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Training in Vascular Access Surgery (VAS) - the Bad News is Worse than Expected

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The classic Halstedian model of surgical training embodied an apprentice-master model whereby surgeons had the necessary technical skills to perform a wide range of procedures. During the 1990's a number of events impacted surgical training and this is no longer the case. The American Board of Surgery recently found that the operative experience of general surgery (GS) residents in a wide range of areas is not at a level sufficient to lead to basic competency (1).

Both DOPPS and a large Veteran's Administration study found that a minimum of 25 AVFs during training was predictive of fistula placement and survival (2-4). Residents in GS and fellows in vascular surgery (VS) and transplant surgery receive training in VAS. Case numbers are not published for transplant fellows but for trainees in GS and VS, numbers are available (5). The threshold of 25 AVFs is not being met in either VS or GS training programs.

Notwithstanding the importance of adequate training, the current system of case reporting has limitations. The definition of what constitutes a "resident surgeon" is subject to interpretation. Residents may report experience in VAS at all levels of their training. Exposure to VAS as a junior resident does not guarantee against deterioration of technical skills over time. Adequate numbers is also not a proxy for acquisition of judgment. Residents are infrequently involved in the evaluation of patients prior to AVF placement.

Only 1 in 4 general surgeons is performing VS, primarily those who trained 20 or 30 years ago (6). The majority of VS cases are performed by ABS certified vascular surgeons. As the dialysis population grows and as the present cadre of general surgeons retires, there will be increasing demands on a small number of trained vascular surgeons. In 2011-2012 there were 1,092 GS residents in the US compared to 124 training in VS. Since the majority of vascular surgeons live in urban areas there will be further constraints on patient access to qualified surgeons.

The next generation of surgeons will work within a continually narrowing scope of practice. This is significant for hospital credentialing bodies where performance of VAS is still considered within the scope of GS. Not all institutions require minimum numbers and have robust professional practice evaluation processes (proctoring) for those requesting privileges in this area. Unless more rigid standards are imposed by all hospitals there will be further erosion in the quality of VAS.

With >70% of GS residents seeking additional fellowship training, acquisition of VAS skills will decline (7). Future solutions include: (a) modification of the GS residency to provide a "flex" final year where the resident receives training tailored to their future practice pattern; (b) more training programs in VS especially focusing on integrated training ("0+5"); (c) use of simulation technologies designed to accelerate acquisition of surgical skills; (d) creation of VAS fellowship.

The story that DOPPS told is now ten years old but the lessons have not been embraced by surgical educators. We can no longer assume that residents will receive adequate training in VAS. Indeed, the opposite will likely occur with less exposure to VAS as priorities change in resident training. With no long term solutions on the horizon, surgeons currently performing VAS must assume responsibility for recruiting and mentoring the next generation of access surgeons both within the residency and more significantly following graduation.

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Education, Training, and Transition to Practice in Dialysis Access Procedures

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Training in hemodialysis access surgery and endovascular therapies for those accesses has been a neglected component of the education of Vascular and General Surgeons. Procedures have frequently been delegated to junior trainees despite the fact that the operations often require complex decision making and technical excellence. In many cases, the Surgical Residents who perform the procedures will not practice access surgery upon completion of their training. Work hour restrictions have also complicated the ability to provide adequate experience and case volumes to appropriate trainees. Over the past 15 years, the volume of dialysis access surgery has increased significantly in Vascular Surgery practices in Academic, Group and Private settings. Generally, training programs have not increased the exposure of senior vascular trainees to these procedures and access surgery is still not considered an Index procedure for the purpose of board requirements.

Endovascular therapies are increasingly important in maturation and maintenance of dialysis access yet even less experience is obtained in Vascular Surgery training programs for these modalities as the procedures are most frequently performed by Interventional Radiologists and their trainees.

The consequence of the above is that many recently trained Vascular Surgeons are not well equipped to practice the broad spectrum of procedures required in a busy dialysis access practice.

Addressing these problems requires attention at multiple points in the process. Training programs are using simulation to enhance the educational experience so that trainees are performing at a higher level when they begin operations on real patients. Additionally, greater monitoring of resident performance and volumes are being utilized in some centers to improve preparation for practice.

In our Vascular Surgery training program, fellows perform the majority of the open and endovascular procedures for dialysis access while at our facility. The practice cares for over 550 active hemodialysis patients as well as a larger population with CKD 4 and 5 being prepared for dialysis. This provides them with a comprehensive experience and the ability to practice in multiple different practice environments. The majority of our graduates enter a practice involving a significant amount of hemodialysis access work.

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The “Access Center Effect”: Are Outcomes Related to the Center?

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The “Center Effect” is a well-accepted concept in the transplant community, where outcomes for various types of solid organ transplantation vary from center to center. The annual Scientific Registry of Transplant Recipients (SRTR) reports list each center and make a notation as to if the outcomes are lower than expected, as expected, or higher than expected. Many different variables go into play here but it can be safely assumed that different centers may have different practice patterns which may affect outcome.

Likewise, dialysis practices and outcomes vary greatly from center to center. For example, early arteriovenous fistula (AVF) thrombosis at 6 weeks varies from 6-28% while primary patency with expanded polytetrafluoroethylene (ePTFE) grafts is reported to range from 23-69%.

The causes of the difference in outcome across centers is likely multifactorial. It may represent the “tipping point” phenomenon where doing the right thing for the right patient at the right time in the right amount for the right reasons is key. Thus, small “rights” for each patient by every team member allow the center to have superior outcome.

The end stage renal disease patient population is a challenging one with an overall annual mortality of approximately 20% in the United States. The choice of dialysis modality, the timing of access placement, and the type (fistula vs. graft) and site of access may mean survival or death for an individual patient. The center’s administrative leadership style, the quality of the protocols and policies in place, how well they are adhered to, and a rigorous and continuous quality improvement process affect the outcome as well.

Trends in Outpatient Access Intervention: Concern for Outpatient Access Center Model?

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Purpose: To understand the status of and clinical and business challenges facing the out-patient dialysis access model of health care delivery.

Methods: Clinical and business analysis of historical and current out-patient access model.

Results: The movement of access-related maintenance procedures away from the hospital setting to the out-patient arena is evidenced by USRDS data showing a drop in hospitalization rates for vascular access by 49.7% from 1994 to 2010. It is unlikely that the patients are requiring less of this care, but rather, that the care is being delivered outside the confines of the hospital. Not surprisingly, this observation parallels the growth and expansion of the out-patient access facilities nationwide.

As far back as the mid-2000’s, it was apparent to a few independent free-standing access facilities, as well as those affiliated with one of the corporate-managed system of centers, that third-party accreditation through The Joint Commission (TJC), The Accreditation Association for Ambulatory Health Care (AAAHC), or The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) was crucial and signaled a level of operations that met stringent standards to which other similar health organizations were held. This accreditation served an important role of dispelling many of the concerns that interventional access care provided outside of the hospital setting was unsafe and not subject to the same rigor or level of scrutiny. Discussions of the safety of performing these procedures on an admittedly challenged and challenging set of patients, outside of the hospital and by nephrologists was the subject of a seminal paper by Beathard (1). Two related publications by the same group enlightened us on the safety of sedation/analgesia (2) and radiation use and exposure (3) as pertains to these procedures in these points of service.

In a study soon to be published, multivariate matching of patients in the free-standing out-patient centers to the hospital out-patient facilities, using the USRDS data set from the years 2006 through 2009 showed that patients treated in the out-patient centers experienced lower per-member-per-month payments for vascular-access related care, lower mortality rates, and lower rates of hospitalization, infections and septicemia-related hospitalizations (4). This is the largest study of this kind that specifically addresses the issues of quality and outcomes.

The challenge of the out-patient access center has primarily been one of ensuring efficient and effective delivery of quality-driven care in a safe environment, in a business climate that is at a minimum, revenue neutral. While the number of free-standing out-patient access centers has risen from 58 in 2004 to 210 in 2013, in fact, the growth of the industry has been stagnant from 2009 to 2013 with a rate of 3% per year. It is not coincidental that the plateau in growth parallels that of the relative reimbursement rate for the same interval. Relative to 2004, the reimbursement rates peaked in 2006 and declined steadily thereafter to a nadir in 2010, followed by a modest upward excursion from 2011 to 2013. Current reimbursement rates are about 69% compared to their peak in 2006. The recent Physician Fee Schedule released by CMS in July 2013 shows a further reduction of about 13-14% for the most commonly utilized dialysis access CPT codes.

Conclusion: The out-patient free-standing facility has evolved into a mainstay of dialysis access care and has been shown to provide consistently reliable and efficient care. Initial concerns with safety and quality have been largely quieted and dispelled. Challenges facing growth and survival of these centers are now largely centered around public policy, regulations and the erosion of reimbursement schedules. With Accountable Care Organizations (ACO) and the ESRD Seamless Care Organizations (ESCO), the access center may have an opportunity to play an even more pivotal role as scarce resources are allocated to delivery systems that are favor efficiency, effectiveness, safety, quality and integration.

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Outpatient Access Centers are a Cost Effective Model for Providing High-Quality Care

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The free-standing dialysis access center (FDAC) is classified as an extension of the doctor's office or place of service (POS) 11 although they are generally constructed to meet state and federal requirements for an ambulatory surgical center. When the relative reimbursement rates for POS 21, 22 and 11 are compared, it can be seen that the FDAC is significantly less (Fig. 1). In a study in which 27,613 patients treated at a FDAC were compared with matched cohorts using a propensity score matching technique and data derived from CMS, it was shown that care delivered at this site resulted in lower mortality rates, lower rates of hospitalization, and lower infection rates at a reduced cost (Fig. 2) (1). This data supports the cost-effectiveness of the FDAC beyond a simple

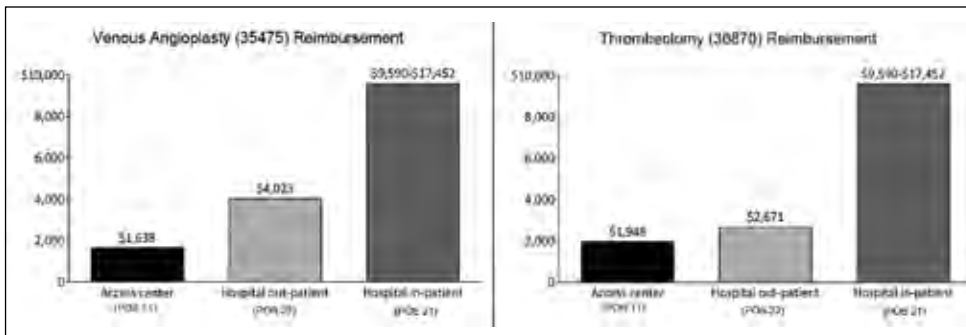


Fig. 1 - Comparison of reimbursement rates for different sites of service.

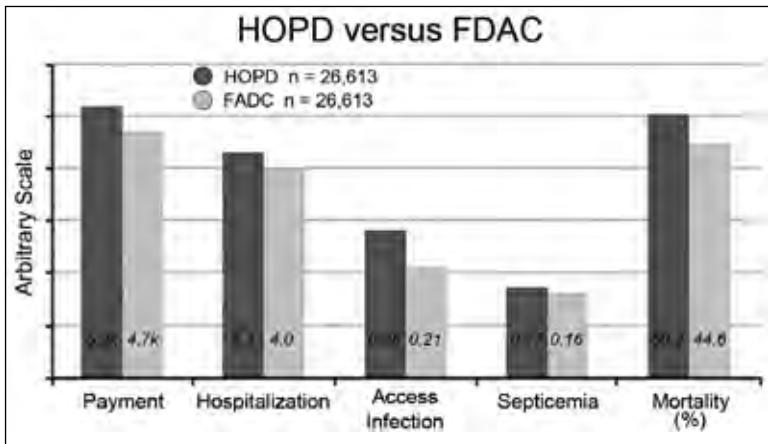


Fig. 2 - Comparison of HOPD and FDAC (matched cohorts) (1).

