Introduction

An annual tradition nine years in the running, the esteemed faculty of the Controversies in Dialysis Access (CiDA) and Simulation of Dialysis Access (SoDA) have authored written abstracts pertinent to the topics they will be present over three days of programming. These concise papers are indended to provide attendees with a practical reference that captures the spirit of each faculty member's presentation and/or important data that may be sited. As you navigate the enclosed *Table of Contents* please note that you can "click" or "tap" on any page number and you will be immediatley directed to the corresponding abstract. No digital flipping or scrolling required! We hope you find our abstract tool to be an informative reference that is easy to use. Should you have questions at any time, please don't hesitate to visit the CiDA or SoDA Registration & Information Desk, located in each program's respective foyer area.

Aknowledgement

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Table of Contents

Simulation of Dialysis Access (SoDA)

Wednesday, October 28, 2015

Controversies in Dialysis Access (CiDA)

Thursday, October 29, 2015

Controversies in Dialysis Access (CiDA)

Friday, October 30, 2015

Simulator Techniques for Dialysis Access Training

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Simulation training is a key safety features in commercial aviation. The use of simulators is also gaining popularity in medical education. Simulation allows for control of the training environment, to practice new techniques without the stress of treating a patient. Training and learning in the field of dialysis access is well suited for simulated learning, and team training. Simulators range from simple suture technique devices, inexpensive systems for pressurized venous puncture conduits, to computer designed interventional procedures such as angiogram, balloon angioplasty and stent placement. Team training capitalizes on the principles used in aviation known as Human Factors (HF). The objectives of team training are to improve communication and leadership skills, the use of checklists, briefing and debriefing to prevent errors. In this context HF aims to promote attitudes change towards vascular access from learning from mistakes in a non-punitive environment, to impacting positively the employee performance and to staff retention by a safer and efficient workplace. Simulation of Dialysis Access (SoDA) will introduce new techniques in dialysis access through hands-on experiences geared to surgeons, interventional radiologists and allied health professionals. SoDA delivers examples of how simulation training can advance the field of dialysis access management. We plan to have one or two surprises from developing dialysis access simulation projects. Eleven stations are planned as outlined below.

Station 1. Neck/Large Vein Ultra-Sound (US) Anatomy and Placement of IJ Dialysis Catheter. The neck vascular anatomy will be demonstrated by ultrasound from a live subject and then practice hands-on needle insertion on a realistic neck simulator. Instructor: **Bart Dolmatch.**
Station 2. Vascular Mapping for Hemodialysis Access. This station will take you through a practical vascular pre dialysis access mapping protocol (see separate abstract). Participants will practice vascular mapping on live subjects. The attendees will have the opportunity to hold a US probe to examine arteries and veins, and suggest the best access type and anatomical placement sites. Instructor. **Jennifer Bartley.**
Station 3: Dialysis Access Cannulation. Using ultrasound guidance, participants will practice placing a dialysis needles into dialysis access conduits (simulators) that is under pressure and filled with red simulated blood to show proper needle placement. **Sandy O'Rear, Lynne J. Dickert.**
Station 4. Peritoneal Dialysis Access. This station's main purpose is to demonstrate the importance of knowing tools and instruments needed for dialysis access procedures in general and for a peritoneal dialysis in specifics, and why basic fact knowledge and the proper use of checklists, briefing and debriefings will improve the quality of patient care. Instructors. **Maurizio Gallieni, Michael Gallichio.**
Station 5: Computer Arm Simulation. The IR Arm Simulator will provide participants a chance to use interventional techniques to treat a dialysis access outflow stenosis. Instructors: **James Caridi MD, Gerald Beathard.**

Station 6: Vascular Anastomoses Suture Lab. Participants will perform a variety of vascular anastomosis, with several suturing techniques displayed in videos. Instructors: **Kate Maxfield, John Lucas III, David Guthrie**.
Station 7. The Dialysis vascular access arm simulator. This is a complete pressurized dialysis access simulation arm. This station will demonstrate a new pulsatile arm model allowing to perform more than eight different vascular access modalities including the radio-cephalic AVF, basilic vein transposition and graft placements (see separate abstract). Instructor. **Matthias Widmer.**
Station 8. Lessons from the flight deck. This station will discuss what hospitals can learn from aviation by enhancing Safety through Simulation. A Boeing 767 airliner Captain and Managing Director of Corporate Safety for a major airline will discuss commercial aviation training principles using simulators and the effect of that training on operational excellence and resilience. Instructor. Captain **Billy Nolen**
Station 9. Tools and instruments. The design of this station will take you from tools and instruments used for Creation of access (Catheters, native veins and grafts) to maintenance (Angiograms thrombectomy, balloon angioplasty, stenting). The pros and cons of commonly used tools and devices in open and endovascular access surgical are also exposed in simulations and video displays. Instructor. **John Ross**.
Station 10. Peripheral Artery Disease (PAD) in Dialysis Patients. This station will demonstrate assessment treatment and tools for interventions on peripheral arterial disease in ESRD patients. Instructors: **Steven Ramee, Fabio Komlos.**
Station 11. Performance review and assessment of dialysis access simulation training. Did the SoDA stations leave a lasting impression? This station will also assess participants performing tasks in stressful situation. Instructor: **Mark Mattos.**

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A New Pulsatile Vascular Access Model

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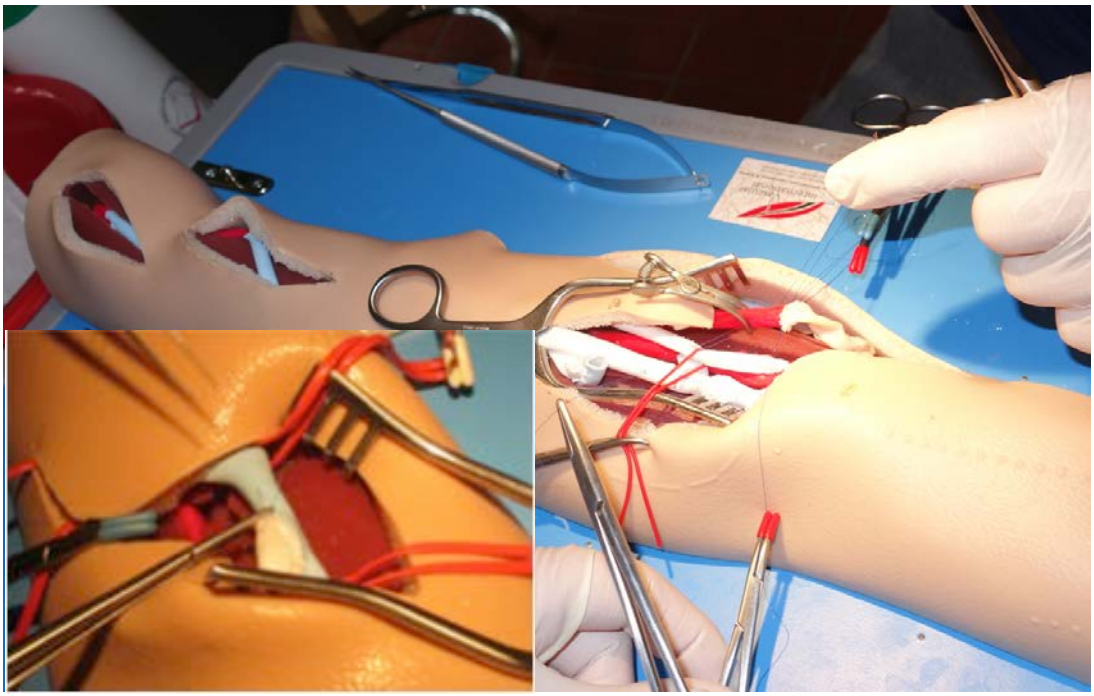
Vascular International School from Switzerland (www.vascular-international.org) runs workshops for skills-training in central Europe since more than 20 years. In 2013, during the CX-Meeting, a new vascular access model was presented (1). It allows the creation of more than eight different vascular accesses with pressurized vessels. The creation of snuff box and radio-cephalic fistulas can be trained, in addition also forearm basilic vein transpositions and straight and loop grafts. Upper arm fistulas and grafts and implantation of hybrid grafts are feasible, even a DRIL procedure can be performed. The workshops are led by dedicated vascular access surgeons with a ratio of 1 : 4 of tutors and trainees. In a manual, all procedure steps are well explained with many excellent illustrations of technical details. Complementary to this practical guide a new book about „Patient Safety in Dialysis Access" edited by M.K.Widmer and J. Malik (Karger 2015) gives an insight on how all kind of dialysis accesses can be performed safely and how concepts of patient safety can be introduced into a clinical setting (2).



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Ultrasound Vascular Mapping for Hemodialysis Access

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INDICATIONS:
- Dialysis access placement

CONTRAINDICATIONS:
- Patients with bandages with recent surgery

PATIENT PREPARATION:
- Patient should be sitting upright with arm extended to the side. Lie patient in supine position with slight head elevation to evaluate IJV and subclavian vein pressures

GENERAL GUIDELINES:
- The examination must be bilateral unless otherwise contraindicated
- A complete examination includes evaluation of the entire course of the accessible portions of each vessel
- Variations in technique must be documented (i.e., stents)

TECHNIQUE:
- Color-flow Doppler images with proper color scale to demonstrate areas of high flow and color aliasing
- 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
- Plaques should be assessed and characterized
- An angle of 60 degrees or less will be used to measure velocities
- Doppler angle should always be parallel to the vessel wall
- Obtain AP measurements of the cephalic vein and basilic vein with a tourniquet
- The tourniquet should be placed around axilla area; do not place if patient has a working graft/fistula, mastectomy, or lymphedema
- Obtain skin depth measurements at all levels of the cephalic vein
- Note high bifurcation of the radial and ulnar vessels, include measurement at AC fossa
- Document areas of wall thickening, thrombus, or branches

DOCUMENTATION:
- **Arteries**
  - AP measurement of radial artery at wrist
  - AP measurement of brachial artery at AC fossa
  - Velocity measurement of brachial artery
  - Longitudinal images with and without color
- **Cephalic Vein: AP measurements and skin depth**
  - Wrist
  - Mid Forearm
  - Superior Forearm
  - Antecubital Fossa
  - Inferior Upper Arm
  - Mid Upper Arm
  - Superior Upper Arm

- **Basilic Vein: AP measurements**
  - Antecubital Fossa
  - Inferior Upper Arm
  - Mid Upper Arm
  - Superior Upper Arm
  - Basilic confluence – if located below level of superior upper arm
- **IJV:**
  - 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)

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Renal Replacement Therapy (RRT): Global Trends

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Health care systems are very different throughout the world, usually reflecting the amount of resources made available for health care, ranging from 2% to 17% of the gross domestic product (1). Every country has some basic public health infrastructure, but only a few provide universal health coverage. The latter approach is unaffordable for low-income countries, but it has been proven to be convenient for high income countries, where unregulated private health care may drive an escalation of costs and unnecessary procedures. Dialysis care represents a peculiar situation, because reimbursement for chronic dialysis consumes a substantial portion of healthcare costs for a relatively small proportion of the total population (2). Prevention is a key issue, because the rapidly rising global rates of chronic diseases will inevitably determine a consequent rise in end stage renal disease. This is already happening, as the 2010 Global Burden of Disease Study ranked chronic kidney disease (CKD) as the 18th most common cause of death, a substantial increase from its 27th ranking two decades before (3).

In keeping with an increased burden of CKD, utilization of maintenance dialysis is already growing substantially in almost all regions of the world. An analysis of data from worldwide national and regional renal disease registries and detailed systematic literature review has been recently published (3), offering a comparison of the status of RRT in 1990 and in 2010, with special emphasis on the change in its prevalence and incidence in 187 countries.
In 2010, throughout the world, 284 individuals per million population (pmp) were treated by maintenance dialysis and over 60 countries provided universal access to maintenance dialysis, accounting for 70% of prevalent maintenance dialysis and 60% of incident dialysis population worldwide. Prevalence in 2010 has increased 1.7 times from the figure of 165 patients pmp in 1990. The rise in global incidence more than doubled from 44 pmp incidents in 1990 to 93 pmp in 2010.

