.031$).

This association may be explained as outflow venous stenosis causes increased back pressure, which would be transmitted to points of relative vessel wall weakness within the AVF. Additionally, repeated punctures in the vein of the AVF would cause weakening of the vein wall. The increased pressure at the AVF would be compensated by dilatation of the weakest point, and thus cause the aneurysmal dilatation of the AVF outflow vein, resulting in a venous aneurysm. In addition, venous outflow stenoses occurred most often peripherally and less common centrally.

In addition, within the aforementioned study, although there was high association between AVF venous aneurysms and venous outflow stenosis, this relationship is not absolute; there were 22.5% of AVF venous aneurysms that did not have an associated venous outflow stenosis. A possible explanation to the formation of these venous aneurysms may be that multiple punctures to the fistula may have weakened the wall to such a degree that the aneurysm was caused by the increased pressure due to high flows through the fistula. This may be reflected by the observation that the age of AVFs with aneurysms and no outflow stenosis was significantly higher than AVFs without aneurysms.

Given our observation of an association of outflow stenosis and incident venous aneurysms particularly in patients with brachiocephalic fistulas, it is yet to be determined if aggressive treatment of outflow stenosis and/or flow reduction within fistulas reduces the incidence of venous aneurysm formation and translates into improved patency. Furthermore, without histological examination, it is unclear how many venous aneurysms are actual pseudoaneurysms related to access needle injury.

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Aneurysm Surgery for Preservation of the Mega AVF - How I Do It

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"To know and not to do is really not to know"

Aneurysm formation occurs with native vein and graft dialysis access alike. True aneurysm (dilatation of the vessel itself) is also seen with native veins sometimes remote from needle puncture sites. The severity of aneurysm varies from cosmetic concerns to life-threatening hemorrhage. The clinician is challenged with what, and when to do. All things considered the timing of intervention is the most important decisional aspect for optimal results (1). Outcome measures include preserving the access, avoiding central line catheter placement; when dealing with the bleeding aneurysm patient survival becomes an urgent outcome parameter. Patents are usually referred to the access surgeon with the question of catastrophic rupture. Most aneurysms do not present with an imminent risk of bleeding or rupture. Below is an attempt to grade aneurysm in terms of severity and hence plan of action.

Many aneurysms are soft with intact skin, having no problems with dialysis cannulation and no real cosmetic issues. Some of these patients are enjoying stable renal function transplants. After a physical examination an ultrasound examination is warranted in all cases with volume flow. With no cardiac impairment from high flow these fistulas should be left alone as a "life insurance" should the kidney transplant fail. The key here is to communicate effectively with the patient and the referring MD, usually the nephrologist.

Aneurysms usually present as two bulging, pulsating masses of various size shape and form. Key determining factors are size, pulse characteristics and skin quality. Much common sense judgment goes into the management of the non-bleeding aneurysms. The size itself can be bothersome both physically and cosmetically. A "hammer pulse' suggest more proximal obstruction, sometimes even between two aneurysms when one has a hard pulse and the adjacent one is soft. If hammer pulse is present, an angiogram and appropriate interventions are performed. Surgical revision sometimes is a better choice dictated by team skills and other circumstances. The skin quality will determine the urgency of intervention. A history of spontaneous bleeding (especially between dialysis sessions) suggests heightened awareness and imminent need for repair. In case of a scab covering an area usually over previous needle cannulation sites the authors suggest applying an antibiotic cream (i.e. Silvadene) cover red with gauze and a circular bandage for 7-10 days to prevent physical trauma causing bleeding. Advise patient and personnel not to pick scab! Then reassess and decide on the optimal timing operative management. Meanwhile appropriate diagnostic radiologic testing will help surgical decision making. Assess the skin thickness by palpation as well as with ultrasound measurements. Skin of 2.5 – 2 mm is safe for elective aneurysm repair.

Type of aneurysm surgical repair vary depending on patient and aneurysm characteristics, including transplant status, comorbidities, access volume flow, aneurysm anatomy and overall quality. The surgical team experience, hospital support and system factors also affect choice of surgical route.

Examples of common surgical options.