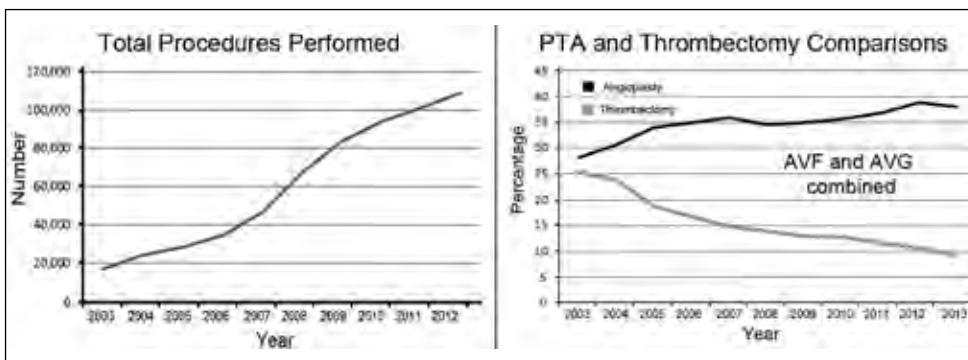


Fig. 3 - Changes in procedure numbers over a 10 year period.

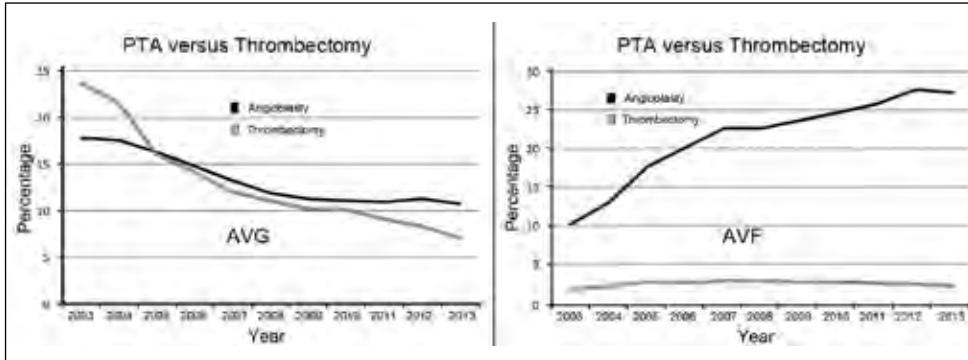


Fig. 4 - Comparison of angioplasty and thrombectomy rates for AVGs and AVFs.

examination of the payment for the procedure only. When hospitalization and infection rates are reduced, a very significant cost saving results.

An issue of considerable importance is the question of whether unnecessary procedures, especially angioplasties, are being performed by any practitioner who might be practicing at any of the three possible places of service. In a group of associated FDACs, it was noted that the total procedure numbers performed increased from approximately 20,000 in 2003 to approximately 105,000 in 2012. This increase was due to three factors – 1) adding new centers to the group, the major issue, 2) growth in the dialysis population being served and 3) the addition of new procedures, especially vascular mapping and clinical evaluation of non-maturing AVFs. During this period of time, the percentage of angioplasty procedures performed increased from approximately 28% to approximately 38% (Fig. 3). This represented a 10% increase in angioplasty procedures performed; however, the type of access involved changed from arteriovenous grafts (AVG) to predominantly arteriovenous fistulas (AVF). With the change in type of access being treated, angioplasty rates for AVFs went up by approximately 17% relative to the total procedures performed, related primarily to salvage procedures on non-maturing AVFs. During the same period of time, angioplasty procedures performed on AVGs decreased by 11% relative to the total procedures that were performed. Coincident with this increase, the ratio of thrombectomies to angioplasties reversed from thrombectomy dominant to angioplasty dominant. Numbers of thrombectomies performed on the AVFs during this ten year period remained relatively flat (Fig. 4).

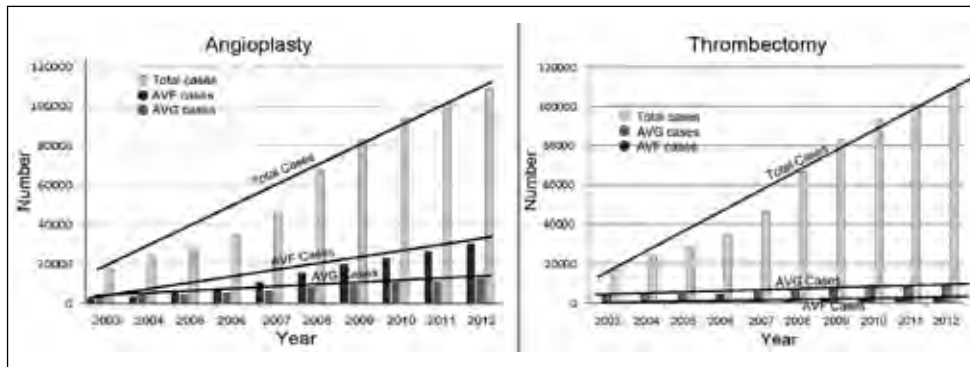


Fig. 5 - Rate of increase (slope of line) for angioplasty and thrombectomy in AVGs and AVFs.

Examination of the slope of increase for angioplasty and for thrombectomies that were performed during this 10 year period (Fig. 5) shows that the increase in total procedures was rather steep; however, that for both AVFs and AVGs was not and that for thrombectomy was actually relatively flat. AVG angioplasties rates have increased slightly during this period, but most of the increase has been due to AVFs. The high primary failure rate for AVF creation has created a need for AVF salvage which has resulted in an increased number of angioplasties.

It is important that interventionalists practicing in the FDAC environment assure that the service provided is cost-effective. Perhaps the best way to do this is to carefully follow accepted practice guidelines that require two indicators for an angioplasty procedure – an anatomical lesion of 50% or greater and documentation that the lesion is hemodynamically significant (2). In the cohort studied, a program of 100% case review has been followed to assure documented indications for angioplasty.

Returning to the question of whether the FDAC is cost-effective, the data presented illustrates that in the cohort reviewed, it is.

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Outpatient Access Centers Churn Patients, Abuse Healthcare Resources, and Offer Questionable Quality. How bad is it out there?

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Purpose: An editorial presentation highlighting corporate management of hemodialysis patients and its influence on current practices in hemodialysis access intervention.

Methods: Review of information obtained from the United States Renal Data Service, and the top two corporate providers of hemodialysis services; DaVita, Inc. and Fresenius Medical Care.

Results: There are approximately 400,000 hemodialysis patients in the United States and 60% of these patients receive their hemodialysis treatment at an outpatient dialysis center owned by DaVita, Inc. or Fresenius Medical Care (1). Lifeline Vascular Access, a subsidiary of DaVita, Inc. operates 72 outpatient access centers throughout the United States. On February 27, 2013 Warren Buffet and the Berkshire Hathaway Fund became the largest shareholder of DaVita, Inc.

In October 2010 Fresenius Medical Care acquired National Vascular Care and its 12 outpatient access centers. One year later (October 2011) Fresenius acquired American Access Care and its 28 outpatient access centers for \$385 million or \$13.75 million per outpatient access center.

Conclusion: The outpatient access center is complementary to the outpatient hemodialysis treatment center (2). Outpatient access centers can provide efficient management of vascular access-related problems. With same-day service the patient has minimal disruption of their hemodialysis schedule.

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In 2011 physicians affiliated with American Access Care, now owned by Fresenius Medical Care, published guidelines for performing interventional procedures in outpatient access centers (3). Efficient management of vascular access problems combined with generous reimbursement rates can transform an outpatient access center into a lucrative medical practice (4, 5). In corporate-owned dialysis centers the patient's care is determined by corporate policies, the competence of the nurses and technicians, decisions made by the medical director, and decisions made by the patient's nephrologist. In such an environment patient care may be adversely affected by business decisions to improve stakeholder earnings.

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Corporate-Managed Outpatient Access Care: Here, Now, and Coming to Your Center Soon?

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Beginning in late 1990s, there has been a continuing development of freestanding dialysis access centers (FDAC). Currently, their number has reached the level of approximately 210 facilities. FDACs treat over 250,000 cases per year, operating as an extension of the doctor's office model (POS 11). Over 50% of these facilities are voluntarily accredited by either the Joint Commission, Accreditation Association for Ambulatory Care or American Association for Accreditation of Ambulatory Surgical Facilities.

Although operating as an extension of the doctor's office, FDACs are typically designed to meet federal and state requirements for ambulatory surgical centers. They are unique in that they are specifically designed, equipped, supplied and staffed for dialysis vascular access management. Additionally, they are generally located in close proximity to patient densities rather than in a centralized medical center. The majority of these are operated by interventional nephrologist.

The typical case-mix for a FDAC involves angioplasty procedures - 38%, thrombectomy procedures - 10%, dialysis access catheter procedures - 19%, vascular mapping - 5%. The remainder is made up of miscellaneous procedures (Fig. 1).

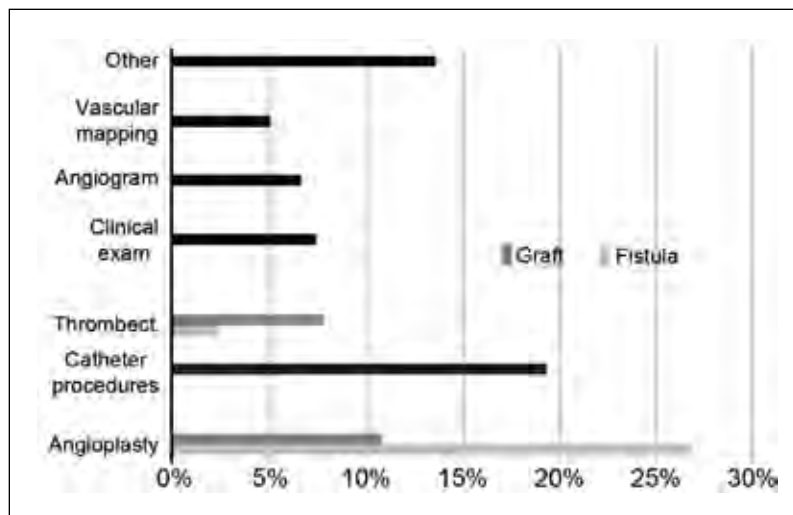


Fig. 1 - Case mix for typical FDAC.

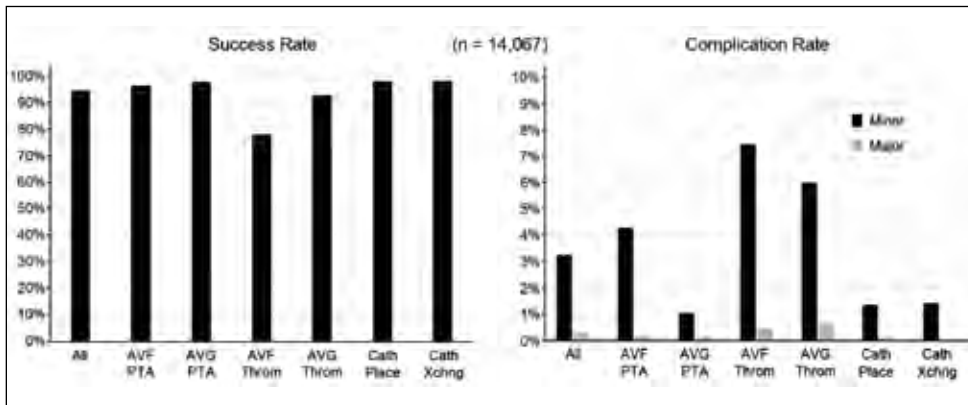


Fig. 2 - Procedure success rate (n = 14,000) and complication rates in FDAC (1).

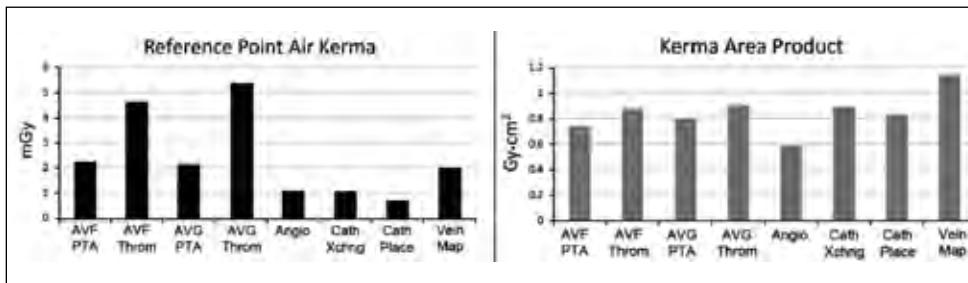


Fig. 3 - Radiation dose metrics for procedures performed in FDAC (3).