Global 2010 prevalence and incidence rate are different in males and females. Man are more likely to receive dialysis than women, although between 1990 and 2010 the change in prevalence and incidence has been greater for women. 2010 prevalence pmp (95% uncertainty intervals): males 301 (293, 310), females 269(262, 276), total 284 (279, 289).79), total 93 (90, 95).

Maintenance dialysis provision has increased in both men and women above what was anticipated secondary to population growth, aging, and increase in prevalence of diabetes and hypertension, with most notable increases occurring in parts of Australasia, Asia, North America, and Western Europe. Oceania and portions of Sub-Saharan Africa have maintained a low prevalence of maintenance dialysis when compared with most of the world.

In some regions of the world with emerging economies, expansion of dialysis for both acute and chronic treatment to larger portions of the population could save lives and deter the difficult task of patient selection when resources are limited. In both low- and high-income countries, more efforts on CKD prevention are needed to contain the rise of dialysis incidence and prevalence and the inherent costs to society.

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Renal Replacement Therapy: What Is India doing Right?

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There are currently only about 55,000 patients on hemodialysis in India (with approximately 4,000 kidney transplants performed annually), out of a population of almost 1.3 billion people. This works out to a dialysis utilization rate of approximately 40-50/million, as compared to a dialysis incident rate of 1,251 per million in the United States. It is important to emphasize that the data for India is one of dialysis utilization as opposed to true dialysis incidence/prevalence since many patients with ESRD are unable to afford dialysis. Indeed the true incidence of ESRD in India is thought to be about 50-70% of that in the United States (at least in urban areas where there is an ongoing epidemic of obesity, diabetes and hypertension). Regardless, the combination of rapid economic growth (India's current growth rate is the highest within any large economy) which makes dialysis more affordable, together with the epidemic of obesity, diabetes and hypertension has resulted in a 10-20% annual increase in the dialysis population in India (as compared to 1-3% in the United States and other developed economies). Some quick arithmetic demonstrates that if India were to achieve only 25% of the prevalence dialysis rate in the United States within the next 10-20 years that would result in 420,000 dialysis patients in India (the current number of dialysis patients in the United States is 408,000). As with any developing country with a rapidly growing economy, India is struggling with the issue of universal coverage for ESRD care. Currently there are some government subsidies available for dialysis (both acute and chronic) and for transplantation, but these vary greatly within different parts of the country; being much more common in the southern states of Andhra Pradesh and Tamil Nadu (as in many other countries, health care is mainly under the jurisdiction of individual states). A major weakness of renal replacement therapies in India is the current lack of deceased donor transplantation with less than 500 deceased donor transplants being performed yearly with the most developed program, being in the state of Tamil Nadu. Last but not least, and clearly very germane to the current CiDA conference, dialysis vascular access problems are becoming more common as the number of patients on chronic hemodialysis increase (as opposed to 10 years ago when the number of hemodialysis patients was relatively small). It is therefore imperative that the vascular access community in India develop process of care pathways for dialysis vascular access that are particularly suited to the Indian setting and take into consideration available local strengths and deficiencies. Despite these many challenges there are a number of positive trends that have occurred in the last few years:

1. There has been a national realization that there needs to be a centralized organ transplant agency and the National Organ and Tissue Transplant Organization (NOTTO) was recently established under the aegis of the Union Ministry for Health and Family Welfare
2. Individual states such as Andhra Pradesh have developed programs that will provide for a major share of the cost of acute and chronic dialysis and renal transplantation, for low income patients
3. Many urban areas now have large corporate hospitals that perform 500-1,000 transplants per annum. These institutions allow for the development of transplant and ESRD expertise previously unheard of in India. Although these hospitals cater predominantly to the more affluent, it is likely that the economies of scale would result in a future reduction of costs.

In summary, while India faces great challenges from a huge increase in the ESRD population, with inadequate emphasis on prevention, there are a number of very positive trends with regard to both the development of appropriate clinical ESRD expertise, and also some initial steps towards the national provision of ESRD care.

How Can We Help Developing Countries?

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Over the last several decades, the worldwide burden of disease has been shifting away from communicable illness toward chronic disease, injuries, and cancer. The complexity and cost of providing care for chronic diseases, such as End Stage Renal Disease (ESRD), are increased by the need for procedural services. The role of surgeons is often overlooked on the global stage; today, only 3.5% of surgical procedures are performed for the poorest one third of the world's populace, and otherwise minor surgical conditions will often progress to incapacitating illness and death. Treatment of patients with kidney disease involves procedures and surgery, is inherently complex, and requires significant training, infrastructure, and coordination between many different members of the healthcare team. Complex, chronic disease care, especially that involving surgery, requires extensive collaboration and participation with the local population and responsible government agencies in order to be effective components of a global health strategy. A strategy to improve the availability of complex, surgical healthcare is to provide education and training designed to enhance outcomes effectiveness. High reliability industries such as airline transportation and petroleum have witnessed success in applying safety – outcomes focused education and training as a routine worldwide. In 2012, a scholarship was awarded to Dr. Slakey from the Vietnam Education Foundation (VEF) to develop and provide an education and training course designed to improve the care and outcomes of patients with kidney disease, from diagnosis to treatment including surgical management. The program involved education and simulation training of healthcare teams treating patients with kidney disease in Vietnam. The course material included evidence based information and technical training, provided within a structure that emphasized human factors and crew resource management (CRM) concepts. The goal was to provide the information and training necessary to improve the system of care, thereby creating lasting improvements in patient outcomes.

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Simulation or Apprenticeship: Which Works Better for Training the Next Generation of AV Access Surgeons? Apprenticeship: Traditional Medical Training.

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Healthcare and dialysis access protocol are rapidly becoming increasingly complex and fragmented. Messy new governing laws are being continually created with a goal of shifting volume-based healthcare to value-based healthcare outcomes. ***Volume*** as a guide to improve care is severely limited, as is the RVU system. From the value perspective, dialysis access patients as a group constitute an ideal population. Yet, education and training in dialysis access skills remains complex and controversial as learners come from a vastly diverse background. As a result, a system of sub-layers inevitably emerges, generating controversy as to what constitutes the best educational model.

Systems are in constant drift towards success or failure depending on infrastructure, utilization of technology, leadership (style) and the application of Human Factor (HF) principles and public acceptance (1-4). Patient care is about successful safe outcome (5,6) — which is to say, a larger, ongoing drift towards success. High liability industries (including healthcare) have drifted from concentration on preventing mechanical failures in the 60th to blaming the individual in the 90th to the current trend to correcting system problems i.e. preventing the individual to making a mistake by systems design (5). Aviation has been leading this development with unprecedented safety record reflected in no passenger mortality in North American commercial airlines in the last five years.

In professional effectiveness and outcome there is no substitute for knowledge and the acquisition of appropriate skills. This is a given and has been the sole objective for decades. The complexity of human factor aspect has a profound impact on effectiveness. Simulation training including communication skills are at forefront of human factor and hence must be incorporated in dialysis access training (7,8).

In this context **patient centered care** is not just a catchy phrase but designed to meet specific patients' (group) needs by specialized team. Dialysis access care meets the criteria for this concept thinking. Then dialysis access training must be done in the context of 1. **Outcome**; 2. **Quality**; 3. Patient and healthcare workers **Satisfaction**; 4. **Cost**. 5. **Safety** is at the core of training and outcome (6-8).

In the **past** dialysis access was performed by self-trained, predominantly renal transplant surgeons. **Presently** there is no recognized or structured training in vascular access during resident training or in vascular fellowships. Dialysis access still carries the stigma of being the red-headed stepchild and not recognized as "real" vascular surgery. The **Future** of dialysis access training is here today. An **Onsite,** tiered, hands-on surgery training in patients and certification course of one week with 49 hours of ACCME credit hours has been in effect for one year. Six more are planned for 2016. The Learning impact is intense but low or five trainees per week. Pre and post training test results attests to this training effectiveness **9. Off-site** training entails 1-2 days with 8-15 hours of ACCME Credit hours with lectures and simulation stations. This teaching module has medium learning impact and moderate number of attendees. An **On line** 10 ACCME credit hour course is being developed with expected high attendee volume, but with low skills learning impact.

Future Dialysis access training will encompass all aspects of stakeholders with diverse individual backgrounds and levels of professional development (10).

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Catheter-Based Dialysis Access Intervention: Do We Have Training Issues Here?

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In discussing this critical issue that affects the future of training in surgery, radiology, and nephrology alike, we will touch on several key points: ASDIN training/certification, SIR/ACGME fellowship, advanced techniques/hands on sessions, and future directions in percutaneous intervention training. Presently, the ASDIN certifies practitioners for hemodialysis vascular access, peritoneal dialysis access, and ultrasound procedures. The percutaneous training requirements include 125 cases specifically related to vascular access with at least 25 cases in each of the relevant categories, e.g. grafts, fistulas, and catheters. The ASDIN specifies that all the cases must be performed as the primary operator. There are two pathways for training in ASDIN: formal teaching and peer recommendation. Didactic training requirements are poorly defined. Continuous quality improvement is required at time of certification. Training in IR is substantially different from the latter. The IR training program tends to be a full, year-long ACGME accredited sub-specialty of radiology. This is only offered to radiology graduates. The didactic and procedural aspects of this educational system are rigorously defined by ACGME and are based on the six core competencies. A total of 500 cases must be submitted, but they are not specific to vascular access *per se*. Scholarly activity and CQI are expected but not required. A variety of hands on training sessions exist via CIDA, ASDIN, SIR, and industry.

The Kidney Health Initiative and Why It Matters to You…

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There is currently an unfortunate lack of innovation within the specialty of renal disease. Of all the subspecialties of internal medicine, nephrology has the fewest number of randomized clinical trials, usually an essential requisite that precedes the introduction of novel therapies. Perhaps as a result there have only been five new products introduced for the treatment of kidney diseases and its complications, over the last five years, of which 3 have been new formulations of existing agents. The Kidney Health Initiative (KHI) is a public-private partnership that was established through a memorandum of understanding between the American Society of Nephrology (ASN) and the US Food and Drug Administration (FDA) in order to try and facilitate the passage of novel drugs, devices and biologics into the kidney space. The Kidney Health Initiative, currently has over 70 members, which include all the stakeholder groups in this area including health professionals, patients and patient organizations, industry partners (both small biotechnology companies and large pharma) and a large number of federal agencies (not just the different centers within the FDA but also NIH, CMS and CDC). The Kidney Health Initiative aims to implement change by doing a variety of projects that could then serve as enablers (white papers, workshops and data standards), that could incentivize innovation and the development of new therapies in this area. Some examples of ongoing KHI projects include the following:

- **Advancing Awareness of Kidney Disease**
  - Facilitating Remote Management of Patient Self-Care in RRT
  - Building Capacity for Patient Powered Research

- **Closer Collaboration with FDA and Gov't Agencies (Breaking down Barriers!!)**
  - White Paper on Barriers and Solutions for Innovation in Nephrology
  - CDRH Regulatory Policies and Procedures

- **Clinical Trial Infrastructure:**
  - Data Standards in Diabetic Kidney Disease
  - Data Standards in Kidney Transplantation

- **Clinical Trial Endpoints and Design:**
  - Clinical trial end points for Lupus Nephritis and Vascular Access
  - Incorporating Patient Preferences into the Device Regulatory Process

Of particular interest to this conference (CiDA), is perhaps the KHI project that focuses on the development of clinical trial end points for dialysis vascular access.
We hope that by bringing together all the stakeholder groups in this area (industry, patients, regulatory agencies and health professionals [nephrologists, interventionalists, surgeons, radiologists, nurses]), that we will be able to put together a set of multi-disciplinary white papers that would hopefully facilitate more interest and enthusiasm for the development of novel therapies for dialysis vascular access dysfunction. Above all the Kidney Health Initiative is in fact a meeting place or platform where all of the diverse stakeholders in new product development can come together in a pre-competitive environment.