1. A singe aneurysm can be dissected free, the excess wall excised and the access sutured into a tube using a sizing rubber tube to create a 6-7 mm conduit. Alternatively, dictated by anatomy the entire aneurysm is removed and a 6-7 mm graft interposed. In case of a short aneurysm a vascular clamp can be placed to "size' the new conduit and a running suture placed behind the clamp. Regardless of technique it is preferable to place the suture lines in the side in order to keep the anterior surface free of sutures for needle cannulations. Temporary central vein dialysis catheter can often be avoided as the remaining access can be used as the surgical site heals.
2. When the entire access is aneurysmatic there are two on site repair options. First, the entire length of aneurysmatic vein is resized over a sizing tube using the same principle as for the single aneurysm. Second, after resecting the entire aneurysms a graft bypass conduit can be placed around and away from the wound connecting the proximal inflow segment to the outflow vein assuming anatomy will allow.
3. In cases of brachiocephalic aneurysms with cephalic arch stenosis the venous outflow may be directed to a brachial or basilic vein in the axilla.
4. When aneurysm repair is beyond likely success, a new access should be placed at a new site and the aneurysm excised at a later time, when the new access is successfully used for dialysis (2).
5. In select cases interventional radiologist may place a covered stent across an aneurysm. This carries a high infection rate as this conduit tends to retain fluid around the stent graft (3).
6. When the aneurysmatic access is beyond repair the peritoneal dialysis may be an option (4).

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AVF Declotting: What's New?

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An arteriovenous fistula (AVF) thrombectomy includes access of the AVF, removing the clot, imaging the inflow through the peripheral and central veins and treating underlying stenoses. Since thrombosed AVF may have a small, medium or large clot burden the techniques used for percutaneous thrombectomy may be dictated by the clot burden. The first step is to assess the clot burden, identify he culprit lesion and plan the access sites. This can easily be done with a preliminary ultrasound. Once a plan for declotting has been made and access obtained the challenge begins.

Percutaneous methods include mechanical thrombectomy devices, pharmacomechanical thrombolysis, manual thromboaspiration, balloon maceration and mobilization, external maceration/manipulation, and incision/extraction. In more difficult cases (large clot burdens, aneurisms) multiple methods may be employed for success. Surgical salvage includes thrombectomy alone, thrombectomy with re-anastomosis, thrombectomy with interposition grafts and thrombectomy with endovascular techniques (angioplasty and stenting).

So what is new? No one specific method may be new; however, the unique and variable combinations of applying several methods to achieve thrombectomy success may be new for a specific challenging case. This includes more invasive methods via a percutaneous approach (incision/extraction) by non-surgeons.

Author	Number AVF	Thrombectomy Method	Clinical Success	1 Year Patency
Overbosch 1996	24	Hydrolyser	63%	30% prim 40% a. prim
Zaleski 1999	17	Balloons (non-compliant angioplsty and compliant occlusion), stenting, 500,000 UK	82%	64% prim 100% sec
Haage 2000	81	58 Mech thrombectomy (long segm, 23 Amplatz, 24 Hydrolyser, 11 both devices) 20 balloon dilation (short segm), 3 lysis	89%	27% prim 51% a. prim
Turmel-Rodrigues 2000	93	Manual catheter directed thromboaspiration using 7-8 Fr catheters and sheaths	93% f 76% u	49% f, 9% u prim 81% f, 50% u sec
Rocek 2000	10	Arrow-Trerotola PTD	90%	60% 6mo prim 80% 6mo a. prim
Schmitz-Rode 2000	15	Rotating Mini-Pigtail catheter	100%	
Rajan 2002	30	PTA macer, sheath aspiration using 4 Fr Fogarty, Hydrolyser combo of lysis with mech tech, 24 lysis (250,000 UK, 2-6mg tPA)	73%	24% prim 44% sec
Liang 2002	42	PTA maceration, 13 requiring UK, 4-8 hr inf 60,000u/hr	90%	70% prim 63% sec
Falk 2004	72	Endovac aspiration thrombectomy device	81%	22% a. prim
Beathard 2004	228	PTA maceration, thromboaspiration and tPA lysis	78%	
Shatsky 2005	62	Arrow-Trerotola PTD, 18 tPA (avg 3.4 mg), hybrids	79%	18% prim 69% sec