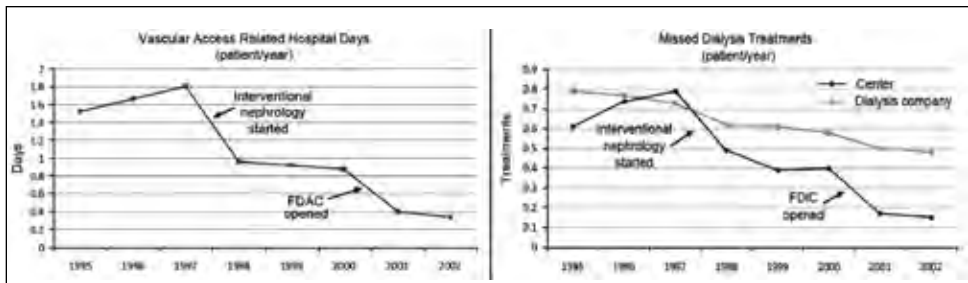


Fig. 4 - Changes in hospital days and missed treatments in dialysis facility related to FDAC (4).

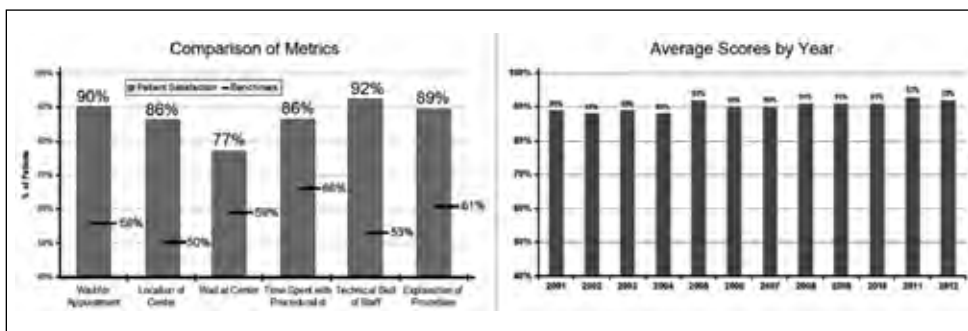


Fig. 5 - Patient satisfaction scores (Ware VSQ survey tool).

It has been shown that dialysis access procedures can be performed in a FDAC with an equal or higher degree of safety and an equal or higher degree of success than those performed in other types of facility (Fig. 2) (1). Additionally, sedation/analgesia can be administered in these facilities with an equally high degree of safety (2). A study examining radiation exposure to patients undergoing procedures in a FDAC showed that they were exposed to a lower radiation dose than has been previously reported in the literature for these types of procedures (Fig. 3) (3). Interventional nephrology as a subspecialty has been demonstrated to result in both a decrease in hospital days per patient for dialysis vascular access and a reduction in missed dialysis treatments. This change was further augmented with the addition of a FDAC to the individual practice (Fig. 4) (4). Two other issues that characterize the FDAC are cost savings to CMS and patient satisfaction. When one compares the cost of a procedure performed at an FDAC with the cost of that same procedure performed at either the

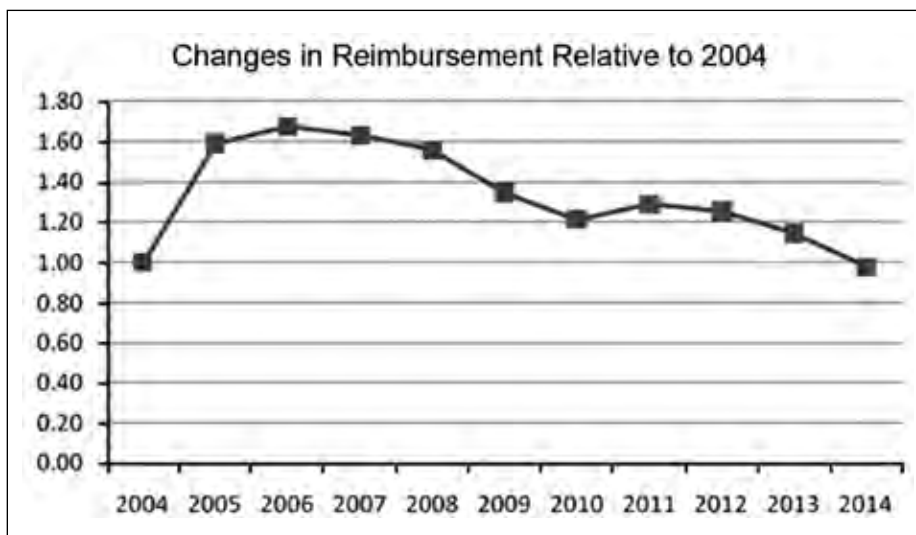


Fig. 6 - Changes in reimbursement rates for procedures performed in FDAC.

hospital outpatient department or within the hospital, the cost savings advantage of the FDAC is significant (5). Patient satisfaction surveys have shown that patients strongly prefer receiving their medical care at this type of facility (Fig. 5).

Unfortunately, CMS reimbursement changes (Fig. 6) are threatening the existence of many of these facilities. These changes have taken the form of code restrictions, code bundling and across-the-board cuts.

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Peripheral Artery Disease Intervention in an Outpatient Access Center – Is this Necessary and Realistic?

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Purpose: Outpatient stand-alone or joint venture access centers have been utilized as a site of service to provide interventions safely and efficiently for approximately ten years. The business model, specific to dialysis access, has been proven by a wide range of physician practice specialties, from interventional nephrology to radiology, surgery, and cardiology. However, there have been consistent changes which lead to the conclusion that diversification of services, to include PAD intervention, are imperative. Reimbursement for services specific to dialysis access has decreased year over year. Image quality has increased. Access to atherectomy, ablation, injectables, angioplasty, and stents has been easier and more affordable. Overall demand for outpatient service has increased. Nationally, there has been a renewed focus on diagnosing and treating PAD in its early stages. And, as more referral sources are becoming familiar with screening for PAD, the referrals to interventionalists have increased. This author will attempt to explore if diversification into PAD intervention is a truly necessary and realistic proposition.

Is It Necessary?

*In 2005, the average reimbursement for a dialysis access intervention, in terms of collected revenue, was close to \$3,500 per procedure. In 2013, that number has decreased by over 35% to less than \$2,200 in collected revenue. And, as an average, dialysis patients will need some sort of access intervention 1.5 times per year. Therefore, an access center that serviced 250 patients in 2005 would have produced \$1.3 million in revenue (1.5 x 250 x \$3,500). In 2013, that same access center would only produce \$787 thousand in revenue (1.5 x 250 x \$2,200). This potential loss of \$1/2 million in revenue does, indeed, necessitate expanding services from a purely financial perspective (*CMS Fee Schedules 2005 through 2013).

In addition to revenue, there is a market need for PAD intervention. PAD affects nearly 12 million Americans, and is largely under-diagnosed. However, as more attention is focused in the medical community on PAD, more patients will be diagnosed. There is a greater need for treatment by experts to curb limb loss (amputations) and other ill effects of PAD (decreased quality of life, non-healing ulcers, ambulation, etc.). It is also estimated that PAD affects 15% of the CKD Stage 5 Population. When combining the captive dialysis referral audience with the potential for additional referrals from the local medical community, there is a compelling case made for expanding PAD interventional services (1).

Is it Realistic?

To use one company as an example: ** Vascular Access Centers performs an average of 20-50 PAD interventions per PAD serviced access center per month. These interventions are all completed by physicians with training specific to arterial disease. The complication rate is less than 1%. This makes a strong case for that performing interventions in the access center is realistic, when a trained provider is available (** Vascular Access Centers, LP internal data).

Conclusion: Expanding access center services to provide PAD intervention is a hot button topic in the industry for a variety of reasons. Reimbursement has decreased for dialysis procedures, reimbursement has trended up for PAD procedures, and market forces are demanding more interventional treatment of symptomatic PAD as disease awareness increases. Properly trained physician providers have demonstrated that PAD interventions can be performed safely in large volumes. Although there are barriers, providing PAD intervention in access centers is necessary and realistic.

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Arteriovenous Access Surgery by Nephrologists in an Outpatient Setting – An Opportunity at Hand?

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Since first described by Brescia and his colleagues (1), the hemodialysis fistula has become the vascular access of choice (2, 3). Any methodology to increase the incidence and prevalence of hemodialysis fistula in the end-stage renal disease population is of value. There is a European tradition of nephrologist placed fistulae. Historically, programs in Italy (4, 5) and Germany (6-8) have been successful. Some AV fistula creation by nephrologists had occurred in the United States in the past (9). In 2004, our practice evaluated the vascular access status of our ESRD population and decided to make a concerted effort to improve the number of fistulas. To affect this, a selected group of nephrologists in the practice would be trained in fistula creation. Initially, a single Interventional nephrologist underwent training by a community vascular surgeon along with mentoring by a colleague from Germany. By July 15, 2013, that individual has performed 2010 AV access surgeries (10). Subsequently, that nephrologist, in conjunction with that same mentor from Germany, trained another operator in 2007 and that individual has now performed 1381 access surgeries through July 15, 2013 (10). A newer colleague had been an orthopedic surgeon in China prior to moving to the US and becoming a nephrologist and hence had some surgical background. He was trained by the existing operators in our practice in 2008 and has now performed 1200 vascular access surgeries (10). The next operator in the practice was totally trained

by the three existing nephrologists in 2010 and has performed 368 AVF surgeries as of July 15, 2013 (10). A fifth nephrologist was trained by the existing operators in 2012 and has performed 148 dialysis access surgeries to date (10). All of this activity has resulted in a greatly expanded vascular access surgical program in our practice. These five nephrologists now routinely perform fistula creation, fistula revision, vein transposition, and superficialization. Three of these Interventional "Surgical nephrologists" also place (where indicated) AV grafts. All procedures are done in any of three outpatient locations using conscious sedation and local anesthesia only. Since 2004, 5115 dialysis access surgeries have been performed. This comprehensive interventional and surgical program staffed entirely by nephrologists has resulted in an increase in the prevalence of AV fistulae in our practice from 34% in 1998 to 44% in 2004 (after 6 years of Interventional Nephrology only) and then (with the addition of nephrologist performed surgeries) to 51% in 2006 and 73% in 2010. Of note, this has also led to a concomitant drop in the incident tunneled catheter rate in new dialysis patients from 60% in 2006 to 40% in 2012 with a 9% drop in prevalent catheters in the ESRD population (10). Outcomes as defined by new vascular access capable of being cannulated for dialysis reveal a 79 to 82% success rate in AV fistulas created by this group of nephrologists, a number quite comparable to results published by other centers. The safety of the program has been demonstrated (11-13). The reproducibility of our approach is demonstrated by another practicing Interventional nephrologist in Virginia, a former fellow in intervention with our center, who received subsequent training by a surgical colleague in 2012 and now has performed 102 dialysis access placements (14). In conclusion, many different training models can lead to a successful AV access surgical program staffed by nephrologists. Creation of fistulae by Nephrologists in the outpatient setting can be a valuable tool to improve the prevalence and incidence of fistulas in an end-stage renal disease program (15). This type of program should be considered in regions where access to qualified vascular access surgery is not sufficient to meet the needs of the patient population.

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The Network AVF/Access Race: Rosling's Bubbles (Gapminder)

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In 2006 Hans Rosling, a professor of global health at Sweden's Karolinska Institute, gave an inspiring talk at TED (TED - Technology, Education and Design - is a non-profit organization) about social and economic developments in the world over the last 50 years. His talk challenged preconceived views and perceptions about the world. Rosling used extensive data analysis to reach his conclusions. To visualize his talk, he and his team at Gapminder developed animated bubble charts. These motion charts allow the analysis of large data sets and permit visualization of multiple variables over time.

Rosling's presentation popularized the idea and use of interactive charts, and as a result, the software behind Gapminder was bought by Google and integrated as motion charts in Google Docs - unfortunately this feature set has recently been discontinued.

Inspired by these talks and the desire to use these interactive data visualization tools to potentially foster a dialogue, I have used the Gapminder approach to examine the Fistula First prevalent patient data for each ESRD network, a kind of Network AVF access RACE! The CiDA audience will be challenged to pick the ESRD network that has accomplished the most over the time period covered by the data: July 2003 to April 2012. Unfortunately with the development and deployment of CrownWeb (or lack thereof) these data are no longer current.

As Hans Rosling's challenged his medical students regarding world wide infant mortality rates, the CiDA audience will be challenged regarding the Network AVF access RACE. Who will win: Network 17 (Larry Spergel) versus Network 14 (Gerald Beathard)?