Percutaneous AVF Creation: Con

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Given that patients are living longer on dialysis, the development of a "life plan" for each dialysis patient is becoming more critical with the goal of optimizing and individualizing renal replacement therapy to meet each patient's needs over their lifespan. For example, many patients with radial artery based autogenous fistula have been able to maintain and use their fistula for greater than 20 years. Indeed, home dialysis, either home hemodialysis or home peritoneal dialysis, is recognized as best renal replacement therapy in terms of survival. In a recent study, home hemodialysis was compared to peritoneal dialysis demonstrating that home hemodialysis has a much better patient and technique survival (5 year patient survival 85% versus 44%) [1]. Moreover, Kjellstrand and coworkers have shown that home hemodialysis patients have survival equivalent to deceased- donor renal transplantation patients. When developing a dialysis access "life plan" the patient care team must recognize the importance of optimizing dialysis access options for their patient.

While the percutaneous AVF creation, which will be discussed by the "Pro" advocate of this debate, is elegant and innovative, there are several concerns. This novel approach to creating autogenous arteriovenous fistulas may actually lead to poor patient outcomes if its use is not carefully and selectively deployed for each patient with their "life plan" as part of the decision process in utilizing this new technology. The concerns include:

1. The current percutaneous AVF creation technique is limited by anatomy to the proximal fore arm because of the requirement for the proximity of artery and vein. This approach bypasses the well-established surgical tenet of distal-to-proximal access construction. [2]
2. Thus, suitable snuffbox or radial cephalic fistula creation may be overlooked or not attempted.
3. The contrast load used during the percutaneous procedure could lead to contrast induced renal failure and to need for early placement of dialysis catheter while the percutaneously created fistula matures.
4. The proximity requirement may lead to Gracz-type fistula without flow to both major upper arm veins, with neither developing adequate flow to support dialysis, requiring another surgery which may limit future access sites.
5. Unfortunately, reimbursement in a fee-for-service environment often drives the use and abuse of new innovative technology. Without careful utilization of this
novel approach, the patient's "life plan" for dialysis access may be truncated.

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New Techniques to Optimize Anastomotic Properties

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Juxta-anastomotic stenosis (JAS) in an arteriovenous fistula (AVF) and stenosis at the graft vein anastomosis are 2 common sites developing venous neo-intimal hyperplasia (VNH) following vascular access creation. Attempts using systemic therapies to target components of this response have not been successful in preventing it. The most important factor inducing this injury appears to be the increased flow resulting from arteriovenous anastomosis. New techniques to optimize anastomotic properties to mitigate this response can be broadly categorized under two groups:

I. Flow modulation to reduce the injury
II. Topical delivery of agents to mitigate injury response.

Attempts to modulate flow by altering anastomotic angle and technique have shown a significant decrease in this injury response (1). Anastomotic technique that channels flow from a circular lumen into a circular lumen with minimal anastomotic angle provides the best hemodynamic sheer stress profile by inducing spiral laminar flow at the anastomotic site. The suture-less hybrid end-graft to end vein-technology provides a similar decrease in the flow related stress however is limited by the need for a stent at the end of the graft, thus restricting its use to more central veins (2. There is very limited data on use of a graft that is intended to induce a spiral laminar flow at the anastomosis.

An attempt to decrease the flow mediated injury is creating a standardized anastomosis using a deployable vascular anastomotic connector that provides a suture-less AVF. Preliminary data using this device suggested a trend towards early access maturation but failed to show significant difference in functional patency (3). Another novel approach is the use of recombinant type I human pancreatic elastase. This acutely dilates of the vessels (inflow artery and outflow vein) in the area of application by digesting the elastin. Preliminary studies with this technology showed a significant benefit in radio-cephalic fistula maturation by ultrasound criteria (4). Phase 3 trials are currently planned to investigate this further.

Currently there is only one innovative product that attempts to mitigate the flow mediated injury response. It is the sirolimus drug eluting membrane. Sirolimus has a clinically proven antiproliferative effect against VNH seen in coronary artery disease. The wrap is a collagen based platform impregnated with sirolimus that is designed for application around the arterial and the venous side of arteriovenous anastomosis (5). While proving the safety, preliminary human trials have shown promising outcome with improved maturation of AVF. Based on these results a phase 2b trial is planned to be launched soon in the US to further investigate this product.

In summary, physiologic changes resulting in an acute increase in the blood flow with the creation of arteriovenous anastomosis initiates an injury response in the outflow vein. Modulation of the flow by altering anastomotic configurations and the use of agents that are capable of mitigating this response have shown promising outcome that need further evaluation.

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New Surgical Devices to Facilitate AVF Cannulations

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New Surgical Devices to Facilitate AVF Cannulation. Vascular Needle Guide Implantation for Cannulation Facilitation. John Ross.

The vascular needle guide is an access device accessory on AV fistulas for hemodialysis procedures. It creates a palpable target allowing for needle access to fistulas that are deep or difficult to cannulate. Additionally, it can be used to reduce cannulation damage of fistulas from improper cannulation technique, usually driven by anatomical challenges such as a short accessible length. Extensive vein elevation procedures are avoided. Targets access away from damaged segments and supports home hemodialysis and promotes self-cannulation

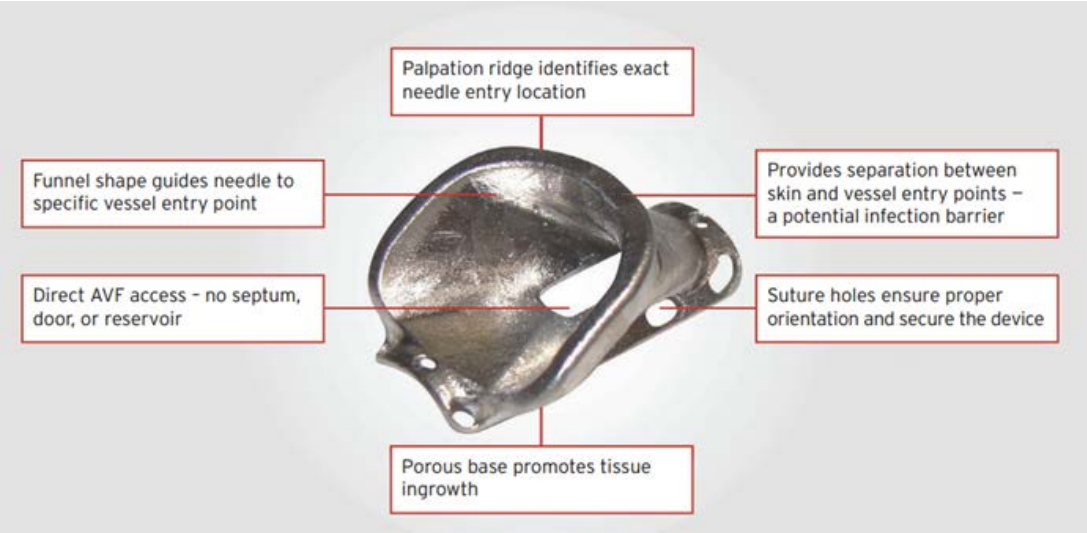

Figure 1. Technical description of the vascular needle guide.

Implantation Technique: In choosing the device height ultrasound is used to confirm the vein depth of less than 15 mm and diameter of at least 5mm. Through a 4-5cm skin incision is on the side of the fistula vein a thin tissue flap is made over the vessel, separating the dermis from the subcutaneous fat. The top portion of the vessel is exposed to the adventitial layer. Device height required is confirmed. The device is sutured to the outside of the vessel, starting with the orientation sutures at the front and back of the device. Ensure the device is aligned with the fistula and parallel with the skin. The device must is palpable and adjust using lipectomy

Clinical Outcomes: A 96% success rate of getting access to "uncannulatable" fistulas was reported (1) Elevation procedures alone have much lower rates of 46% (2). Improved fistula survival over elevation procedures (3) by allowing fistula to remain in native position: 100% and 91 % at 6 and 18 months respectively vs 81% and 65 % with no needle guide. Low infection rates of 0.038 patients/year at 6 month, compared to AV fistula USRDS of 0.18 patient /year (1).

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New Surgical Devices to Facilitate AVF Cannulations

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The self-sealing vascular patch is a durable, membrane material that reinforces a region of repeated large bore needle punctures during hemodialysis (1). The patch is designed to provide a bleed-free access site and to reduce the degradation of the underlying vascular structure and associated complications. It is designed with nitinol structure embedded in elastomeric substrate covered with polyester. The nitinol alloy mesh enhances durability and acts as the sealing mechanism against repeated cannulations. It permits passage of instruments, e.g. dialysis needles, angioplasty balloons, and acts as a compression element. The mesh returns to its original structure when dialysis needle is removed effectively sealing the puncture site.

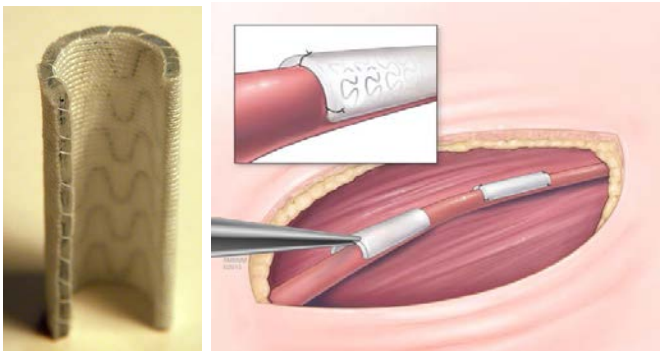

Figure 1. The patch is available as a 230° curved patch in lengths of 45 and 60 mm and diameters of 6, 7, 8, 9, 10 mm.

Implant Technique: 1. Measure the diameter of the fistula vein. 2. Select the appropriate size of patch by under sizing it relative to the measured vein diameter (e.g. if vein measurement 7.1 to 8 mm, select patch with a 7 mm inner diameter). 3. Ensure conformance to vein. 4. Place two tacking sutures at each end of patch. 5. Defat flap tissue with finger, ensure patch is easily palpable when covered with skin flap.

Cannulation can be done 4 weeks after placement. Twenty-five patches have been implanted with no complications. The indications have been patients with a history of access failure from infiltration and hematomas. Patients with the second stage basilic or cephalic vein transpositions and radio-cephalic AVFs are candidates for the patch. The patch is readily identifiable by palpation, and should be cannulated like a graft. The patch has eliminated the need for conventional methods of compression, cannulation difficulties and catheter dependence in select patients.

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Translating Biology into Therapy: Challenges and Opportunities

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Arteriovenous fistula (AVF) and arteriovenous graft (AVG) stenosis remain the most important cause of hemodialysis vascular access dysfunction. At a pathogenetic level, both AVF and AVG stenosis are likely due to a combination of an aggressive venous neo-intimal hyperplasia and a lack of outward or positive remodeling, secondary to vascular (endothelial and smooth muscle cell) injury. The main causes of vascular injury in the setting of dialysis vascular access dysfunction include:

- Hemodynamic stressors particularly non laminar flow and oscillatory shear stress
- A foreign body reaction engendered by the PTFE graft
- Cannulation injury
- Surgical and angioplasty injury
- Inflammation and oxidative stress secondary to uremia

In an attempt to reduce the huge co-morbidity burden associated with AVF and AVG stenosis, a number of innovative therapies that attempt to target some of the above biologic mechanisms are being developed.