Sahni 2005	7	Oasis	100% technical 86% clinicall	50% 6 mo prim 75% 6 mo sec
Heye 2007	16	Castañeda Brush (with 250,000 UK)	94% clinical	50% prim 80% sec
Jain 2008	41	Arrow-Trerotola PTD	76%	20% 6 mo prim 54% 6 mo sec
Ponikvar 2009	128	Surg thromb by nephrol, 91 with re-anast, 37 alone, few interpose grafts	94%	68% sec pat
Yang 2012	275	AngioJet, Arrow-Trerotola PTD	76%	44% 6 mo prim 80% 6 mo sec
Won 2012	69	Venotomy and manual propulsion	91%	58% prim 92% sec

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Update on Patency Following AVF Thrombectomy

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In an attempt to maximize the prevalence of arteriovenous fistulas (AVF), there are several steps that should be taken: 1) maximize efforts to create AVFs, 2) maximize efforts to assure that they function, and 3) maximize efforts to preserve the ir function once established. An important component of this later category is the salvage of those that thrombose.
Although AVFs have been in use (underutilized) since 1966, salvage when thrombosed is a concept that did not gain emphasis in the KDOQI guidelines on vascular access until their third iteration. At least part of this relates to the fact that AVF thrombosis is so different from the more commonly occurring arteriovenous graft (AVG) event (1, 2).

TABLE I - COMPARISON OF AVF AND AVG THROMBECTOMY

	AVG	AVF
Incidence	1/ pt-year	0.15 pt-year
Stenosis		
Incidence	85 %	100 %
Timing	Early	Late
Severity	Moderate	Severe
Location	Outflow	Inflow
Thrombus		
Volume	Minimal	Variable, may be very large
Inflammation	No	Yes
Technique	Standard algorithm	Individualized

The spectrum of cases that are diagnosed in the dialysis unit as being thrombosed is broad (2). This ranges from cases that have no thrombus, only severe stenosis limiting detectable flow, to cases that can have a massive clot

volume. Even in the interventional suite, it is sometimes difficult to know how an individual case should be classified for coding purposes. As a result, of this heterogenicity, small reports of treated cases vary in their success rates and patency statistics due to sample bias.

Another issue is the timing of the salvage procedure. Unlike the latitude that is possible with declotting an AVG, removal of thrombus from an AVF is time dependent. Since the thrombus is in contact with endothelium and is mildly inflammatory, it begins to organize very quickly (as is the case with thrombus in a vessel in general) and removal becomes increasingly difficult (4). This is not to say that a effort should not be made. There may have been very little clot present. Even after a protracted period, a "thrombosed" AVF may be reconstituted because of its propensity to develop collaterals. These vessels may allow for the reestablishment of flow sufficient for its use as a dialysis access.

TABLE II - REPORTS OF AVF THROMBECTOMY

					% Primary patency (months)		
	Year	Cases	Method	Success (%)	3	6	12
Poulain	1991	16*	L, A, PTA	59*			59*
Overbosch	1995	22	M	89		Median of 14 weeks	
Vorwerk	1996	19*	M	84*		Cumulative patency 37 at 6 mo 32 at 12 mo*	
Zaleski	1999	17	L, PTA	82		71	64
Schon	2000	15	L, PTA	94		>30 days - 81	
Turmel –Rodrigues	2000	73	A	93	89	70	49
Haage	2000	54	M	89	63	52	27
Schmitz-Rode	2000	15*	M	100*	65*	47*	
Rocek	2000	10	M	100	70	60	
Liang	2002	42	L, PTA	90		81	70
Rajan	2002	25	L, PTA	73	36	28	24
Clark	2002	12	L, PTA	66	60		
Schon	2003	25	L. PTA	92	88	82	82
Beathard	2004	228	L, PTA	78			
Sahni	2005	5	M	86		50	
Littler	2009	44	M	91	61	34	

L - Thrombolytic, A - Thromboaspiration, PTA - Angioplasty, M - Mechnaical device
* - AVF & AVG combined series

In a series of 13, 819 cases of AVF and 62,354 AVG thrombectomies, success rates of 82.5% and 92.3% respectively, were documented. Median primary patency in a subset of these was found to be 4 months for AVGs and 10 months for AVFs. This observational comparison suggests that thrombectomy of an AVF is not as successful as in an AVG, but its long term benefit once flow has been restored is significantly greater.

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A "Good" 3-week-old AVF Just Clotted Yesterday: Is it worth Declotting?