Selection is Key to Success

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All surgeries are not suitable for all patients. As there is with all aspects of medicine, the appropriate treatment must be selected for the appropriate patient. For example, with kidney transplantation, candidates undergo a rigorous screening process, including interviews with a nephrologist, a transplant surgeon, and social worker to ensure he will have a successful outcome after transplantation. Likewise, the same can be seen for dialysis access surgery. With appropriate patient selection, excellent outcome can be achieved in maintaining various types of dialysis access over time. At our institution, for example, patients who undergo peritoneal dialysis (PD) catheter placement have superior outcome when compared to those who undergo either arteriovenous graft or fistula placement for hemodialysis (HD) access. Of the cases we have performed in the first half of 2012, primary patency rates of PD catheters far exceed either those for grafts or fistulae (95% vs. 78% vs. 75%, respectively).

The key in obtaining such outcomes is selection. Selection is important in all aspects, including patient factors, the nephrologist, the surgeon, and hospital resources. Factors associated with the patient are numerous. The first question to be answered is if the patient is a candidate for PD or HD. If the patient is a candidate for PD, then the next question that needs to be answered is if the catheter is to be placed in either the open or laparoscopic approach. Surgeon experience and hospital resources may determine this. On the other hand, if the patient chooses HD, again, patient factors will dictate the best access. The site of access must be chosen based upon the patient's vasculature and body habitus, and the decision of graft vs. fistula should also be made. In addition, other patient comorbidities should be taken into account, such as potential for the patient developing steal, which may again determine the type of access to be placed. In regards to the nephrologist, a discussion should be done to have a team approach in deciding the best type of access for the patient. As previously alluded to earlier, surgeon factors will also determine the type of access placed. Ideally, the access surgeon should be familiar with all types of access, including both PD and HD, and should be facile at open and laparoscopic approaches to PD catheter placement as well as placement of both grafts and fistulae. Finally, hospital resources may dictate the type of access.

Once these issues are addressed, an appropriate treatment plan can be formulated that can allow for the highest chance for success with the patient.

Lifeline(s) for a Lifetime: Patient Considered Access Planning

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Traditionally, nephrologists have viewed hemodialysis vascular access as the ‘Achilles Heel’ of hemodialysis. While this is true, our views have broadened with the inception of peritoneal dialysis, where peritoneal dialysis is not possible without a reliable peritoneal dialysis catheter. Thus, ‘Dialysis Access’ encompasses the access to the circulation and/or the access to the peritoneum to allow for effective dialysis according to the modality chosen. Three important questions arise when considering Dialysis Access: 1) what is the ‘right’ dialysis modality for the patient; 2) given the modality chosen, what is the ‘right’ dialysis access for the patient; and lastly 3) can one access help strengthen the ‘Achilles Heel’ of another?

To answer these questions, a patient-centric approach must be taken which considers not only the typical history and physical exam, but also the patient’s age, comorbidities, lifestyle, support system, financial situation, residential circumstances, and life goals. Specific kidney related considerations include stage and/or rate of progression of CKD, prior hemodialysis or peritoneal dialysis access creations/insertions and consequences, transplant status and residual renal function. The timing of access placement and/or the utility of new access creation prior to either dialysis start or a current RRT modality failure are controversial. These questions and issues will be addressed in unique case presentations that highlight the need to consider both evidence based medicine along with patient based medicine.

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Tunneled Hemodialysis Catheters: Are They Ever the Best Access?

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Although the tunneled hemodialysis catheter has been vilified by various authorities, the surprising answer may in fact be a resounding “YES”. This question is however complex and requires a multifaceted answer – that is to say, a tunneled hemodialysis catheter (TDC) may be the best access in specific clinical settings.

It is important to understand that the TDC was initially devised to serve as a bridge to other more permanent methods of overcoming renal failure (1). In fact, even in an ideal world, where genetically engineered kidneys would become abundant, one would still need TDC’s while awaiting surgical planning and management. In the current climate of medicine, which is far from ideal, TDC’s may be the sole means of life saving dialysis access (2). This is further exemplified via the data report from the 2011 United States Renal Data System (USRDS) indicating that in 2009, more than 80 percent of patients utilized central venous catheters as their initial conduit to hemodialysis (3). Although TDC’s are thought of as a single entity, a multitude of catheters exist which are vastly different in their composition, luminal structure, tip design and coating. Thus, not all TDC’s are created equal. The various attributes of the catheters aid in addressing the main problems plaguing TDC’s, such as clotting, infection, fibrin sheath and long term vascular damage (4, 5). As innovative technologies emerge to address these issues, the incidence of complications undoubtedly decrease, however exact figures do not exist as there is a clear void in high powered head to head randomized control studies comparing TDC’s with arteriovenous fistulas (AVF) or arteriovenous grafts (AVG) (2, 6, 7). The vast majority of studies are retrospective analyses with glaring inaccuracies and short-falls which are clearly delineated in their respective discussions. Despite the clear lack of randomized control studies, consensus groups such as Fistula First Campaign, The Choices for Healthy Outcomes in Caring for End-stage Renal Disease (CHOICE) Study and The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) have condemned TDC’s as increasing mortality by up to 47% (8-10). We would argue that these assertions are based on suboptimal studies containing the sickest patients. In addition these studies do not incorporate the evolution of the TDC’s.

The current literature fails to account for patients' clinical status, comorbid conditions and the gravity of their underlying illness. It is a reasonable assumption that given the push for increased utilization of AVF's, many patients who are dependent on TDC's are too sick to undergo surgery or more commonly, multiple surgeries. Thus, the increased mortality attributed to TDC's may lay not only in poor studies looking at antiquated technology, but also as result of patient population. So stating that TDC's lead to death is akin to the assumption that nursing homes invariably lead to death, a relationship with may not be causal.

The current 'holy grail' of dialysis access remains the arteriovenous fistula, a concept invented by Dr. Alwall and published in 1947 (11). Is our gold standard in dialysis access unchanged since World War II? It is therefore not surprising that this outdated procedure is plagued by failed maturation, failed patency, patient's surgical fatigue, low/high flow rates, unsuitable anatomy for fistula creation, infection and early thrombosis to name a few (12-14). Fistula maturation failure rates are staggering; with some estimates reaching 66.9 percent when utilizing forearm fistulas, even in the setting of clopidogrel (14).

Hemodialysis access is far from ideal and new ideas and advancements are paramount. In the era of personalized medicine, a one size fits all approach of AVF first and TDC last is obviously extreme and does not optimize individual care and confounding variables. Although TDC's are far from perfect, current perception appears skewed, based on inadequate research and old technologies. In any case, TDC's are here to stay and fill an imperative niche now and in the future.

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When Is Access Flow Too High And What To Do About It?

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Purpose: Cardiovascular diseases account for the half of the end-stage renal disease (ESRD) patients mortality. Mechanisms include arterial hypertension, cardiovascular calcifications, coronary artery disease, cerebrovascular disease, peripheral arterial disease, heart failure and pulmonary hypertension. The latter two are probably also influenced by the dialysis vascular access flow as could be suggested by the rat model of heart failure (aorto-caval shunt).

Methods: Trials testing the influence of vascular access flow on the cardiovascular system were collected and analyzed. They were divided into two groups regarding the studied effect of access flow: 1) heart failure; 2) pulmonary hypertension.

Results: There are 2 forms of heart failure – hyperkinetic and classical-congestive. The former is characterized by the high access flow AND symptoms of heart failure. Otherwise it is typical for left-to-right cardiac septal defects, anemia, beri-beri and also for the very high access flow. The diagnosis regarding access flow is usually easy and various flow-reduction techniques is the causal therapy (1). There is no clear cut-off values of the access flow. The easiest technique – banding – is safe if the flow is at least 1200ml/min.

Classical heart failure is much more common in ESRD patients – according to a US study published in 2001 (2) it is present in approximately one third of newly dialyzed patients. Moreover, such patients have significantly shorter lifespan. Somewhat conflicting data regarding the effect of access flow on the heart (failure) were published. Increase of cardiac output, ejection fraction, sympathetic activity and levels of BNP were observed together with worsened left ventricular diastolic function in some studies (3, 4), but all of them followed-up the patients for less than 3 months after access creation. These changes were observed in accesses with “normal” flow with the mean values around 750 ml/min. On the contrary, another study (5) has observed lower frequency of dialysis-induced cardiac injury in patients with higher access flow.

Pulmonary hypertension is also a relatively frequent consequence of ESRD, partly due to uremic toxins and left-side heart failure. Nevertheless, there is always a functional component, depending on cardiac output, which is also increased by access flow. Symptoms include pleural effusions, ascites, peripheral edema and tiredness. It could be easily estimated by the echocardiography (peak tricuspidal regurgitation gradient). Development of pulmonary hypertension was observed after access creation and some patients are more prone to this complication (6).

Conclusions: In hyperkinetic heart failure and in pulmonary hypertension, the therapy should be driven by the symptoms and not by a particular value of access flow. Unfortunately, significantly less is known about the long-term effects of access flow on the heart. It is advisable to perform a regular echocardiography follow-up (at least once in a year) in patients with higher access flow – above 1500 ml/min. Left ventricular dilatation, decrease of ejection fraction and/or presence of symptoms should lead to consideration of flow-reduction surgery.

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Fistula First: The Message is More Important Today than Ever - AVF Rates Aren't There Yet

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Since 2003, arteriovenous fistula (AVF) use has increased from 32% to 61% in the United States, through the focused efforts of the AV Fistula First Breakthrough Initiative (FFBI). The FFBI had an AVF target of 66% for prevalent hemodialysis (HD) patients, based on the AVF prevalence in Europe and Asia. Additional FFBI outcomes included a reduction in arteriovenous graft (AVG) use from 42% to 21%, and catheters (CVC) in use >90 days from a high of 27% to the current 19%.

While prevalent AVF use has nearly doubled since 2003 in the United States, there is still room for improvement. Additionally, the impact of the FFBI on CKD and incident HD patients has been minimal. Further, although catheter use has declined, long-term catheter use continues to be a serious problem, and the rate is still almost twice the KDOQI benchmark of 10% (1-3). Recent USRDS and DOPPS data indicate that 81% of incident patients initiate chronic HD with a catheter in the United States, with high catheter use (65-70%) at HD initiation even among patients having seen a nephrologist >4 months prior to HD initiation (4-6).

After a decade of work that improved the health of the ESRD population and received international recognition in the ESRD community, the Fistula First Breakthrough Initiative (FFBI) contract ended on 12/31/12. On January 1, 2013 CMS issued a new Statement of Work for the ESRD Networks and the ESRD Network Coordinating Center (NCC), setting new access outcome goals, specifically a prevalent AVF rate of 68% and a catheter rate of < 10% (patients with catheters in use for > 90 days). With support from CMS, the ESRD Network Coordinating Center has launched the FF/CL Workgroup Coalition to continue the work of the Fistula First Breakthrough Initiative to improve AVF rates and access outcomes, with an enhanced focus on catheter reduction.

Building on the foundation of the Change Concepts and success of the FFBI, three FF/CL areas of focus have been identified. They are 1) Access Planning and Co-ordination, 2) Access Monitoring, and 3) Access Infection Reduction/Prevention.

Over-arching objectives within the FF/CL initiative include 1) Fostering patient and family engagement at the facility, 2) Improving AVF rates and reduction of catheter rates for prevalent patients, and 3) Establishing and supporting facility VA reporting and providing VA technical support.

The FF/CL Work Group Coalition is a diverse group of ESRD Stakeholders that will assist with providing guidance to highlight and share best practice and tools, and to identify measureable outcomes--focusing on improving the completeness and accuracy of the data to achieve better outcomes for ESRD patients.

The Initiative not only addresses improvement in the population, but also affords the ESRD Networks the ability to use facility-level data to work with clinics on improvement for individual patients.

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Fistula First: The Message Is Out-of-date - The Issue Is Selection of the Best Access for Each Patient

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Controversy surrounds the best practice pattern of dialysis access procedures. The different dialysis modalities and access types must not be seen as competitive. In fact over the patient's lifetime the different access strategies become complementary, where the outcome strategy is the effective utilization of several Renal Replacement Therapy (RRT) options. This includes renal transplantation. In contrast to this statement individuals, institutions, governments, and specialty societies subliminally and creatively influence the selection of dialysis modality. The most visible and widespread effort in this regard is the CMS (Center for Medicare and Medicaid Services) Fistula First National Vascular Access Improvement Initiative (also known as FFBI) (1). Also, the International Society for Peritoneal Dialysis (ISPD) is stressing the underutilization of the Peritoneal Dialysis (PD) modality. Rather than adopting the doctrine of one modality fits all, selecting the most optimal access for each patient, at all times, is ethically and morally a better model (2).