Elastase Therapy: This constitutes a recombinant elastase which when dripped onto the AVF or AVG at the time of surgical creation of the access, is thought to result in the fragmentation of elastin within the adventitia; with the elastin fragments then exerting anti-migratory signals within the adventitia. An initial Phase II study documented a significant benefit of recombinant elastase therapy in radio-cephalic AVFs and a large Phase IIb study is currently enrolling.
Paclitaxel: is a potent anti-proliferative agent which when applied to the dialysis vascular access, either at the time of surgery or following angioplasty, could potentially inhibit the potent smooth muscle cell migration and proliferation that occurs following such vascular injury. While an initial large randomized study on the use of perivascular paclitaxel eluting wraps was discontinued at the 25% DSMB review due to an increased infection rate, there has been a current resurgence of interest in local paclitaxel delivery through the use of paclitaxel coated drug eluting balloons. An initial study from Greece suggested a marked reduction in re-stenosis following the use of these balloons, and a large randomized controlled clinical trial is currently under way in the United States.
Proteoglycan Therapy: This comprises a special therapy which when applied to the AVF or AVG, coats exposed collagen with a smooth non-thrombotic layer.
In summary, we currently live in exciting times for dialysis vascular access wherein for the first time we are attempting to develop novel therapies that actually target relevant vascular biology, in order to reduce the huge clinical and economic burden associated with dialysis vascular access dysfunction.

AV Grafts - Patent Upper Arm and Antecubital Veins. Forearm Loop AVG or Upper Arm AVF First? Of Course NOT – Make an AVF

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Arteriovenous fistulae (AVF) once mature, provide a longest lasting access with least complications. Vascular access (VA) guidelines such as NKF-KDOQI, Society of Vascular Surgery[1] and from Japanese, Australian and European societies universally recommend and endorse construction of upper arm fistulae prior to graft placement for patients with suitable anatomy.

Brachiocephalic (BC) or brachio-basilic transposition (BBT - one or two staged) using the median cubital vein for inflow are two options commonly used to create upper arm AVF. Successful creation of a selective BC fistula can provide working access that is lasting and requiring minimum additional interventions. BBT using the upper arm basilic vein risks development of outflow stenosis in the deep venous system. It does not jeopardize the option of upper arm graft placement using standard surgical techniques but obviates the opportunity to use a forearm loop graft. Placing an upper arm graft on the other hand obviates the option of any attempt at future AVF creation in most patients.

A single available randomized controlled trial (RCT) on this topic suggests superiority of BBT over forearm loop grafts[2]. Other retrospective studies comparing upper arm fistulae to upper arm grafts also support attempting an AVF prior to placement of the AVG. Thus, a critical review of available literature substantiates superior long term survival of upper arm AVF (fewer interventions and infectious complications). Single center studies that report equivalence or inferiority of UA AVF compared to UA AVG report a significantly worse outcome with UA AVF[3] in contrast to other reports where the opposite is true[4] suggesting the presence of a center effect.
The goal of access planning is to design a sequence of surgical options for providing vascular access throughout the ESRD lifespan of a patient. The intention is to provide a durable access needing minimal interventions in a timely fashion without jeopardizing future access options[5]. Fistulae do take a longer time to mature and have a variable incidence of primary failure. While AVG have less primary failure but higher complications and require larger number of procedures to maintain patency over their short life span. It is critical to take into consideration the urgency of the need for access, available number of surgical options, longevity of the patient and also the available surgical expertise when making a decision on the choice of access for a patient who has a failed a forearm access attempt.

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AV Grafts - Patent Upper Arm and Antecubital Veins. Forearm Loop AVG or Upper Arm AVF First? The Right Access for Every Patient

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Notwithstanding guidelines promulgated by the KDOQI Vascular Access Guidelines and by the Fistula First Initiative, arteriovenous fistulas (AVF) are not the right access for all patients. If one reviews the published literature objectively, it's obvious that each type of permanent access has some advantages. Arteriovenous grafts (AVG) have a lower primary failure rate than AVF. Two large contemporary observational studies compared the clinical outcomes in concurrent patients receiving an AVF or AVG at the same medical center. A study of 322 AVF and 289 AVG placed at University of Alabama at Birmingham reported a primary failure rate of 38% in AVF vs 15% in AVG [1]. Likewise, a similar study from University of Toronto observed a primary failure rate of 40% with AVF vs 19% with AVG [2].

A second advantage of AVG is that they require fewer interventions prior to successful use for dialysis. At one center, 42% of AVF required an intervention prior to maturation, as compared to 16% of AVG [3]. AVG can also be cannulated much faster than AVF. The DOPPS Study reported that in the U.S., only 2% of AVF, but 78% of AVG were cannulated within one month of surgery [4]. This difference results in a shorter duration of catheter dependence, and as a consequence fewer episodes of catheter-related bacteremia (CRB). In one study, the frequency of CRB prior to successful access use was 3-fold higher (1.33 vs 0.38 episodes per patient) for AVF vs AVG [3].

On the other hand, AVF have some advantages over AVG. Once they are successfully used for dialysis, cumulative survival is substantially longer for AVF than for AVG. However, if one includes all patients from the time of surgery, including those with primary access failure (intent to treat analysis), the cumulative survival is comparable for AVF and AVG [1]. In fact, AVG survival is superior to that of AVG in the first 1.5 years, an important consideration in patients with limited life expectancy. A second advantage of AVF is that they require fewer interventions (PTA, thrombectomy or surgical revision) to maintain their long-term patency for dialysis. In one center the annual frequency of interventions was 0.73 for AVF vs 2.38 for AVG [3].

In other words, there are tradeoffs between AVF and AVG, and careful clinical judgment is required to select the best access for every patient. The optimal access strategy is to place AVF when there is a relatively high likelihood of success, but an AVG if there is a low likelihood of AVF maturation. Multiple studies have reported a higher AVF non-maturation in older patients, females, blacks, and patients with severe vascular disease [5,6]. In a given patient, the choice between AVF and AVG should be based on several considerations, including the likelihood of AVF maturation, whether the patient is already on dialysis (i.e., catheter-dependent and at risk for CRB), the patient's life expectancy, and the outcomes of previous vascular access in that patient [7]. The advantage of an AVG is particularly compelling in older patients dialyzing with a catheter.

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CiDA's on the Case #2: The Slippery Slope

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There is much health care debate about the care for the elderly, such as use of hospice, as a dignified end-of-life solution. These discussions are grounded in humanist ethics, but frequently dovetail into questions about money and who is going to pay for costly care. The questions are tedious, draining and without easy answers. There is a deep, encompassing implication that aging means deterioration; to age is a path downward towards eventual demise. To age is human, a part of the life cycle and of course, inevitable. And yet, age and the aging process is not specific nor uniform in its manifestation.

The concept of optimizing vascular access in the elderly stands on solid ground (1). And yet, on another level it opens up pathways for much needed conversation about age, ageism and the power of words in framing these discussions. There is value in redirecting the discussion for a moment to consider the subject matter through a semantic filter; after all, words are powerful. The words we use affect our way of thinking and ultimately patient care (2).

Age discrimination is real and pervasive. It affects patients as well as caregivers. Facing the scarcity of jobs post-transplant fellowship, a young transplant surgeon recently remarked (somewhat jokingly) that older transplant surgeons should retire or go home and die. The real question then becomes: who do you want to do your surgery: a 35 year old just out of fellowship or a 60 year old surgeon with many thousands of procedures under his belt? The evidence vastly favors the mature surgeon.

On the other side of the coin, it is also worth noting that age and patient status are not mutually exclusive. Consider this hypothetical pair in the chronic kidney disease area: a 35 year old type-1 diabetic on dialysis with blindness, several amputations, coronary artery disease, on a catheter vs. a 75 year old on Peritoneal Dialysis without co-morbidity (except age!). Who is better off?

So, we suggest a semantic paradigm shift. Instead of utilizing the laden word 'age,' let's address co-morbidity as the main subject line. Then, age becomes one of the many co-variants. This simple change of words will cancel out age and all of its attendant implications and re-focus the thinking towards the actual causes of kidney disease to focus on the best treatment options. With co-morbidity as the primary focus, age is likely to be secondary but a significantly contributing factor.

Second, most publication in this field, point out the benefits with native vein access over other dialysis access. Phrases such as 'gold standard, preferred, proven and superior, should be tried first, CMS mandated' are utilized to frame and shape a particular line of thinking. The fistula first concept was built on data, with early failures were excluded (3). Yes, native vein do better when they mature in patient who have the suitable anatomy. Grafts do better than native veins AVFs in co-morbid patients with suboptimal vein anatomy. Catheter may be the most humane mode of dialysis in end of life situations regardless of age. The better way of thinking about dialysis access is to seek to place the most optimal access for each patient, every time based on the teams' knowledge and skill set (including the surgeon), co-morbidity, physical exam, ultrasound mapping, surgical anatomy without using age as an independent covariant. With this approach (external) pressures or mandates to place or favor a certain access is eliminated. Just do the right thing! The right thing to do for your fellow human is to use you skills

and knowledge and available resources modelled by the culture and beliefs in the society where you live and work (4). By cases reports, our intent is to bring to the readers a different way of thinking about age and the selection process of dialysis access in the ESRD comorbid population.

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PD Catheter Design: Can it be Improved?

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In peritoneal dialysis (PD), a well-functioning catheter is of great importance, because a dysfunctional catheter may be associated with incidence of peritonitis, efficiency of dialysis, and to the overall quality of treatment, representing one of the main barriers to optimal use of PD (1). In addition, about 30% of drop-out cases from PD to hemodialysis are due to catheter failure and PD catheter complications accounted for 40% of transfers to hemodialysis during the first 3 months of treatment (2).

When considering the possibility of improving PD catheter design, we should keep in mind the different types of available PD catheters, those that are most commonly used in clinical practice, and the available head-to-head comparisons in the literature (3-5). In addition, we should also keep in mind the characteristics of the ideal PD catheter, which should enable simple, repeatable long-term access to the peritoneum (table 1).

The main differences in PD catheter design include the number of cuffs, the shape of subcutaneous tract (straight vs. swan neck), and the shape of intraperitoneal tract (straight vs. coiled). It is now established that the use of straight catheters may improve outcomes and technique survival (6), but further advances in PD catheter technology can potentially improve technique survival.

Despite the advent of several new catheter designs, the curled and straight Tenckhoff catheters (first introduced in 1968) continue to be the most commonly used. In the past 30 years there have been new PD catheters with many modifications, but no breakthrough advances. However, the self-locating PD catheter is a well established device that has not been fully studied (5) and it may represent, based on the available observational evidence and on the clinical experience, an already existing technological advance deserving further studies. Based on the clinical needs of patients, new design approaches should consider improving stability of the catheter tip, dialysate flow, and reduced infection rates.

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Characteristics of the ideal PD catheter. (Reproduced with permission from reference 4)

Hydraulic function

- Optimal inflow and outflow (fast and complete draining of the peritoneal cavity)
  - Largest possible internal diameter
  - Kink resistant
  - Design preventing obstruction
- No migration and displacement
- No fluid leakage

Biocompatibility

- No effect on physiology of abdominal tissues (catheter invisible to body)
- No induction of inflammation, sclerosis and adhesion of the peritoneal membrane

Resistance to infection

- Act as a barrier against microorganisms present at the exit site, preventing their entry into the subcutaneous tunnel
- Absence of factors favoring peritoneal infection (no biofilm, catheter invisible to bacteria and fungi)

Surgical handling

- Ease of implantation and removal

Patient friendliness

- Minimal interference with abdominal function and clothing

Low cost

Debate #4: Percutaneous PD Catheter Placement. You Must Use a Scope or Open Visualization for Safety

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There are three approaches to the insertion of a peritoneal dialysis (PD) catheter: surgical placement (open), peritoneoscopic (or laparoscopic) placement and percutaneous placement (with or without ultra sound or fluoroscopic guidance). Essential differences between the 3 techniques are enumerated in table 1.