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While fistulae can be successfully declotted there is a paucity of information regarding flow restoration in newly created thrombosed fistulae. We present our experience with thrombectomy procedure of newly created (<4 weeks old) arteriovenous fistulae (AVFs). The diagnosis of fistula thrombosis was made by the absence of thrill, bruit and pulse in a fistula that previously demonstrated these elements. Patients were promptly referred to an intervention. Thirteen patients underwent a thrombectomy procedure. Demographic characteristics revealed that 69% were females and 77% had diabetes. Time to clotting was 24.2±3.3 days. Procedure was successful (restoration of flow) in 9 (69%) of the patients. In the remaining 4 cases the flow could not be restored (vessel rupture=3, unsuccessful thrombectomy=1). Of the 9 cases where flow was initially restored 2 clotted within a week and another 2 suffered from fistula thrombosis at a follow-up of 3 and 4 months. One patient with functioning fistula was transplanted after over 2 years of the initial declotting fistula. This fistula remained patent and provided dialysis for 48 months months at the expense of 2.7 procedures/year. Another fistula remained patent for 36 months and required 3.4 procedures/year until patient's death. Three of the nine fistulae remain patent and have provided dialysis at a mean follow-up of 23 months. These patients have required 3.4 procedures/year. Early arteriovenous fistula thrombosis can be a significant problem. While there is a high rate of vessel rupture slightly over one third of such fistula could provide long-term dialysis therapy. Nevertheless, this success comes at an increased frequency of reinterventions. It is prudent to consider these factors when planning interventions on such fistulae.

A "Good" 3-week-old AVF Just Clotted Yesterday: Don't Bother

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When deciding whether to declot a fistula, the available evidence suggests that a few key clinical and imaging parameters can help determine whether there is any benefit to an attempted salvage procedure. These include:

- Assessment of maturity
- Duration of thrombosis
- Confirming thrombosis versus short segment occlusion

There is ample evidence that the results associated with declotting immature fistulae are poor (1-3). Even the most optimistic report of immature fistula declotting admits to exceedingly poor primary patency and a secondary patency that requires multiple repeat procedures to achieve (4). Thus, the first question to consider when determining whether to declot a never-used fistula is whether it has matured. Nothing in the available literature suggests that the results of declotting mature yet young fistulae should be any worse than mature yet older fistulae, and thus an attempt at declotting in that setting would be warranted. For the purposes of this debate, a three week old fistula is highly unlikely to be mature by the K/DOQI definition, and thus even if someone's assessment was that it was "good" (perhaps the surgeon who made it), one has to personally examine the fistula to see whether there is a nicely developed vein filled with clot or an atretic cord which will not respond to declotting. The latter is far more likely in this setting.

The duration of fistula thrombosis is quite relevant when considering declotting, however in this case the thrombosis is less than a day old, if the history can be believed. It is always important to confirm the duration of thrombosis with the patient however, as often upon careful questioning, the event may prove to have been more remote. While a report has now emerged of resurrecting long-dead "mummy" fistulae (5), for most patients this extreme and difficult intervention will not be warranted. Again, for the purposes of the debate we will assume the history is accurate and thus the timing with respect to potential thrombectomy is ideal.

Confirming true thrombosis versus short segment occlusion is critical. If no vein is visible or palpable, one must determine whether there is a collapsed vein with high grade stenosis or short segment occlusion in the inflow, which is readily treatable with good outcomes, versus complete occlusion of the inflow with either a very short

or very small segment of vein and no vein beyond this. In my opinion, as well as that of Turmel-Rodrigues et al, these fistulae are not salvageable and even if patency can be restored, the long term results are poor (1, 3, 6). Conversely, the results associated with short segment occlusions, as reported by Liang et al as well as Wu et al (7, 8), are excellent. Incidentally, we prefer not to refer to these as "declots" because of the tiny clot burden associated with them (8, 9). However, in order to make this distinction, one may need either an ultrasound exam or fistulogram (performed with 3F arterial puncture, as for an immature fistula study), as the physical examination may be inadequate to detect a collapsed but still viable vein beyond the occlusion.

In summary, while early fistula failure should be considered for possible declotting, the majority of such failures will prove not amenable to percutaneous management, if acceptable outcomes are expected. Of course, if one is willing to expect repeated, costly interventions, even a bad fistula may be able to be kept on life support for some time (4). Each clinical scenario must be evaluated individually, as available access sites, patient prognosis, available expertise and resources as well as patient preference must all be considered. A multidisciplinary discussion between nephrologist, interventionalist and surgeon is the most productive way to decide what is best for the patient.

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