Native vein vs. Graft or PD. Outcomes of native veins AVFs are generally reported superior to those of grafts, while the PD modality is not considered in such reports. Using the selection principles outlined above, Doing the Right Thing for the patient at all times, becomes the decision making algorithm philosophy. As a consequence, based on objective selection criteria, outcomes are optimized for choice of dialysis modality and for each type and site of dialysis access. This is true for PD (3), with catheter function of 93% at one year, as well as for the grafts (and native vein hemodialysis access, each enjoying one year function of 78% and 75%, respectively) (Fig. 1). These outcomes are preferable to recent reports with grafts (23-27%) or native vein access (40-45%) function at one year, when selection criteria are favored by authoritarian policies or selection bias (5, 6).

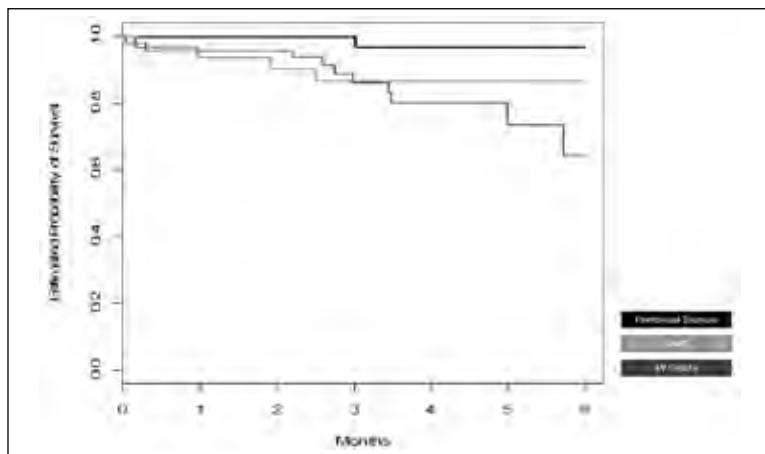


Fig. 1 - When selecting dialysis access modality on patient driven criteria 6 months function is 95% for PD, 78% for grafts and 75% for native vein AVFs.

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Non-Functional, Retained AVG's Correlate with Severity of Inflammation in ESRD Patients

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Purpose: The contribution of multiple retained, nonfunctional arteriovenous grafts (AVG's) to the burden of chronic inflammation in chronic hemodialysis patients has not been well studied. Here we sought to evaluate the association between plasma levels of CRP, interleukin-6 (IL-6), tumor necrosis factor alpha (TNF-alpha) and albumin and the number of retained, nonfunctional AVG's.

Methods: This cross-sectional study enrolled 91 prevalent patients undergoing in-center hemodialysis without evidence of infection or inflammation. A baseline blood sample was obtained at study enrollment. A general linear model was used to compare levels of biomarkers of systemic inflammation across groups defined by the number of retained, nonfunctional AVG's.

Results: 43 patients had one or more retained, thrombosed AVG and had significantly greater plasma log-CRP levels compared to patients without a previous AVG (P=0.036), regardless of current AV access type. Using a general linear model, we found that for every additional retained, thrombosed AVG, plasma log-CRP, log-IL-6 and TNF-alpha concentrations increased significantly by 0.30 mg/L (P=0.011), 0.18 pg/mL (P=0.046) and 0.72 pg/mL (P=0.046), respectively, following adjustment (Fig. 1).

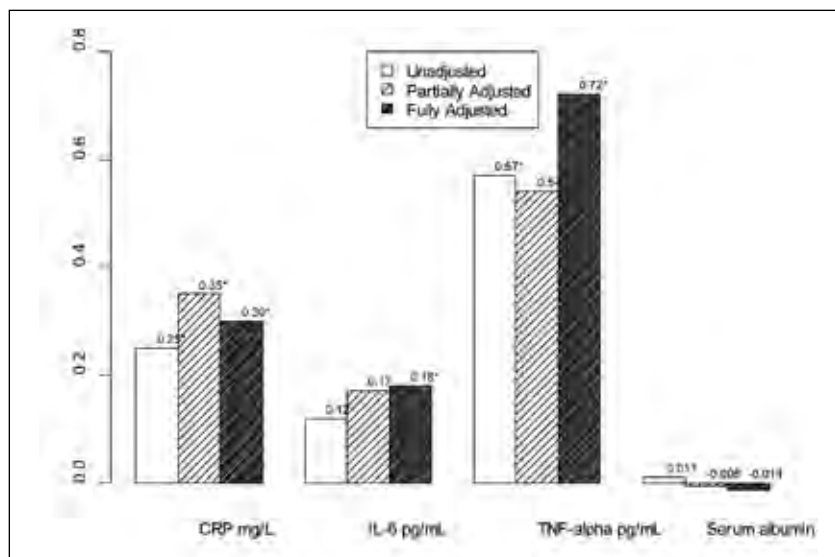


Fig. 1 - Change in inflammatory biomarker level for each additional retained, thrombosed AVG, treated as a continuous variable, where CRP and IL-6 are log-transformed. Partially Adjusted: adjusted for age, length of time on dialysis, and type of AV access (AVF vs. Other). Fully Adjusted: adjusted for age, sex, body mass index, smoking status, diabetes, length of time on dialysis, and type of AV access (AVF vs. Other). *P-value < 0.05.

Conclusions: Hence, the severity of inflammation increases with the number of retained, nonfunctional AVG's, suggesting that AVG accumulation may contribute to the cardiovascular morbidity and mortality associated with chronic inflammation in asymptomatic ESRD patients. Further study is indicated to determine whether patients with one or more thrombosed, retained AVG may benefit from periodic screening with CRP monitoring to identify those patients who may benefit from AVG resection.

Excision, Plication or Abandonment of the Aneurysmal AVF: What's the Best Strategy?

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Aneurysmal dilation of the outflow vein is a long term complication seen in a subgroup of patients with a functioning arteriovenous fistula (AVF) (1). While cause for such dilation is not clearly understood, it is usually seen after repeated punctures (area cannulation) and a slow stretching of the needle puncture scar over a period of time. This tends to occur in a fistula that has increase in the intra-access pressure. Such increase in intra-access pressure (pulsatility) is a result of high flow through a relatively narrow outflow vein or due to the development of stenosis in the outflow vein (2). Venous aneurysms can develop secondary complications. Development of chronic thrombi results in difficulty to access the AVF. They may also harbor low grade infection, presenting as cellulitis. Skin overlying aneurysms may thin out; may develop needle access site ulceration and bleeding. Because these aneurysms are in reality true dilation of the outflow vein, they are amenable for direct surgical intervention and reconstruction (3, 4). This article presents our experience on surgical management of symptomatic AVF outflow vein aneurysms with long term followup information which makes a strong case to adopt surgical approaches to manage this problem.

Method: Our practice is to expend resources to salvage fistulae with aneurysmal complications when possible. We reviewed data on procedures performed on AVF aneurysms between January 1st 2000 and December 31st 2012 in our prospectively maintained database.

Results: 80 consecutive, aneurysm related, surgical procedures performed in 69 patients were reviewed. 11 patients needed 2 procedures (3 staged procedures to avoid catheter dialysis, 6 on aneurysms at separate location, 2 (2.5%) for recurrent aneurysm). Fistula ligation was performed in 9 AVF which were abandoned previously. 69 (97%) of remaining 71 active fistulae were reconstructed and 2 (3%) needed ligation. Mean age of patients was 50.3 (\pm 14.9). 39 patients were male (56.5%). Location of aneurysm was 27 forearm, 41 upper arm and 1 thigh. Of 69 aneurysm reconstructions 8 were in fistulae that were not in active use (8 post transplant working access, 1 predialysis). Urgent presentations included threatened rupture (33), ulceration or infection in chronic thrombus (27) and active bleeding (5). 15 were reconstructed for size and difficulty in needle access. 41 (68%) reconstructions were planned and executed without need for resting the fistula using tunnel dialysis catheters (TDC). 14 patients received TDC and 5 had PD catheters used during AVF repair. Tubular reconstruction (38) and aneurysm excision with end to end anastomosis (25) were the commonest repair procedures. Majority received a skin flap reconstruction of the skin defect. Kaplan-Meier analysis showed primary patency of 64%, 46%, 43%, secondary of 89%, 80%, 76% and a cumulative patency of 95%, 92%, 92% at 1, 3, 5 years.

Summary: Surgical correction of AVF aneurysms provides excellent short and long term results. With proper planning the majority of surgical reconstructions of aneurysms can be performed without a need to rest the aneurysm and necessitate catheter dialysis. Ligation of the AVF with excision of aneurysm is rarely needed to manage this complication in a functioning AVF.

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AV Access Surveillance: Gotta Do It, But Does it Ever Matter?

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Vascular access related morbidity and mortality remains a significant problem for patients on hemodialysis. Recently, Lacson and coworkers tracked mortality in a large cohort of 79,545 patients. As many other studies have shown, central venous catheters had the highest associated mortality risk. The risk of mortality for a graft was similar to a fistula. Importantly, changing from a catheter to either a fistula or a graft significantly improved patient survival. Moreover, in patients with a failed fistula or graft, converting to a catheter increased the risk of mortality two-fold. The authors conclude that fistulas are associated with the best survival with grafts having a mortality risk similar to fistulas. Catheters have the worse survival and should be avoided if possible. Minimizing time at risk using a catheter improves survival (1).

Given the above observations, the ability to identify a fistula or graft at risk for failure, and electively repair the cause of impending failure before it occurs, would be a significant improvement over the common practice of placing a central venous catheter when the access fails. Indeed, this has been the goal of vascular access monitoring and surveillance. Monitoring and surveillance are frequently used interchangeably, however, they have distinctly different meanings related to vascular access. Monitoring is "the examination and evaluation of the vascular access by means of physical examination to detect physical signs that suggest the presence of dysfunction". Surveillance is "the periodic evaluation of the vascular access by using tests that may involve special instrumentation and for which an abnormal test result suggests the presence of dysfunction" (2). Numerous techniques have been used to detect vascular access dysfunction. Physical examination of the vascular access has been shown to work well in detecting dysfunction (3). Unfortunately, the physical examination of the vascular access is rarely done in a systematic manner. Blood flow surveillance is the most frequently used method. Although multiple observational studies have shown a benefit from blood flow surveillance, these studies generally had no control population, used historical controls or used incorrect statistical analysis. Three randomized controlled trials failed to demonstrate a benefit of surveillance (3-5). On the other hand, surveillance of arteriovenous fistulae may be of benefit (6, 7). The results of the randomized controlled trials showing no benefit of surveillance prompted the KDOQI Vascular Access Working Group to change the wording of describing the benefit of prospective surveillance to "may improve patency rates and may decrease the incidence of thrombosis" (2).

The Centers for Medicare and Medicaid Services recently "muddied the water" over the monitoring and surveillance issue when the updated Conditions of Coverage appeared to mandate surveillance of vascular access (8). This apparent mandate has provoked controversy in the nephrology community (9).

Although preemptive angioplasty outcomes are better than angioplasty post- thrombectomy, the results remain dismal with six-month intervention-free patency between only 50-60%. Angiographic results fail to predict outcomes and intra- access pressure to systemic systolic pressure ratios add little to identifying optimal angioplasty outcomes. In the study by Van der Linden et al multiple angioplasty procedures were required in a substantial number of grafts, and the time interval to repeat angioplasty was less with each subsequent intervention, suggesting that the treatment itself, namely angioplasty, accelerated the decline in blood flow (10). This initial stenosis and the restenosis after angioplasty results from neointimal hyperplasia. In a recent randomized control trial comparing stent graft (treatment group) versus balloon angioplasty alone (control group) in failing grafts, Haskal and colleagues "hypothesized that revision of the venous anastomotic stenosis with a stent graft constructed with the same material as the graft would prevent elastic recoil and tissue in growth, thereby improving long-term patency as compared with that afforded by standard balloon angioplasty" (11). Restenosis was more frequent in the angioplasty group compared to the stent graft group. This study has been criticized because the graft thrombosis rate in the two groups was not different and cumulative graft survival was not reported (12). The cost to benefit of placing a stent graft for the modest improvement in patency has also been raised based on the estimated cost per patient benefited was in excess of \$38,000 (13).

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Detecting AV Access Dysfunction: Man vs. Machine

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Machines of various types have been pitted against man since their very inception. While John Henry beat the steam engine, doing so killed him, and in more recent battles machines have won handily, witness Deep Blue over Kasparov or Watson over Ken Jennings.