	Percutaneous	**Laparoscopic**	**Surgical**
Peritoneal entry	Blind puncture	Blind puncture or open	Open
Entry complications	Inherent to technique	Inherent to technique	No risk
Set up	Clean room set up	Sterile Operating room (OR)	OR /clean room set up
Anesthesia	Local and sedation (LS)	General (G)	LS or G
Entry and exit site	Not predictable	Predictable constant	Predictable adjustable
Catheter function	Unreliable	Reliable	Reliable
Catheter Leak	Common	Uncommon	Rare
Patient selection	Not for all	Not for all	Rare exceptions
Learning curve	Relatively short	Fairly long	Fairly long

Success of PD depends on catheter function. Catheter infection and peritonitis significantly impair the longevity of this dialysis modality. Hence it is extremely important to take into consideration risk for these complications while selecting the catheter insertion technique.

Assessment of safety of a technique is based on evaluation of inherent risks for complications associated with individual steps of the procedure. Patient selection, experience and technical ability of the operator can reduce such risks but fails to eliminate them. Techniques that require a blind entry into the peritoneal cavity have an inherent risk of inadvertent injury to the deeper structures. While the risk of bowel perforation with blind trocar insertion in a large laparoscopic series was estimated at 0.11%, each episode is associated with a mortality rate of 3.6% [1]. Major vascular injuries have been reported during PD catheter insertion[2]. Inability to provide a watertight seal and seal the cuff within the rectus muscle during percutaneous techniques has an inherent chance for fluid leak resulting in infectious complications[3].

Current literature considers percutaneous bedside PD catheter placement as a procedure to be used selectively in specific occasions[4]. Fluoroscopic and ultrasonography guided placement may improve accuracy of percutaneous placement, reduce this risk of injury but continue to have increased risk of fluid leak. While experienced hands may see a reduction in the incidence the technique continues to suffer from this inherent risk.
Open insertion of trocar during the laparoscopic procedure and making the peritoneal opening with direct visualization has no inherent risks. It makes the procedure safe and universally applicable. Laparoscopic visualization provides an opportunity to perform additional procedures such as adhesiolysis and pelvic fixation that may aid PD catheter placement and function. Open surgical insertion provides opportunity to use techniques that are safe and allow precise placement with minimal risks.

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Debate #4: Percutaneous PD Catheter Placement. Percutaneous Technique With Fluoroscopy Is Just as Safe

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Patient Selection

Percutaneous peritoneal dialysis (PD) catheter placement is appropriate for most patients without a contraindication to PD. PD candidates who are better served with surgical implantation include those with extensive adhesions ("frozen abdomen"), abdominal hernias that are suitable for repair during concomitant surgical catheter placement, those who cannot safely undergo moderate sedation, and the morbidly obese. Percutaneous placement may be the preferred alternative to surgery in patients who are unfit for general anesthesia or those requiring immediate dialysis, i.e. "urgent start PD".

Pre-procedure Preparation

Preoperative evaluation begins in the outpatient clinic prior to elective PD catheter placement. A directed history and physical examination is performed, and factors that could cause unsuccessful PD are identified. Examination of the abdomen is performed with the patient in both supine and upright positions in order to identify a suitable catheter exit site away from skin folds and the belt line. Preoperative imaging is not typically required, but in patients with multiple prior surgeries computed tomography (CT) of the abdomen and pelvis without IV contrast is useful to identify suspected hernias, abdominal loops that may be fixed to the abdominal wall or the location of abdominal mesh. CT can also be used to estimate residual peritoneal volume in patients with enlarged kidneys due to autosomal dominant polycystic kidney disease.

The international normalized ratio (INR) should be less than 1.5, and anticoagulants or antiplatelet medications are stopped for an appropriate interval prior to the procedure (1). A bowel preparation is recommended prior to elective catheter placement if there is a history of constipation or if excess stool and bowel gas are identified on pre-procedural imaging. Enemas may be used, but phosphate- or magnesium-containing enemas should be avoided in patients with advanced kidney disease. Bisocodyl suppositories and oral laxatives may also be given for several days before the procedure (2). The patient's bladder should be emptied before entering the procedure room. A single IV dose of first- or second-generation cephalosporin is given, or an institution-specific alternative antibiotic if cephalosporin-allergic (3).

Careful site planning is required to optimize catheter performance and reduce complications. Catheters positioned excessively high or anterior in the pelvis are prone to malfunction and migration, whereas catheters forcefully embedded in the deep pelvis can produce rectal or bladder pain. Choosing to insert catheters on the side of the abdomen opposite dominant surgical scars may help to avoid adhesions. Placement accuracy is improved with the use of a non-sterile catheter or a plastic template applied to the surface of the abdomen. With the patient in the recumbent position, the superior border of the symphysis pubis is palpated and marked with indelible marker. The upper border of the catheter coil is then aligned with the mark. The anticipated location of the deep cuff, skin incision and exit site are marked on the skin. The distance between the skin incision and planned deep cuff location should be adjusted to compensate for the thickness of the subcutaneous tissues. Preliminary grayscale and Doppler ultrasonography is preformed to identify the location of the rectus abdominis muscle and inferior epigastric artery. The image depth and focal spot are adjusted to optimize visualization of the echogenic line of the parietal peritoneum and mucosal signature of the underlying bowel loops.

Catheter Selection and Preparation

Double-cuffed, internally coiled catheters are most commonly used for percutaneous placement. A pre-formed bend ("swan neck") in the inter-cuff segment helps to create a downward facing exit site, reducing the risk of migration, kinking and exit site infection (3). Longer or shorter coil-to-cuff length catheters can be used to

compensate for large or small body habitus, respectively. The catheter is prepared by flushing and placing into a bowl filled with sterile saline. The polyester cuffs are manually compressed to extrude trapped air that could impede tissue ingrowth.

Procedural Details (2)

The procedure is performed under moderate sedation (e.g. intravenous midazolam and fentanyl). The abdomen is prepped with chlorhexidine 2% solution or povidone iodine 10% and draped. The superficial tissues are anesthetized with infiltration of lidocaine 1% and bupivacaine 0.25% using a 25-gauge needle. The anesthetic is then infiltrated into the rectus muscle and anterior surface of the peritoneum along the intended access tract under real-time ultrasound. A 4-6 cm long horizontal incision is created over the planned location of the inter-cuff bend with a #15 scalpel. Because platelet function is frequently impaired in uremic patients, Bovie electrocautery is useful to maintain hemostasis. The tissues of the anesthetized path from the skin incision down to the rectus muscle are bluntly dissected with a clamp or Metzenbaum scissors to create a tunnel. The surface of the rectus fascia is palpated and gently swept with a finder tip to ensure no residual intervening subcutaneous tissue remains along the needle path. If intramuscular placement of the cuff is preferred, a small opening can be created in the anterior rectus fascia.

A variety of needles are suitable for peritoneal access. Many interventionalists use a 21-gauge blunt trocar needle with a diamond tipped inner stylet (Merit Medical), but other options include a 21-gauge Chiba needle, 21-gauge micropuncture needle, blunt-tip 18-gauge Hawkins-Adkins needle or Veress-type needle. Regardless of design, needles with echogenic tips are recommended when using ultrasound guidance. The needle tip is placed against the dissected surface of the rectus muscle while widening the tunnel with a retractor, or by sliding the needle tip along the surface of an inserted metallic instrument. The needle is oriented at a maximum angle of 45° to vertical, directed caudad and angled slightly toward the midline. The needle is then advanced under ultrasound guidance through the rectus abdominis muscle and pushed against the peritoneal membrane until it penetrates with a loss of resistance. The needle tip often becomes poorly visualized on the ultrasound image after passing beyond the peritoneal membrane. After access, the outer cannula of a blunt trocar style needle may be advanced forward an additional 1-2 mm without significant risk of bowel perforation, but a hollow bore needle or sharp Chiba type cannula should not be manipulated at this point. Extension tubing is connected to the needle hub and non-ionic contrast media (iodine, 300mg/mL) is injected under fluoroscopy. Appropriate intraperitoneal needle tip position is confirmed by the outlining of bowel loops with contrast. Unintended contrast injection within the properitoneal space results in a smooth round focal collection, whereas injection into the rectus abdominis muscle produces a vertically striated appearance.

If using a 21-gauge needle, an packaged transition set (MAK-NV, Merit Medical) can be used to introduce a 0.018" guide wire into the peritoneal space, followed by a 0.035" stiff hydrophilic guide wire. Fluoroscopic manipulation of the wire is performed in combination with intermittent injections of contrast through an angled 5 Fr angiographic catheter (Kumpe, Cook) to negotiate a pathway through bowel loops, the mesentery and any possible adhesions. Alternating between frontal and contralateral oblique angulation of the image intensifier during guidewire manipulation is useful to ensure a posteriorly oriented guide wire path and helps reduce exposure of the operator's hands to the x-ray beam. An appropriately sized peel-away sheath is introduced over the wire. The dilator is removed from the peel-away sheath but care should be taken to retain the position of the guidewire in the pelvic cul-de-sac. The catheter is threaded over the guidewire and through the sheath without a stiffener. Insertion of the catheter without a guidewire increases the risk of entanglement within the mesentery or greater omentum and should be avoided. Use of a stiff hydrophilic guidewire and coating the catheter tip with water-soluble lubricant eases passage of the catheter through the sheath. Under contralateral oblique fluoroscopy, the catheter coil is allowed to form in the posterior pelvic cul-de-sac while partially withdrawing the guidewire. The peel-away sheath is removed while gently advancing the deep cuff toward its final position. The guidewire is then fully removed.

No single method for implantation of the deep cuff has been shown to be superior, but there is little doubt that a cuff floating free in the subcutaneous tissues increases the risk of dialysate leakage. Most surgeons place the deep cuff within the substance of the rectus abdominis muscle or in the properitoneal space, but published series

of percutaneous placements have reported a low incidence of leaks when the cuff is securely positioned against the anterior surface of the rectus fascia. (8-10). A stable deep cuff position can be established by creating downward pressure on the catheter swan neck during layered closure of the overlying soft tissues, but some interventionalists attach the cuff to the rectus fascia with an anchoring suture (Vicryl, Ethicon) (11). Intramuscular cuff placement can be aided by the use of a dedicated instrument (Cuff-Implantor Tool, Merit Medical), if desired

A vertically oriented exit tunnel is made with retrograde blunt dissection of the soft tissues through the incision using a clamp or Metzenbaum scissors. A skin incision 1-2 mm smaller than the catheter diameter is made at the exit site with a #11 scalpel. A curved stainless steel Faller or plastic tunneler is used to pull the catheter through the exit site, while taking care not to unseat the deep cuff. The orientation of the white or blue longitudinal catheter stripe should be checked to avoid an axial twist within the tunnel. A plastic or titanium luer-locking hub is attached and catheter function is confirmed with the instillation and free drainage of 500-1000 mL warmed saline or dialysate. After draining, the catheter is flushed with a full 10 mL heparin 100 units/mL and capped. A transfer set that has been primed with sterile saline is attached to the catheter hub (MINISET, Baxter; Safe-Lock, Fresenius). A fluoroscopic image is obtained for archive. The subcutaneous tissues and dermis are closed with layered or interrupted absorbable suture (3-0 Vicryl, Ethicon). The epidermis is approximated with adhesive strips (Steri-strips, 3M). To avoid infection and irritation, the catheter should not be stitched to the exit site; instead, the catheter is looped and attached to the skin with adhesive strips. A breathable absorbent dressing is placed over the site and secured with hypoallergenic tape (Medipore, 3M). Tubular netting is stretched around the abdomen to help stabilize the dressing (Elastic Net, Medline). The patient is discharged with detailed printed instructions regarding care of the catheter. The catheter is flushed by the nurse in PD clinic in one week and re-bandaged. Full-volume exchanges and training begin after two weeks.

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Carbon Dioxide as a Contrast Agent for Dialysis Access Intervention

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Carbon dioxide (CO_2) has been used as an imaging agent since the early 1900's (1,2). In the 1960's it was used intravenously for the detection of and diagnosis of pericardial effusion (3). With the advent of new imaging techniques, especially digital subtraction angiography, there was the proliferation of CO_2 as an intravascular contrast agent both arterial and venous.

CO_2 as an intravascular imaging agent has a multitude of advantages. It is non-allergic, does not affect renal function, has low viscosity, does not mix with but displaces blood for an image and refluxes centrally (4). This makes it an ideal agent for both evaluation and treatment of dysfunctional dialysis access.

More specifically, if a patient with an iodinated contrast allergy has acute access failure and requires immediate intervention, CO_2 provides an excellent alternative to liquid contrast and prevents delay in care. The fact that it displaces blood and does not mix with it permits better visualization of the venous structures, especially centrally, as it is not diluted like typical contrast. Its low viscosity allows administration through smaller needles and catheters. The low viscosity also allows cross visualization centrally in obstructed systems and as a result there is better visualization of collateral flow. Previously, patients considered vasculopaths could be pre-evaluated with magnetic resonance venogram (MRV) as a road map for treatment. Since the advent nephrogenic systemic fibrosis (NSF) this evaluation has been precluded and unguided potentially more dangerous approaches have resulted. A CO_2 venogram can often supplant this study, demonstrate the anatomy and establish the least invasive approach.

The most important reason for the use of CO_2 is to avoid renal decompensation from iodinated contrast. Unfortunately there is a wide held belief that if a patient is on dialysis, contrast can be administered without an untoward effect. This couldn't be further from the truth. The negative effects of contrast are already set before dialysis is even performed. Recent studies have shown that residual GFR in dialysis patients correlates and is directly proportional to survival and quality of life (). Native renal function is superior to dialysis in electrolyte and solute control. Patients are easier to manage and have less medical issues. A less than 2 point lowering of GFR increases mortality by 12%. It stands to reason that anything subjecting the patient to compromise of their residual GFR should be avoided. Since iodinated contrast can significantly adversely affect renal function, especially in those patients already compromised, its use should be limited. To limit contrast's potential deleterious effects there have been many suggestions but the primary, undisputed method is one in which the volume of iodinated contrast is limited. This can easily be accomplished by supplanting liquid contrast with CO_2.

In the past, the use of CO_2 as a contrast agent was impeded by concern for safety and cumbersome delivery systems. Currently, this is no longer the case. There are safe, user-friendly systems available which make it easy to employ. These systems combined with the advantages noted above, basic CO2 knowledge and a few caveats make carbon dioxide the preferential agent for preserving renal function in dysfunctional dialysis access intervention. This simple step can add both quality of life and improved longevity.

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Tip Design - Are We There Yet?

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When considering dialysis with a catheter, there are several issues of concern that involve tip design: problems associated with placement, adequate blood flow (Qa), recirculation and catheter thrombosis. There have been a series of catheter tip designs to address these problem (Table 1).

The major issue that has driven changes in tip design would appear to be the problem of recirculation. There are two issues of concern in relationship to recirculation - when the blood lines are connected normally and when the blood lines are reversed. Prevention of significant recirculation with the blood lines in the normal position was first achieved by separating the proximal and distal catheter openings by at least 2 cm with a step-tip design or by using a split-tip catheter design. In one study looking at recirculation at different blood flow rates, a split-tip catheter was found to have less than 5% while a step-tip catheter had less than 10 [1]. Catheter-based dialysis is approximately 10% more efficient than is dialysis through a peripheral access because of the lack of cardiopulmonary recirculation with the absence of an arteriovenous access [2]. Clearance is enhanced and therefore recirculation below 10% is not felt to be clinically significant [3].

Recirculation with the lines reversed is a major concern. When there is a problem with catheter blood flow, the natural response is to reverse the lines. With the frequency of fibrin sheath formation, this is not an unusual situation. Some studies have shown that 20% of catheter patients in a dialysis clinic are being run with lines backwards. While this results in improved blood flow, it also creates significant recirculation. This can be as high as 20% or more. In these cases it is possible to increase blood flow to obviate the effects of recirculation and achieve the goal of solute removal, but there is a limit. A new approach is the symmetrical-tip catheter. These are designed to be placed into the middle of the right atrial like all single body catheters. The lumen of both sides of the catheter are at the same height, but are directed toward the side. On the return lumen, the kinetic energy of the returning blood propels the returning blood into the atrium. This results in spatial separation between the points of blood entry/egress which is true regardless of the direction of flow. This spatial separation prevents significant recirculation regardless of whether connected in the normal position or with blood lines in a reversed position [4].

With changes in catheter design that have introduced in recent years most of the acute and functional problems associated with catheters have been resolved to an acceptable degree. However, the chronic effects of catheters on central veins, and infection continue to be major problems. It is doubtful that further catheter tip innovation will have any significant effect on these complications. However, the catheter market is lucrative and very competitive. It is very likely that we will continue to see innovations in catheter-tip design.

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Table 1 – Tip Designs to Minimize Catheter Problems

Ease of insertion	Single body catheter
Improve blood flow	Double D design
	Split tip catheter
	Side holes at tip
Decrease recirculation	Separation of arterial and venous ports
	Symmetrical tip catheter
Decrease fibrin sheath	Self-centering catheter

The Stuck Catheter: What to Do When the Catheter Won't Come Out and Is There a Role for Routine Exchange?

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Background: The "stuck" or adherent venous catheter or device is one which demonstrates resistance to removal from the venotomy site with gentle traction, after dissection to free the cuff or any securing device. We report a review of the literature for adherent catheters including risk factors for development and methods to facilitate removal, including experience from our own local institution.

Methods: Medline search was performed using the Boolean combination search of "central venous catheter," "access" combined with the terms "stuck", "adherent", and "complication". Literature was reviewed for content related to adherent catheters including patient age, gender, diagnosis, site and type of access catheter, and material if noted. Complications and removal techniques were also reviewed.

Results: 26 references, primarily case reports and a single letter to editor, were identified dealing with stuck or adherent catheters with a total 88 patients reported. 8 publications included case reports as well as techniques for removal. The average age of the patient was 27.7 years, range 7 months to 94 years of age. A single report of a stuck PICC in a 25-week premature neonate was excluded. Almost half of the patients (n=40) were less than 19 years of age, primarily involving stuck ports (31/40). We report the first case of an adherent hemodialysis catheter in a child. The majority of adult cases are stuck hemodialysis catheters with only 5 adherent ports described in the adult literature. Average implant duration was 56 months for all patients, ranging from 4 months to 146 months. Equal numbers of right and left internal jugular catheters were reported with slightly higher incidence in the left subclavian vein compared to the right (10, 4 respectively). The Tesio 10 Fr dual silicone catheter was reported with the highest frequency of hemodialysis catheters. Removal techniques ranged from burying the ends of the catheter and leaving in situ, snare techniques, endoluminal balloons and transvenous angioplasty. Complications of catheters left in situ are not uncommon, especially if catheter infection is the indication for removal.

Conclusions: The adherent catheter is uncommon with the number of cases reported nearly equal in adults and children. In adults, a stuck hemodialysis catheter is reported more frequently compared to a stuck port in the pediatric population, likely a reflection in the overall prevalence of catheter type by age. Prolonged catheter duration is the most consistent finding with the average age of the catheter being over 4 yrs. Various percutaneous techniques are reported to assist with removal.

Will Drug Coated Balloons Matter?

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In 2010, the world of hemodialysis access interventions was changed forever with the first ever publication of high level evidence showing a device or technique could significantly improve outcomes in such interventions (1). The FLAIR trial, and the as-yet unpublished REVISE trial, both large multi-center prospective randomized trials, have cemented the role of stent-grafts in HD interventions by proving beyond any reasonable doubt that stent grafts are better than angioplasty *at the venous anastomosis of grafts*. The also as yet unpublished RENOVA trial further strengthens the level of this evidence in this application. The RESCUE trial, in which bare metal in-stent restenosis was found to be better treated with stent grafts compared to angioplasty and which included fistulas and central veins as well as grafts will, when published, even further expand that role. Against this backdrop, it is very reasonable to ask whether drug coated balloons matter. If we have a device that is better than angioplasty, why not just use that all of the time? This question is not fully answered as yet. First, the superiority of drug coated balloons over plain old balloon angioplasty will have to be established, and while preliminary evidence suggests that this is the case for both grafts and fistulae, the data are by no means incontrovertible and at least for fistulae are not yet as compelling as they are for grafts (see below). The other way to look at this is that stent grafts are by no means a panacea. First, their utility compared to angioplasty in fistulae, with the exception of in-stent restenosis, has not been proven. Second, they have significant limitations when used in selected locations, including an increased risk of infection when used in cannulation zones (2), and the possibility of severely compromising future access sites if used improperly in the terminal arch of the cephalic vein (3). Stent-grafts can and do fracture and fracture fragments can and do centrally embolize as well as erode through the skin (4). Their benefit is also time limited and it is not at all clear whether re-application of stent-grafts in the same location, i.e. stent graft to treat stent graft restenosis, will yield the same kind of durable results as have been seen in other applications. The detritus of stent graft placement can be seen in the majority of patients with hemodialysis access presenting for further interventions: stent-grafts, fractured or not, in and out of the circuit, littering their arms, legs, chest and abdomen and evoking the outdoorsman's adage cited above. Would an alternative that is as good as or better than stent grafts yet leaves behind no lasting footprint matter? Absolutely!

Even if drug coated balloons were found to be simply comparable to stent-grafts, i.e. better than balloon angioplasty, they would immediately be preferable to stent grafts in any application in which restenosis is the major concern and not elastic recoil. In our experience, plain old balloon angioplasty can be successfully used, if judiciously applied including prolonged angioplasty, in over 95% of hemodialysis access interventions, both peripheral and central. Thus, failure of plain old balloon angioplasty due to elastic recoil is quite uncommon and thus the need for stent-grafts to treat that would also be uncommon. What if drug coated balloons are found to be slightly inferior to stent-grafts, but still better than angioplasty? There too, they would have a substantial role in at least those applications where stent-grafts are decidedly undesirable, namely in cannulation zones, the cephalic arch, where desirable side branches would be affected and possibly across joints, although the REVISE trial showed the Viabahn to be durable in this location at least in the relatively short-term.

Admittedly, this abstract is long on conjecture and short on data. The limited randomized data supporting the superiority of drug coated balloons (DCBs) over angioplasty in hemodialysis access interventions can be summed up in a brief paragraph. Kitrou et al, in three separate manuscripts describing two separate clinical trials have shown that paclitaxel coated coronary balloons (i.e., smaller than desirable sizes for HD interventions) yield better patency at 6 and 12 months than balloon angioplasty at the vein graft anastomosis as well as in fistulae. As noted above, the divergence of the survival curves in the graft population remained at the end of the study, whereas for fistulae, there was a convergence at 12 months which could theoretically suggest a time limited benefit of the drug and will require further study. Lai et al in a cleverly designed trial, treated patients with forearm fistulae and tandem stenoses near the anastomosis, randomly treating one of the two tandem stenoses with a paclitaxel coated balloon, again a coronary device, and the other with plain old balloon angioplasty. In half of the patients,

the lesion treated was the upstream one, and in the other half it was the downstream one, an ingenious control. In both groups, the drug coated balloon lesions yielded better results than the plain old balloon treated lesions at 6 months but not at 12 months, again suggesting a time-limited effect. The DEBAPTA randomized trial (NCT01544907) in which paclitaxel coated balloons were used in grafts and fistulae and compared to conventional PTA has not yet been published; preliminary results presented at several meetings did not show a benefit of the DCB. Of course, large multi-center randomized trials are necessary and are desirable and absolutely necessary to determine the efficacy and durability of drug coated balloons in both grafts and fistulae. The Lutonix AV trial (NCT02440022), begun in mid-2015, will enroll 284 patients at up to 35 sites in the United States with failing AV fistulae. The control device in the Lutonix AV trial is plain old balloon angioplasty, the appropriate predicate technique given the lack of proven superiority of stent-grafts over angioplasty in fistulae and given the strong desire to avoid leaving "footprints" in those fistulae. Other trials are under development or just underway can be found on clinicaltrials.gov, including a randomized trial of DCB in recurrent cephalic arch stenosis (NCT02368197). It has been suggested that in grafts the predicate device should be a covered stent (9) and at least at the vein graft anastomosis this should probably be the case, although in other locations where stent-graft superiority has not been proven, and in particular in cannulation site lesions, this is certainly not the case.