In the area of AV access dysfunction, it appeared for many years that flow measurement ("machine") was destined to replace other screening tools, including the physical examination ("man"), until a series of randomized trials in the past decade called that logic into question. While the pendulum has swung back toward man, it may be that both man and machine have value when it comes to detecting impending access failure.

It is not the purpose of this presentation to debate the value of screening. I will take the position, one in which I firmly believe, that screening and appropriately applied treatment of impending access failure offer substantial benefits to patients with ESRD. Even if this practice does not prolong access life (it may or may not), there is evidence showing that it reduces the thrombosis rate (it very likely does), and thus with it reduces catheter use, missed dialysis, hospitalization, all of which benefit our patients as well as the health care system. Given that position, the question at hand is whether flow measurement is superior to the physical examination, or vice versa. Whether graft or fistula, physical examination of access is a skill that is easily learned and taught to others. In one study of grafts, in which the observers were an interventionalist, a nephrologist, and two nephrology nurses, the interobserver agreement was very good (1). All three of the non-interventionalists had no prior experience or training with graft PE and had been taught how to examine grafts immediately before the study.

In another study, after brief training, nephrology fellows performed as well as an experienced interventionalist in examining access (2). In addition to being easily taught, the fact that there is no cost is a major advantage compared with machine based alternatives.

There are several excellent publications describing PE of access (3-5) as well as on-line resources through the Fistula First website (www.fistulafirst.org). PE has been validated versus fistulography (6-8) and ultrasound (9); it has been shown to predict access failure (10) and has been shown to be the best predictor of outcome after PTA in grafts (11). The utility of PE in access management is unquestioned.

But how does it compare to machines? In terms of screening for access dysfunction, the physical examination has been compared to flow measurement independently as well as in combination with a variety of clinical parameters (12-14) in both randomized and non-randomized studies. In most of these comparisons, the clinical

parameters, including PE, have fared as well as flow measurement.

However, as beautifully demonstrated by Tessitore et al, even the physical examination has its limitations, particularly in detecting inflow stenosis in fistulae (12). Consequently, in access types in which there is a high prevalence of stenosis, such as forearm AVF, flow measurement was superior to PE; whereas in the upper arm, where outflow stenosis dominates, PE was superior to flow. Further, PE interobserver variation was much higher with inflow stenosis. This group concluded that a combination of man and machine was the best means to detect access dysfunction. In the interventional suite, while PE has been compared to pressure for grafts (11), no such direct comparison has been made for (intra-access catheter based) flow measurement, thus it remains possible that the latter is a better predictor than PE. This question awaits further study. Further, at least in certain clinical scenarios, direct flow measurement can serve as a problem solving tool where PE fails (15).

Thus, in contrast to chess and trivia game shows, the man vs machine battle is far from over in access management. Physical examination is inexpensive, easily disseminated and highly accurate. It is also not infallible, and in those situations where the PE is contradictory, unreliable or inconclusive, there is a very important role for flow measurement.

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The Hidden Cost of Access Complications: Facility Perspective

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Purpose: Thrombosis of vascular access is a significant fraction of the cost of ESRD care. In addition to the cost of the thrombectomy, there is frequently a cascading set of add-on expenses including (1) catheter insertion

in some cases; (2) loss of the access sets up the need for a new access evaluation and creation. The cost of access complications from the perspective of the dialysis facility is underappreciated. If these costs were better understood, dialysis facilities might see the financial benefit to improving vascular access care.

Methods: We obtained records from Vasc-Alert (Vasc-Alert LLC, 3000 Kent Ave, West Lafayette, IN 47906, USA), which provides vascular access surveillance services to dialysis facilities. At these same facilities we obtained intervention records. To examine the cost of access complications, Vasc-Alert developed an analysis ‘engine’ that examined these data sources in order to determine missed treatments and the use of catheters in AV access capable patients. (Under the bundle, catheter usage costs an extra \$30 / treatment in drugs, components and time.)

Historical records covering both session treatment data and intervention records were obtained from 28 dialysis centers for either 6 or 10 months periods. A number of rules governed eligibility resulting in 1,677 patients. AV access patients were divided into categories, 1) no access issues, 2) angioplasty only, 3) thrombectomy only, and 4) AV capable patients who also used a catheter.

To determine missed treatments, anything less than 3 sessions per week was counted as missed. Since every dialysis patient misses treatments, a baseline of 5.3 missed treatments per year was established by taking the weighted average of missed treatments for patients without complications and those undergoing only angioplasty. Catheter sessions for AV capable patients were counted from the treatment records.

Results: Of the 1,677 patients, 313 (18.7%) were considered as having an access complication, i.e. either a thrombosis (57) or use of a catheter (256). The number of missed treatments in excess of this baseline was determined and extrapolated to a full year:

	Avg. Missed Treatments	Less Baseline	Difference	No. of Patients in Category	Missed Treatments per Year
AV access with thrombectomy	7.11	5.32	1.79	57	102.04
Treatments both on AV access and catheters	8.77	5.32	3.45	256	882.8
Excessive missed treatments per year due to access complications					984.9

Counting catheter usage for patients who were AV access capable and extrapolating for a full year yielded 15,050 treatments or an average of 58.8 treatments per year for patients in this category.

Multiplying these results by their costs, i.e. missed treatments at \$220 (blended rate less consumables not used) and catheter costs at \$30, totaled \$668,171 or an average of \$398 per AV access patient in the study.

Conclusions: The costs of access complications to the dialysis facilities are considerable and should provide a financial justification to improve vascular access care.

Debate: How to Follow an AVG after Declothing. Monitoring and Surveillance at the Dialysis Unit is the Standard of Care - Not Clinic Visits and Duplex

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In this debate, the question “How to follow an AVG after Declothing” compares current standard of care monitoring and surveillance to frequent interval studies which includes fistulography during multiple post-thrombectomy scheduled visits. This debate raises several issues, the most important being which approach results in the best patient outcome?

Indeed, a recent issue of Endovascular Today addressed this precise issue whereby the question was posited to three renown interventional radiologists. Their responses reflected both extremes of this debate: one supporting

ongoing surveillance and pointing out that “a patient should not be brought back routinely for fistulography - it is considered screening, and to bill for that is against the law.” On the other side of the debate, one of the responding interventional radiologists stated “Usually we do 3-month follow-up surveillance. If it’s a simple declot and you’re pretty confident there are no big problems, treat it like a simple PTA, and bring the patient back in 3-4 months” (1).

Several issues arise from the frequent follow-up approach: Who is the referring physician? The original physician who sent the patient for the thrombectomy? If it is the interventional radiologist who did the thrombectomy, is the original referring nephrologist aware of the scheduled follow-up? If the interventional radiologist is not part of the nephrology practice, does the follow-up visit constitute self-referral? What is the medical indication for the follow-up visit? What is the three-month interval follow-up based upon? Published data suggest that subsequent graft thrombosis occurs in over 50% of thrombosed grafts within 90 days (2). Thus, follow-up interval studies at 3 months would miss half of the recurrent graft failures. Interestingly, this 3 month follow-up interval does correspond to the 3 month global period for the thrombectomy CPT code. Perhaps this interval was selected for another reason!

Are there data available which support each approach? Unfortunately, there are no data that directly address this issue. Most data support the finding that monitoring and/or surveillance can identify grafts with stenosis. However, these tools fail to predict which grafts will develop thrombosis. Clinical monitoring appears to provide equivalent benefit to surveillance programs. However, surveillance coupled with preemptive angioplasty fails to provide prolonged graft survival (3). The frequent interval studies approach after a thrombectomy advocated in this debate will most likely only improve the bottom line but not the patient outcome.

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Clinically Timed Evaluations Reduce Thrombosis Rates

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Purpose: To improve upon existing monitoring and surveillance techniques by introducing the Clinically Timed Evaluation.

Background: The basic tenet for vascular access monitoring and surveillance is to treat underlying stenoses in order to avoid under-dialysis as well as access thrombosis (1, 2). According to the NKF-KDOQI guidelines monitoring is defined as “the examination and evaluation of the vascular access by means of physical examination to detect physical signs that suggest the presence of dysfunction.” Surveillance is defined as “the periodic evaluation of the vascular access by using tests that may involve special instrumentation and for which an abnormal test result suggests the presence of dysfunction” (3). Great debate exists in the literature regarding the ability to perform adequate monitoring, the value of surveillance testing and interpretation, and their utility in prolonging the useful life of an access (4). This controversy has led to the development of the Clinically Timed Evaluation (CTE). CTE is the evaluation of a patient by an access specialist at regularly timed intervals. The goal of a CTE is to detect and treat access problems before they lead to inefficient dialysis, or possibly thrombosis and access loss. The clinically timed evaluation does not pre-ordain the patient to a procedure but allows for both a thorough history and physical exam with immediate access to treatment, in order to maintain an optimally functioning vascular access. The first efficiency is derived from patient and lesion specific individualization of care. The second efficiency is the distinct advantage of providing immediate access to intervention when combined with clinical data and a physical exam.

Methods: Retrospective analysis of data from 28 outpatient centers specializing in hemodialysis access

management. Unique patient identifiers and billing data were analyzed and compared to determine interventions per access year and thrombosis events from years 2011 and 2012. Separate data from the event database was analyzed from 2009 to present specifically tracking emergent hospital transfers and adverse events.

Results: Across 97449 procedures performed in 2011 and 2012, 9719 were thrombectomies. We found an inverse relationship between frequency of repeat interventions and access thrombosis. Centers which engaged in higher interventions per patient year (ppy) had a reduced thrombosis rate. The disparity between the centers performing the most procedures ppy and the least procedures ppy resulted in a decreased thrombectomy rate of 5%. This translates to 486 preventable access thrombosis procedures.

The impact of this 5% difference is not immediately apparent without analyzing the risk of hospitalization between patients undergoing elective intervention versus urgent thrombectomy procedures. We queried our database on critical events and hospital transfers. Since 2009 we performed 198,980 procedures including 12,824 thrombectomies. During that time 0.00072 of all patients undergoing a procedure had a critical event necessitating hospital transfer. In contrast, 0.0075 of thrombectomies had a critical event, requiring hospital transfer, representing a 10 fold increased risk.

Conclusions: A decade ago it was unclear as to whether monitoring and surveillance was appropriate and cost effective. While today the nephrology community still grapples with the best technique, it is very clear the next large scale prospective study will need to take into account the cost of proactive interventions and their ability to prolong access life thereby reducing overall cost to the system (2, 4, 5). As noted above, access thrombosis should be avoided as it carries a 10 fold risk of procedural complications over pre-emptive interventions. Since improving patency and avoiding thrombosis is ultimately the goal, the CTE offers the highest level of care by individualizing treatment regimens. The most cost effective care targets interventions, at the precise time.

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Post-Market Study of a Stent-Graft in AVG's: What We Learned from the RENOVA Trial

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Purpose: A prior randomized trial demonstrated 6-month primary patency superiority of an ePTFE stent graft (Flair®, Bard Peripheral Vascular) over PTA alone for primary treatment of venous anastomotic stenosis in hemodialysis access grafts ($p < 0.001$) (1). This report presents the 12-month results of the 2-year RENOVA study, conducted to compare long term use of the Flair® stent-graft compared to PTA alone.

Materials and Methods: 28 U.S. study sites enrolled 270 patients in this registered trial. Inclusion required patent but failing upper extremity arteriovenous grafts with $\geq 50\%$ venous anastomotic stenoses associated with hemodynamic, functional, or clinical abnormalities. 138 patients were randomized to stent grafts vs. 132 to the PTA group. Patency, graft function, and subsequent access interventions were recorded. Primary outcome measures (intent-to-treat basis) included Access Circuit Primary Patency (ACPP), Index of Patency Function (IPF) defined as the average number of months between interventions, and adverse events (AEs).

Results: There were no significant differences in demographics or baseline criteria between the groups. The mean deployed stent-graft length was 45 mm (SD 4.9 mm). 12-month ACPP for the stent graft group was significantly better than the PTA group, 24.1% vs. 10.3% ($p = 0.005$), respectively. 12-month IPF for the stent-graft group was

significantly better than for the PTA group, 5.3 ± 4.1 months/intervention vs. 4.4 ± 3.5 months/intervention ($p=0.008$), respectively. There were no significant differences in AEs between groups (96.2% PTA and 92.8% stent graft group experienced at least 1 AE), with the exception of "stenosis requiring intervention" which occurred significantly more frequently in the PTA group, 82.6%, ($n=109/132$) vs. stent graft group, 60.1% ($n=83/138$), $p<0.001$.