In summary, drug coated balloons matter a great deal. They offer the tantalizing possibility of prolonged patency compared to plain old balloon angioplasty with resulting better long-term outcomes and thus fewer visits to the interventionalist for the hemodialysis patient population. Further, because they leave no lasting footprint, they can be reapplied indefinitely without the major downsides of leaving the metallic and plastic trash behind.

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Debate #5: Accessory Veins: Fact or Fiction? Fiction: They Are Not Real and Do Not Require Embolization or Ligation

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A mature fistula may be defined as a more than 600ml/min flow rate fistula showing a 6 mm minimal venous diameter less than 6 mm deep from the skin at 6 weeks from surgical creation.

Once vein depth is ruled out, a significant stenosis is invariably identified and should therefore be dilated. Angiography should be performed preferably through the brachial artery so that the upper arm arterial supply, the anastomosis, the arterialized vein and its venous outflow architecture can be properly assessed (1-3).

Any significant stenosis along the axis of an arterialized vein can cause reflux through collaterals upstream from the stenosis although this is not the majority of cases since stenoses most often develop at the anastomosis (1). The more effective measure at addressing the underlining stenoses is dilation with a balloon of sufficient size at sufficient (sometimes ultra-high) pressure. Underlining stenoses are often missed because orthogonal views of the AVF are not performed. The problem is that non radiologists or radiologists with insufficient expertise in fistulas can miss stenoses or underestimate their hemodynamic impact (4). We reported an underlying stenosis in 100% of non-maturation cases as early as 1999 (1), which was confirmed by Asian radiologists in 2005 (5). In contrast, one American nephrologist was able to diagnose a stenosis in only 33% of cases in 1997 but the proportion rose to 78% in his 2nd report in 2003 and is probably even higher today (6-. A Dutch surgeon diagnosed stenosis in 64% of cases in 2003 and American radiologists in 88% of cases in 2007 (7).

Yet several publications recommend coil embolization or ligation of collaterals and overlook underlying stenoses. A comparison can be made with subclavian stenoses, which invariably presents with collaterals upstream to the lesion. No one ever thinks of embolizing these collaterals and leaving the stenosis alone.

The best evidence of the maturation of a fistula is a steep increase in flow rates as it was reported after dilation of stenoses (2). No publication has ever reported any increase in flow rate after embolization/ligation of side-branches and no randomized trial has ever been initiated to compare the outcomes of fistulas showing collaterals after embolization or not. It seems logical to conclude that the reason such a trial has not been carried out is that those promoting accessory vein treatment simply do not want to see the results of such a trial, because it may represent the death knell for a lucrative practice…

Long-standing segmental venous occlusions induce formation of well-developed collaterals which take over the venous drainage of the fistula. Thus, in spite of partial or complete recanalization of the occlusion, these collaterals continue to be the preferred route for venous drainage leaving the main AVF lumen with a low blood flow. Under such rare circumstance ligating or embolizing the collaterals may help redirect venous drainage through the AVF lumen but the best course of action in such cases is to intervene early, within 2 months of fistula creation.

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When to Abandon the Thrombosed AVF?

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The topic of timing of abandonment of a thrombosed AVF remains very controversial. In discussing this topic we will address the simple question, "when should we abandon a thrombosed AVF," very simply. We will then engage in a more sophisticated discussion by asking a different question: "When should we not perform a percutaneous thrombectomy on a thrombosed AVF?" the answer to the former question is obvious to most experts in vascular access planning and patient care. If we define abandonment as "create a completely new access unrelated to the original AVF, then the answer to the question is: NEVER. That is to say, "there are no absolute rules or cases in which a thrombosed AVF should be abandoned." The reason for this simple observation is that multiple solutions besides abandonment exist, including bypass the problem with PTFE surgically or percutaneously (1). The second question requires a more circumspect answer that is largely governed by the size of the AVF, the thrombus burden, the risk of complications, and the frequency of interventions required for AVF maintenance. The presentation will focus on a discussion of these principles.

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Declotting Under Fire: How to Minimize Risk to the Patient and Reduce Radiation Exposure to Everyone During AVF Declotting

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Ionizing radiation can result in two categories of detrimental effects: stochastic and deterministic. Stochastic effects are those that occur by chance, the best example of this is cancer induction. Deterministic effects will often be evident within hours or days. Deterministic effects include skin injuries, hair loss, cataract formation, and sterility (1).

While the potential for stochastic effects in patients should never be ignored, the more immediate concern is deterministic (2). Skin injuries are the most commonly encountered clinical effects from fluoroscopically guided procedures. The dose to this skin area may be high enough to cause a sunburn-like injury, hair loss, or in rare cases, skin necrosis (3). The threshold for skin injury (erythema) is 2 Gy (3).

Most of the issues of importance in reducing the dosage of radiation delivered to the patient and to staff involved in the procedure are listed in Table 2, only a few will be singled out for discussion. First, the mobile C- arm is the ideal equipment for reducing the radiation dosage when doing dialysis access interventional procedures. The dose levels delivered during a procedure are considerably lower with a mobile C-arm, as much as 10 to 15 fold lower, than with a fixed C-arm (4).

As an essential part of a facilities ongoing quality assurance (QA) program, radiation dosage should be monitored and recorded in all cases. Four dose metrics have been developed to estimate patient radiation dose for fluoroscopically guided procedures (5): Peak skin dose (PSD), fluoroscopy time (FT), reference point air kerma (RPAK) which was referred to as reference dose or cumulative dose, and kerma-area product (KAP) which is also known as dose-area product (DAP). The significance of each of these parameters for estimating radiation dosage is different (Table 1.

PSD is the best metric for estimating deterministic risk with a critical value of > than 2 Gy (2). Unfortunately, PSD is not available on the fluoroscopy machine. RPAK correlates with PSD relatively well and can be thought of as an approximation of the patient's total skin dose for the procedure (6). Measurement of RPAK is probably accurate to within $\pm$ 50% of the actual PSD (6). Since the value registered represents the total obtained by measuring skin dose at multiple points on a patient's body as the field of view is moved from one area to another during the procedure (7), it does not actually represent the radiation exposure for a single defined area. Since RPAK is not affected by collimation, it will always tend to be higher than true PSD.

In a study of radiation dosage resulting from dialysis access maintenance procedures, the RPAK geometrical mean value for AVF thrombectomy was 4.9 mGy (median 4.78, range 2.78-8.04) or 0.0049 Gy (8). Only a small fraction of the 2 Gy threshold for skin injury. In the system in which the author works (interventional nephrology) there are 1800 personal dosimetry badges. Only 3% exceed the ALARA level 1 limit of 125 mrem each year.

Table 1 – Decreasing Radiation Dosage

Reduce dose
Use mobile C-arm
Optimize exposure factors (mA, kVp)
Use pulsed fluoroscopy
Reduce field size (collimate) and minimize overlap
Filtration use
Limit use of digital subtraction
Limit use of magnification
Minimize use of alternate projections (oblique views)
Minimize exposure time
Do not wear lead gloves
Use proper radiologic technique
Optimize exposure factors (mA, kVp)
Optimize x-ray tube position
Maximum distance between x-ray tube and tabletop
Minimize distance between patient and image receptor
Control fluoroscopy time
Limit use to necessary evaluation of structures
Employ last-image-hold to review findings
Control images
Limit image acquisition to essential diagnostic and documentation purposes
Avoid redundant views

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Advanced Symptomatic PAD in ESRD Patients and the Impact of Limb Salvage

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Peripheral artery disease (PAD) is a common medical problem in hemodialysis patients. PAD can be broadly divided into two categories. Early PAD is diagnosed in patients with asymptomatic disease with an abnormal ankle-brachial index (ABI) or in patients with stable intermittent claudication. In contrast, advanced PAD is present in patients with impending limb loss (rest pain, ischemic ulcers or gangrene). Treatment options for patients with advanced PAD include revascularization with percutaneous transluminal angioplasty (PTA), surgical peripheral bypass or amputation.

It is well known that PAD is much more common in dialysis patients with diabetes than those without diabetes [1]. It is less commonly appreciated that there are substantial differences in the frequency of advanced PAD among countries. A recent large international study highlighted the magnitude of these differences. A history of prior amputation in diabetic HD patients was present in 23% of patients in Germany, 17% in the U.S., 10% in Spain, and only 4% in Japan [1]. In each of these countries, a history of amputation was 5-10 fold higher among diabetic vs non-diabetic HD patients. As compared to diabetic HD patients in the U.S., the relative risk of a new amputation was 2-fold higher in Belgium, and only 0.3 times as frequent in Japan [1].

A large prospective study of incident HD patients in the U.S. observed a PAD procedure (PTA, peripheral bypass or amputation) at 3 years in 30% of diabetics and 10% of non-diabetics [2]. In 63% of the patients the first procedure was an amputation. Kidney failure is associated with worse limb salvage in patients with renal dysfunction. In a large U.S. study, the 1-year frequency of amputation after revascularization for lower extremity ischemia was 29% in HD patients, as compared to 10% in patients with normal kidney function [3]. The results are more encouraging in other countries. Thus, the 3-year risk of amputation after PTA in HD patients with 15% in an Italian study and only 10% in a Japanese study [4 5]. Amputation after PTA was more likely in diabetics or in patients with distal disease [4]. In a large U.S. study, amputation after revascularization in HD patients was more likely in diabetics, blacks, and uninsured patients or those with Medicaid insurance [6].

Cardiovascular outcomes in patients with PAD are also worse in HD patients. In a study from the Veterans Administration, the 30-day postoperative mortality after an amputation was 15% in HD patients, as compared to 6% in those with normal kidney function [7]. Comparable data were reported from a USRDS study, in which the 30-day mortality was 12.6% after peripheral bypass and 7.3% after PTA [6]. In a Japanese study of patients undergoing PTA for lower extremity ischemia, mortality at 3 years was 30% in HD patients vs ~10% in those with normal kidney function [5]. Again, patient survival is worse in the U.S., with 2-year mortality being ~60% after peripheral bypass and ~40% after PTA [6].

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Here's What You DON'T Know About Central Vein Stenosis and Occlusion

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Central venous stenosis (CVS) remains one of the most troublesome problems in the hemodialysis patient population. While substantial strides have been made in the treatment of peripherally located access-related venous stenosis, such as proven superiority of stent grafts over balloon angioplasty in selected locations (vein graft anastomosis and bare metal in-stent restenosis), to date no treatment has been shown superior to PTA in CVS. Given the less-than-ideal results of PTA in central veins, prevention remains by far the best measure in "managing" this problem. Only one bare metal stent design has received FDA clearance for CVS and this device, the Wallstent, is generally undesirable in this location. Even that clearance was not supported by a randomized trial (1). What the hemodialysis access intervention community does not know about central venous stenosis could easily fill the pages of a textbook. Rather, it may be better to think about what interventionalists **should** know about such interventions yet seemingly ignore with regularity. These are outlined in the list below.

Myth #10: Adequately sized stents grafts are available for the treatment of central venous stenosis in the United States.

In most patients, the subclavian vein measures in the vicinity of 12 mm, so to allow some oversizing a 14 mm device is desirable. With maximal stent graft diameters in the US reaching just 13.5 mm, these devices may in some patients be just barely adequate for this vessel. However, the brachiocephalic vein (BCV) is at least 14 and often 16 mm in diameter, and it is not uncommon to need 16 or even 18 mm PTA balloons to get a satisfactory result. Thus, no covered stent, nor for that matter bare metal nitinol stent available currently in the US is even close to being adequate for this vessel. This leaves only the Wallstent or large balloon expandable stents; given the issues of limited hoop strength (particularly at the ends of the stent) and shortening with the former it is highly unsuited to this vessel, especially the right BCV which is very short. We have had good experience with the latter, in particular in the right BCV, however to the extent that stent grafts could potentially have the same benefit over PTA centrally as they do peripherally, there is an acute need for larger stent grafts in this population.