Conclusion: Mid-term 12-month results of the RENOVA trial demonstrated both statistically significantly better ACP (2x superiority) in the Flair® stent-graft group compared to PTA alone, and IPF, resulting in fewer follow up interventions per unit time per patient.

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REVISE Update - Stent Grafts Improve Patency at Venous Anastomosis

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Purpose: To review recent information regarding use of the Viabahn stent graft for treatment of stenoses at the venous anastomosis of PTFE hemodialysis grafts. And to compare the effectiveness of angioplasty versus stent grafting for treatment of these common lesions.

Methods: Review of recently published, peer-reviewed studies reporting results of treatment of stenosis at the venous anastomosis of PTFE hemodialysis grafts.

Results: A review of the subject reveals continuing controversy regarding the cost-effectiveness of using stent grafts, instead of angioplasty only, to treat venous anastomotic stenoses (1).

A recently published, prospective, randomized trial compared angioplasty to primary stent grafting for treatment of significant stenoses (>50%) at the venous anastomosis of 190 patients with PTFE hemodialysis grafts (2). The access circuit 6-month primary patency rate was 20% for angioplasty and 38% for stent grafts. The target lesion 6-month patency rate, at the venous anastomosis, was 28% for angioplasty and 78% for stent grafts.

A recently published, retrospective study reported results following use of stent grafts ($n = 29$) or bare metal stents ($n = 32$) for treatment of venous anastomotic stenoses (3). The access circuit primary patency rates at 3, 6, and 12 months were 59%, 52%, and 29%, for stent grafts and 50%, 41%, and 22% for bare metal stents. The secondary patency rates were 76%, 69%, and 61% for stent grafts and 78%, 78%, and 68% for bare metal stents. The target lesion primary patency rates at 3, 6, and 12 months were 100%, 85%, and 70% for stent grafts and 75%, 67%, and 49% for bare metal stents.

Another recently published, retrospective study reported results following use of stent grafts to treat a variety of access problems in 58 patients with PTFE grafts and 43 patients with fistulas (4). The access circuit 6-month primary patency rate was 62% for fistulas and 35% for PTFE grafts. Larger diameter stent grafts (9mm-10mm) had better patency (91% vs. 73%) when compared to smaller diameter (6mm-8mm) stent grafts.

Conclusion: The access circuit primary patency following percutaneous treatment of a venous anastomotic stenosis is generally abysmal. This review of recently published studies revealed significant variability in the 6-month primary patency rates for both angioplasty and stent grafts. The majority of studies report superior patency following use of a stent graft but the cost-effectiveness, compared to angioplasty, remains a topic of debate.

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Rescue the Access! FLUENCY® PLUS Endovascular Stent Graft for In-stent Restenosis (RESCUE) Trial Update

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Background: In-stent restenosis remains an important clinical problem in the care of vascular access for hemodialysis patients (1). Stent grafts may reduce migration of adventitial macrophages and smooth muscle cells to the intima-media level. Animal studies have demonstrated significantly less neointimal formation in stent grafts as compared to bare metal stents. The barrier protection afforded by the PTFE covering appears to be more effective where the stenotic lesion is shielded from mediators that lead to an accelerated proliferative response (2).

The FLUENCY® PLUS Endovascular Stent Graft for In-stent Restenosis (RESCUE) trial is:

- Prospective, multi-center, and randomized
- Enrolling ~200 patients at 25 sites in the United States

Objectives:

- To demonstrate that the FLUENCY® PLUS Endovascular Stent Graft can effectively and safely treat in-stent restenosis in the venous outflow of arteriovenous (AV) grafts and AV fistulas
- Investigational Device Exemption (IDE) study comparing 6-month access circuit primary patency of patients treated with either the FLUENCY® PLUS Endovascular Stent Graft (following percutaneous transluminal balloon angioplasty -PTA) or PTA alone for the treatment of in-stent restenosis in previously placed bare metal stents
- To follow subjects through 24 months

Results:

- Access Circuit Primary Patency through 6 months
- Post-intervention Lesion Patency (Secondary Patency, Index of Patency Function)
- Safety through 30 days

Discussion:

Is the FLUENCY® PLUS Endovascular Stent Graft the same, better or worse than PTA alone in the treatment of in-stent restenosis in the venous outflow of AV grafts and/or AV fistulas?

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AV Fistula Cannulation Device, Clinical Trial Update for the Venous Window Needle Guide

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Purpose: Arteriovenous fistulas (AVF) remain the gold standard for hemodialysis vascular access. When compared with catheter or graft dialysis, AVFs have lower morbidity and mortality rates in addition to lower costs, fewer interventions, and longer access survival (1, 2). A mature, well functioning fistula that is not able to be reliably cannulated leads to prolonged catheter dependency and frustration for the patient and the renal healthcare provider team. The increasing number of obese patients with end stage renal disease has challenged vascular access surgeons in establishing a functional autogenous vascular access. In such individuals the AVF outflow vein matures into an otherwise successful fistula but is often too deep for reliable cannulation. Other difficult cannulation patients may have vein segments that are too short, tortuous, or otherwise difficult to palpate. Establishing a mature and functional AVF in these patients is more complex and will require additional operations. The Venous Window Needle Guide (VWNG) for salvage of AVF (SAVE) trial was designed to evaluate the efficacy and safety of the VWNG device for salvage of such non-cannulatable AVFs that are otherwise functional.

Methods: The SAVE study involves patients with an established and otherwise mature AVF, where an additional procedure such as AVF superficialization (3), a lipectomy (4) procedure, or other surgical revision (5) would otherwise be necessary to establish reliable cannulation. The VWNG is comprised of a single piece of titanium allowing repeated access of an AVF through a single puncture site (buttonhole cannulation technique) for maintenance hemodialysis. Inclusion criteria included mature AVFs 6.0 to 15.0 mm in depth with multiple failed attempts at cannulation or where the access could not be palpated. Qualifications were independently reviewed prior to entering a patient in the study. The devices were implanted subcutaneously and sutured to the anterior wall of the mature fistula. Study patients were followed for six months with both physical examination and US evaluations. The study end-point was reliable and successful cannulation while avoiding adverse events. Secondary study objectives included technical success, initial clinical success, and buttonhole clinical success. Patients with recent myocardial infarction or stroke were among those excluded.

Results: Enrollment included 54 subjects at 11 locations with implantation of 82 VWNG devices. BMI was 26-50kg/m² (median=36). 40 (74%) patients were female and age was 17-84 years (median=59). Diabetes was the cause of renal failure in 40 (74%) individuals. 33 (61%) patients were White, 16 (30%) Black, and 10 (18%) patients were Hispanic, Pacific Islander or Native American. Three patients were excluded from the study for reasons unrelated to the device. Successful AVF access was achieved through the VWNG in 49 (96%) of the 51 patients evaluated. The rate of device related serious adverse events was 0.31 per patient year, each of which was resolved leaving the fistula intact and functional. The rates of sepsis and study related interventions were relatively low: 0.04 and 0.65 per patient year, respectively. There were no study related deaths. One device was removed due to infection. The AVF survival rate at 6 months was 100%. The total number of study days was 9,497 and the estimated number of device cannulations was 4,238. There were no unanticipated adverse events, interventions, or cannulation complications observed in the study.

Conclusion: The VWNG was safe and effective in facilitating AVF cannulation for patients with an otherwise mature but non-cannulatable fistula. Successful AVF access was achieved through the VWNG in 49 (96%) of the 51 patients evaluated. The AVF survival rate at 6 months was 100%.

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Recombinant Human Elastase to Promote AVF Maturation and Patency

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Background: PRT201 is a locally acting type I pancreatic elastase that in the appropriate dose and setting can enlarge blood vessels, increase blood flow, or inhibit neointimal hyperplasia. Pharmacology studies in models of Arteriovenous fistulas (AVF) suggested that PRT201 might increase inflow artery and outflow vein diameter, blood flow, and decrease neointimal hyperplasia formation.

Methods: Randomized, double-blind, placebo-controlled trial. Adults with chronic kidney disease undergoing creation of a radiocephalic or brachiocephalic fistula were treated with PRT-201 10 µg (n=51), PRT-201 30 µg (n=49), or placebo (n=51). The primary efficacy measure was primary unassisted patency over 1 year. Secondary efficacy measures were secondary patency, unassisted maturation, use for hemodialysis, and hemodynamically significant lumen stenosis.

Results: In this phase 2 study, patients treated with PRT201 at doses of 10 and 30 µg experienced prolonged AVF primary unassisted patency (time from access creation to a first patency loss event), fewer procedures to restore or maintain patency, prolonged secondary patency (time from access creation to complete abandonment of AVF and need for new vascular access placement), and increased proportion with unassisted maturation (by ultrasound measurement) compared with placebo treated patients. The greatest benefits were seen in the subset of patients who had radiocephalic AVFs. In general, PRT201 at a dose of 30 µg appeared superior to 10 µg. No dose-related increases in adverse events were observed.

Conclusion: PRT-201 is a novel treatment that may improve the function of AVFs. These results will need to be confirmed in large, well-controlled, phase 3 studies which are planned to commence in 2014.

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Percutaneous AVF Creation: A New Endovascular Procedure

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Almost 50 years since Brescia and Cimino introduced the autogenous fistula (1), many new types of autogenous fistulas, prosthetic dialysis accesses, different materials and modifications of current concepts have been introduced. Despite these advances, the requirement for surgical placement remains constant and is associated with significant wait times, costs, resource utilization, complications and the actual surgical creation has been associated with later formation of venous intimal hyperplasia (2).

Given the many limitations, an entirely percutaneous creation of an autogenous hemodialysis fistula may address many of the aforementioned limitations in addition to known improved patency and lower infection rates compared to prosthetic accesses (3). Issues that will require addressing initial technical success of creation, maturity rates, time to maturation and durability.

There are prior reports of attempts at creating percutaneous hemodialysis accesses with no device yet introduced for human use. Companies currently developing percutaneous access creation technologies include Phraxix and Caymus Medical. Caymus is working on an autologous AV fistula creation device called the Vessel Select Vascular Access System, while Phraxix is developing a subcutaneous AV graft technology.

We are investigating the use of radiofrequency energy to percutaneously create an arteriovenous, sutureless, anastomosis in humans. The TVA Medical Flex system requires percutaneous delivery of an arterial and a venous catheter. The devices contain rare earth magnets that pull the vessels together and align the devices for delivery of the radiofrequency energy. The first in man study has been performed with a subsequent pilot human clinical study. We have now performed the procedure in 24 patients with a 96% technical success rate (23/24). Twenty patients initiated dialysis or were judged to be ready for dialysis at an average of 76 days post procedure. Follow-up extending to six months in the first 15 patients demonstrated 12 patients dialyzing via their percutaneously created fistula with one patient fistula deemed dialysis ready but not yet requiring dialysis. There were four procedure related adverse events, all rectified without further adverse sequelae. Since no surgical anastomosis is created and no prosthetic material is placed, the potential advantages are many including reduced wait times, costs, improved patency and lower infection rates.

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Covered Stents in the Management of Central Venous Stenosis

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Purpose: To analyze and interpret the effectiveness and long-term results of covered stents in the treatment of Central Venous Stenosis.

Background: Central venous stenosis is a frequent complication of prolonged central venous catheterization and complicated efforts to provide dialysis access. This complication causes manifestations of venous hypertension and limits hemodialysis access options.

Management may include: abandonment of current access site and moving to an uninvolved extremity until all options have been exhausted, repeated central vein venoplasty with or without stenting, switching from hemodialysis to continuous ambulatory peritoneal dialysis (CAPD), or utilizing the HeRO graft catheter. Our strategy includes aggressive recanalization of occlusions in conjunction with repeated venoplasty and stenting of the central veins to maintain effective and acceptable dialysis.

Significant experience in restoring central venous patency and long-term management is reviewed.

Methods: A retrospective review of 152 patients with central venous stenosis (subclavian, innominate, SVC, or some combination) managed with Polytetrafluoroethylene covered stents (PTFE-CS) was conducted, with follow-up to eight years in the earliest cases. Other patients without at least one year follow-up were excluded. All interventions were done by the first two authors.