Myth #9: All central venous occlusions must be treated with stents or stent grafts

PTA remains the mainstay for central venous disease in the HD population as no other technique has been shown superior in a randomized trial. Tantalizing non-randomized studies abound suggesting stents and stent grafts, particularly the latter, might improve outcomes, and all are subject to the strong limitations of retrospective work. There is a desperate need for randomized studies of these devices in HD related CVS. However, even those who are content to use PTA as the mainstay of CVS treatment often primarily stent CV occlusions, based either on experience, limited retrospective studies, hearsay or all of these. However, placing a stent device into the central veins in this population has multiple potential drawbacks, including the possibility of device misplacement with compromise of future access sites as well as the inevitable restenosis which ultimately results in the abandonment of that side of the body for access. Further, in the presence of rhythm device wires, stent device placement is considered contraindicated by the cardiology community (2). Thus, PTA with an adequately sized balloon (see above) should always be tried, even in occlusions, and if a satisfactory result is achieved, nothing further should be done.

Myth #8: All central venous stenosis is caused by prior catheterization

While it is true that central venous catheters, in particularly subclavian catheters which inexplicably continue to be placed in HD patients even in high-profile institutions, are the cause of most CVS in this population, other causes

exist and must be considered in order to choose the correct treatment modality for the lesion. Extrinsic compression of the left brachiocephalic vein by the great arteries (3) is usually asymptomatic (see Myth #1) however when symptomatic will not respond to PTA and must be treated with a stent or stent graft. Given the limited sizes available for this vessel as outline above, this is a problematic lesion for affected patients. Likewise, malignancy can coexist in this population, whether active or treated. Patients who have had radiation therapy to their chest may be at substantially increased risk for complications of PTA, and those with malignant stenosis must be treated very differently than the above algorithm. Last and not least, the role of extrinsic compression by the first rib-clavicle complex is becoming increasingly recognized and with it, surgical treatments for this (4).

Myth #7: Central venous stenosis usually affects access function and/or flow

Many interventionalists justify treating asymptomatic CVS (see Myth #1) by claiming that the lesion is causing access dysfunction. It is certainly possible for this to occur: in patients with grafts and high venous anastomoses ie axillary vein, coupled with a very peripherally located subclavian vein stenosis, this CVS may serve as an outflow stenosis and provide the same clinical presentation (prolonged bleeding, high pressures, pseudoaneurysm formation, and pulsatility) as any other venous outflow stenosis. Such lesions are increasingly rare, as grafts are less frequently encountered and subclavian lesions are also less frequently encountered (as compared to brachiocephalic ones, see Myth #4). With this rare exception, treatment of a CVS and in particular a brachiocephalic CVS to improve access function is pure folly. If the interventionalist carefully assesses the lesion, which may involve pressure measurements (5) or flow measurements (6), he or she will nearly always find that the lesion is not the culprit. Indeed, in a study in which flow measurement was performed immediately before and after successful PTA of symptomatic CVS, flow measurement usually did not change, and went down as often as it went up. When it did increase, it was only modestly (6).

Myth #6: SVC syndrome in HD patients is caused by SVC stenosis

An understanding of the collateral pathways in central venous stenosis and occlusion is critical to understanding and correctly treating CVS, and nowhere is this more important than SVC syndrome. Many interventionalists assume (incorrectly) that SVC syndrome in HD patients is, like in those with malignancy, a result of SVC involvement. This often leads to unnecessary PTA of the SVC with its attendant risks and additional costs and sheath size for larger balloons. In fact, SVC stenosis is exceedingly rare in the HD population, and "SVC syndrome" in these patients is nearly always due to bilateral brachiocephalic disease, especially if the jugular venous arch, made up of the anterior jugular veins, has been compromised by tracheostomy. A description of this anatomic situation can be found in reference 7. Treating one or both affected brachiocephalic veins appropriately, starting with PTA and using stents or stent grafts only when PTA fails, will result in symptom resolution in such patients. Rarely, jugular stenosis or occlusion from prior catheters coupled with brachiocephalic CVS can produce "SVC syndrome" and will also respond to PTA and/or stent device placement (7). In contemplating such patients, careful analysis of the collateral pathways will help to plan the appropriate treatment.

Myth #5: Symptomatic central venous stenosis is manifested by arm swelling alone

While it is true that CVS in the HD population most commonly presents with arm swelling, as noted in #6, SVC syndrome can be a manifestation and is one that is generally if not always recognized. However, unilateral breast swelling is a clinical presentation of symptomatic CVS that is very often overlooked. These patients can have completely normal arms and at times may not relate this symptom unless explicitly asked. Further, this symptom can be misconstrued as inflammatory breast cancer, leading to unnecessary, costly and/or invasive testing and even treatment as well as emotional distress for the patient. Of note, all of these clinical presentations respond well to PTA of the offending lesion(s).

Myth #4: Internal jugular catheters don't cause central venous stenosis

There is no question that subclavian catheters cause more CVS than IJ catheters, as evidence by decades-old comparative studies and emphasized repeatedly by the K/DOQI and FFCL. However, it is very important to realize

that IJ catheters are not without morbidity. In addition to the roughly 25% chance the IJ will become thrombosed with each IJ catheterization, there is a reported up to 10% incidence of CVS, usually in the BCV but often involving the subclavian vein in particular at its junction with the BCV. This risk likely relates to the duration of catheter dwell, as one study with venographic FU at the time of TDC removal at average 90 days showed only a 4% incidence of any abnormality (8). The morbidity associated with even IJ catheters underscores the need to remove TDC (that can't be avoided completely) as soon as possible-a major thrust of FFCL.

Myth #3: Central endovascular interventions are the only way to manage CVS

Most discussions of symptomatic CVS center around PTA, stents and stent grafts. However, symptomatic CVS is the result of an interplay between inflow to the central veins (ie, access flow) and both intrinsic and extrinsic blockage of the outflow (See Myth #8). Much more research is needed to help understand this interplay and a central tool in that research needs to be direct flow measurement. Further, in clinical practice, flow measurement can help determine who may be more likely to benefit from flow reduction (surgical or percutaneous), surgical decompression, or revascularization. Finally, in some patients with mild symptoms and particularly those with fistulae, who tolerate CVS better than those with grafts (9,10), a watchful waiting approach may allow collateral formation and resolution of symptoms without intervention. The astute clinician will consider all of these options before applying the oculotherapeutic reflex and "treating the picture" with PTA or other devices.

Myth #2: It's "OK" to stent over cardiac rhythm device wires

While cardiac rhythm devices (CRDs) may be soon destined for replacement by epicardial ones, the sequelae of prior devices will persist in the HD population for decades to come. With a reported 50% incidence of CVS, CRD are a major cause of symptomatic CVS in the HD patient. In spite of a lack of evidence that placing a stent over CRD wires is detrimental (indeed, several reports to the contrary exist [11]), the electrophysiology (EP) community is sufficiently concerned about this practice to issue a statement that is it not acceptable to do so (2). Thus, at very least, when PTA fails in this situation, a conversation with the EP team is critical before proceeding.

Myth #1: All central venous stenosis should be treated regardless of symptoms

In spite of a continued stream of evidence showing that asymptomatic CVS should not be treated, as well as that treating such asymptomatic lesions may worsen outcomes (12,13), many interventionalists still apply the oculotherapeutic reflex when faced with these lesions. The evidence against this practice has been discussed in detail previously (14). The message is clear, yet the practice persists. Whether further changes in reimbursement that cloud the horizon of HD interventions will affect this practice is unclear. For the present, anyone treating a CVS must justify doing so either on the basis of symptoms or the rare exceptions to this rule cited above and discussed in prior reviews of the subject (14).

My Top Ten Myths and Misconceptions Regarding Central Venous Stenosis

1. All central venous stenosis should be treated regardless of symptoms
2. It's "OK" to stent over cardiac rhythm device wires
3. Central endovascular interventions are the only way to manage CVS
4. Internal jugular catheters don't cause central venous stenosis
5. Symptomatic central venous stenosis is manifested by arm swelling alone
6. SVC syndrome in HD patients is caused by SVC stenosis
7. Central venous stenosis usually affects graft or fistula function
8. All central venous stenosis is caused by prior catheterization
9. All central venous occlusions must be treated with stents or stent grafts

10. Adequately sized stents grafts are available for the treatment of central venous stenosis in the United States

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Recanalization, PTA and Stent Placement: Tools and Tips

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Central vein disease, either stenosis or occlusion of the superior vena cava, brachiocephalic vein, subclavian vein and/or the internal jugular vein are common in the dialysis population. Patients can be asymptomatic, present with difficult central venous access, swollen extremities or SVC syndrome with or without the presence of a functioning AV graft or fistula. If the AV shunt is working adequately and the patient is not complaining (other than large chest wall collaterals or tolerable arm swelling) and the central vein disease is noted to be an occlusion, we would consider observation. In the presence of an occlusion with significant symptoms intervention would be indicated. Significant central vein stenosis should be treated even if the patient is minimally symptomatic when there is a functioning AV shunt or if the shunt is functioning suboptimally. Stenoses can and should be dilated without stent placement. If the result is suboptimal then a stent can be placed. There is recent evidence that covered stents may function better than bare metal stent especially in the cephalic arch. More evidence is needed to prove the long term efficacy of stents or covered stents in central vein stenosis.

Recanalization of central vein occlusions may be straight forward or very difficult. Interventional radiologists should be familiar with all the tools available to them when a wire does not easily cross the occlusion. Also, if acute clot with a significant clot burden is present, IRs should be comfortable with the use of lytics, mechanical, or pharmaco-mechanical devices to remove the clot burden prior to angioplasty or stent intervention. If a non-hydrophilic wire cannot cross an occlusion a hydrophilic wire with a directional catheter may be used. Sharp recanalization with a needle can be used, however, there is concern that adjacent structures may be injured and the complications may be excessive. Recently RF wires (Baylis Medical) have been used to cross central occlusions. It is important to be familiar with this device and how to advance the wire so as to limit the inadvertent extra-venous passage of catheters and devices.

Although stenting stenosis may be controversial, I believe that if you are successful in recanalizing an occlusion it is probably a good idea to stent it. I would favor a covered stent as long as you can position the covered stent without crossing a patent jugular vein.

Finally, any intervention in the central veins can lead to potential complications. Most complications are usually recognized and managed by IR. We have seen and I have been informed of several cases of pericardial tamponade that have gone unrecognized. Any time a patient develops symptoms that may represent tamponade, such as, acute mental status change, respiratory issues, hypotension etc do not write it off as excessive conscious sedation. It is tamponade until proven otherwise. Appropriate diagnostic and therapeutic maneuvers should be urgently performed.

PTA, PTA, PTA. Only Use Stents or Stent Grafts for Bailout

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The arguments in favor of PTA as front line therapy for CVS are discussed in "What you don't know about central venous stenosis and occlusion" and selective references are listed below. To summarize the salient arguments:

1) Stents and stent grafts cost more than PTA
2) There is no proven superiority of stents of stent grafts over PTA
3) Therefor, PTA cannot be cost-effective
4) Randomized trials in this area are desperately needed and will help bring new technology to the market if successful, which to the advocates of stents and stent grafts is considered a foregone conclusion; so why have such trials not been done?
5) Put another way, if interventionalists persist in using stents and stent grafts without any evidentiary support to do so, why would a manufacturer risk the cost of a randomized trial?
6) There are multiple locations where stents and stent grafts are at least relatively if not absolutely contraindicated, a point already conceded

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