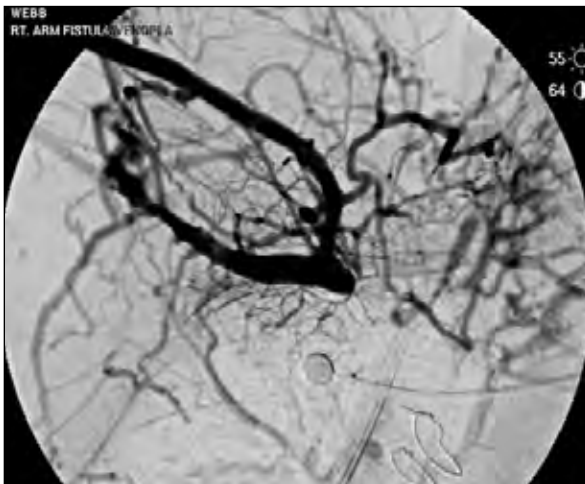


Fig. 1 - Occluded subclavian.



Fig. 2 - Same after stent.

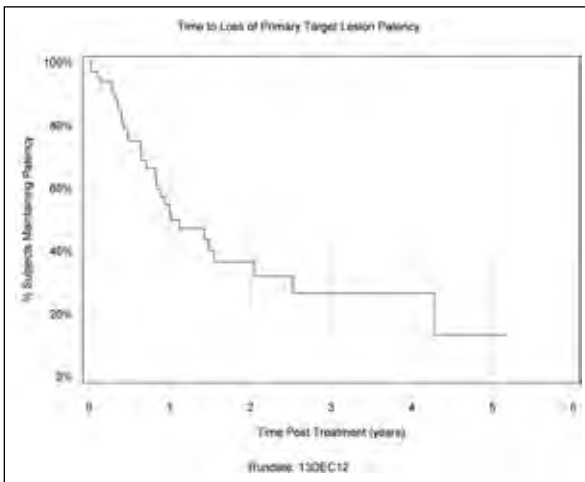


Fig. 3 - Primary patency.

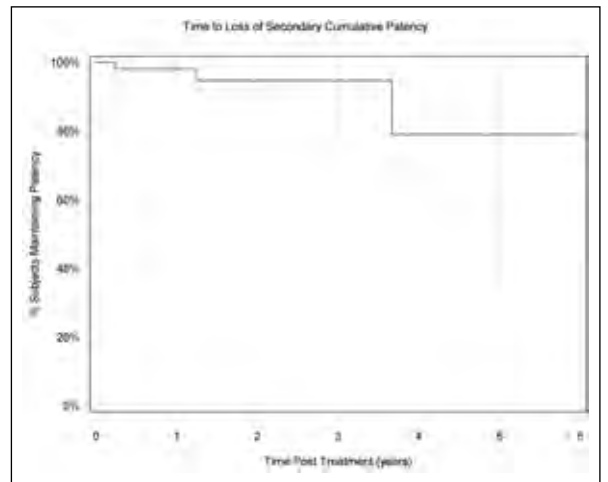


Fig. 4 - Cumulative patency.

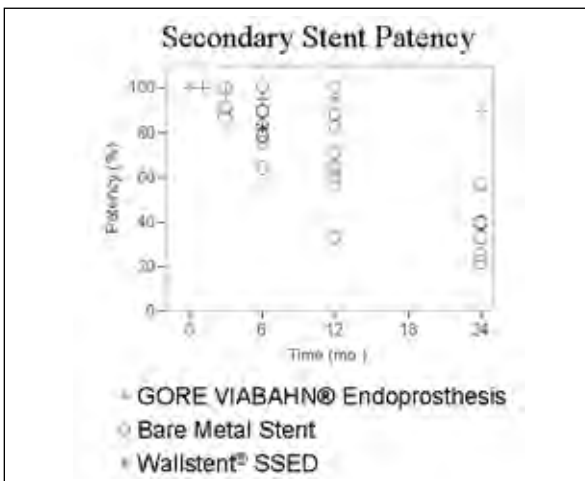


Fig. 5 - Historical comparison.

Results: The results are compared with previous studies conducted mainly with bare-wire stents (BWS). Primary patency of the PTFE-CS was similar to that of BWS but cumulative patency was far better, being over 90% effective over three years.

The startling difference between our primary patency and cumulative patency may reflect a policy in our program

of aggressive follow-up with early detection and re-intervention. This can blur the differences between marginally and severely dysfunctional accesses, leading to earlier intervention and skewing primary patency results. The better cumulative patency measure in the PTFE-CS group reflects better long-term patency and greater ease of restoring patency in PTFE-lined conduits versus bare-wire interstices with tissue ingrowth. This is also a reflection of greater success rate due to special interest and experience of the group.

Conclusion: This study demonstrated that central venous stenosis or occlusion can be managed long-term with a program involving Polytetrafluoroethylene covered stents, close monitoring and re-intervention as needed by a group interested in the management of these patients. Long-term costs and differential benefits are undefined and beg further study.

Acknowledgement: Statistical analysis and graphs were provided by Gore, Inc.

Surgical Decompression and Treatment for Central Venous Obstruction in Dialysis Access Patients - How to Select Patients for Success

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While avoidance of central venous catheters may help, central venous stenoses/occlusions are still a significant cause of dialysis fistula failure. Central venous obstructions can occur within the subclavian vein at the costo-clavicular junction (thoracic outlet) or more centrally in the innominate veins or superior vena cava. The location of the stenosis has implications both for the options for effective treatment and treatment durability.

Subclavian venous stenoses/occlusions at the costo-clavicular junction are an uncommon, but significant cause of venous hypertension in the dialysis access patient. Similar to non-dialysis patients who develop subclavian venous thrombosis (venous thoracic outlet syndrome), the subclavian vein in dialysis patients can be compressed at this area by the subclavius muscle and tendon, by the costoclavicular ligament or between the first rib and the clavicle. This chronic compressive injury is exacerbated in the high flow, turbulent systems of the venous system in dialysis access patients, leading to stenosis and occlusion. These subclavian venous stenoses at the costoclavicular junction do not respond well to angioplasty, and stenting of this area is fraught with complications including recurrent occlusion and stent fracture.

Surgical decompression of the thoracic outlet provides the best chance for long-term subclavian vein and access patency. This surgical decompression should include first rib resection, resection of the subclavius muscle and tendon and costoclavicular ligament, anterior scalenectomy and extensive venolysis. This can be performed through either a trans-axillary or paraclavicular approach. The transaxillary approach allows for first rib resection and scalenectomy, but makes extensive subclavian venolysis, patch angioplasty and interposition bypass grafting difficult. A supraclavicular incision permits excellent visualization of the thoracic outlet and direct access to the subclavian vein for open patch angioplasty or bypass. This incision can be supplemented with a medial infraclavicular incision for subclavius muscle and tendon removal and more central removal of the first rib at the costochondral junction. While access for venous thoracic outlet patients is optimized via the paraclavicular approach, these incisions are less cosmetically appealing. Regardless of the surgical approach, adequate venous decompression and correction of the stenosis should be confirmed at the end of the procedure with venography. Supplemental percutaneous balloon angioplasty can be performed at the same setting, if residual venous stenosis persists after external venolysis. Once the thoracic outlet has been decompressed, stents may be utilized, if needed, when venous recoil occurs following angioplasty. Complications from surgery for venous thoracic outlet syndrome include recurrent stenosis/thrombosis, lymphatic leak, hematoma, brachial plexus and phrenic nerve injury and pneumothorax. Patients are routinely anticoagulated for 3 months post procedure. Primary patency of up to 75% at 8 months has been achieved in dialysis patients who had had multiple previous failed endovascular interventions of this venous segment (1). Alternatively, symptomatic subclavian vein stenosis/obstruction can be treated with jugular vein transposition or PTFE or venous bypass to the ipsilateral jugular vein or contralateral axillary vein.

Central venous stenoses of the innominate vein or superior vena cava can often be treated with endovascular techniques with good technical success, but relatively poor long term success rates, primary patency of 30% at 12 months (2). Stenting and stent grafting of these veins can be used to treat occlusions, perforations following angioplasty and recurrent stenoses, but primary stenting does not improve patency in comparison to angioplasty alone in central venous lesions in dialysis patients (2). For central venous occlusions, techniques are described for

sharp needle recanalization (3). Surgical bypasses for patients with these more central occlusions are more limited and include axillary vein or artery to contralateral axillary vein bypass with PTFE or vein, arterial-arterial bypass and bypass to the right atrial appendage. A HeRO device can be used to maintain an upper arm fistula, if the central venous lesion can be crossed but develops rapid recurrent stenosis. Finally, ligation of the arteriovenous fistula may be necessary and almost always resolves the symptoms of arm swelling and venous hypertension.

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Bypass the Occlusion (HeRO or Surgical Reconstruction)

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Maintenance and revision of hemodialysis access is a challenging problem for surgeons and interventionalists alike. Management of central venous pathology can be one of the most vexing issues in access management as there can be few, or no remaining hemodialysis access options if the current access fails. Options for hemoaccess salvage include endovascular intervention, surgical revision, or a blend of the aforementioned techniques in a hybrid approach. The choice of intervention depends on the location and the cause of the lesion within the axilla and thorax. We identify 3 main causes/zones in the central venous circulation that lead to vascular access failure: axillary/subclavian, costo-clavicular (thoracic inlet), and true central (brachiocephalic/SVC) occlusive pathology. Axillary/subclavian venous occlusion secondary to recurrent, local, venous outflow intimal hyperplasia, may be the only central vein abnormality temporarily treatable with a purely endovascular approach. Recurrent stent-graft failure at this location typically results in abandonment of this site for durable venous outflow requiring bypass to a more central location of the venous circulation via conventional surgical exposure, deployment of a Hybrid vascular graft or using the HeRO graft outflow component. Costo-clavicular impingement of the subclavian vein is resistant to traditional endovascular therapies such as balloon angioplasty and/or stenting given the rigid external compressive nature of the two bony structures leads to stent-graft fracture and rapid in-stent occlusion. The HeRO graft can bypass this junction with an IJ vein approach which completely mitigates this anatomical impediment but has also been used with reasonable durability in the subclavian location as the rigid construction of the nitinol braided silicone Outflow Component (OC) is more resistant to these external compressive forces. In cases of OC stent-strut fracture, luminal integrity is typically preserved. In cases of OC failure, this removable stent can be replaced with relative ease, which is in stark contrast to traditional stents. An alternative option to this hybrid approach requires first rib resection, which resolves the external compression, but does not directly address luminal abnormalities and hyperplastic lesions that have developed as a result of the repeated insult from the thoracic inlet impingement. And finally, true central vein (SVC/brachiocephalic) occlusive disease secondary to shear stresses, central venous catheters, and geometric dynamics, responds poorly to purely endovascular therapies. Angioplasty and/or stenting typically lead to rapid recurrence or occlusion of the central veins that may obviate future attempts to establish central vein access. Surgical reconstruction of the central veins, or direct bypass to the right heart adds a significant element of morbidity and mortality to the patient without any added patency or durability benefits over the HeRO graft. Due to its design, the OC of the HeRO graft resists the dynamics of the central venous system, thus providing durable, removable/reliable outflow. While purely endovascular therapies have merit and utility in the management of peripheral hemodialysis access, given the complexities and variety of central venous pathologies, in our institutional experience, the hybrid approach (endovascular device coupled with formal surgical revision) has proven to be most durable and versatile for hemodialysis access salvage (1).

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How Early Can Arteriovenous Fistula Immaturity Be Detected?

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Purpose: When a fistula is created, a continuous flow from the artery to the vein initiates a cascade of changes, altering wall structure and rapidly increasing flow (1). The definition of fistula maturation is not well established. One suggestion is that a fistula is considered mature when cannulation can be performed with minimal complications, delivering the prescribed blood flow throughout the dialysis session; it can be considered adequate for dialysis when it has been cannulated successfully with two needles over a period of at least 1 month within 6 months of its creation (2). However, as many as 34% of native fistulas, will never mature to enable cannulation and successful hemodialysis (3). Besides surgical technical error, early fistula failure and non maturation are frequently caused by anatomic lesions that may exist anywhere within the access circuit. Up to 88% of patients may harbor venous stenoses and often have multiple lesions (4). In addition to venous stenosis, arterial inflow lesions, large patent branches and excessive depth relative to the skin surface may also prevent maturation. Postoperatively there are acquired lesions, such as arterial anastomotic stenosis and venous swing point stenosis causing delayed maturation and failure.

Non maturation and early failure should be detected and minimized early in the preoperative phase by meticulous preoperative assessment taking into account all the anatomical considerations including arterial inflow, quality of veins including diameter and stenoses, central vein patency or other problems. Preoperative venous imaging can reduce the proportion of patients with non maturing fistulas (5). Preoperative Doppler ultrasound (DUS) to identify a suitable artery and vein for fistula construction improves outcomes (6). Suboptimal veins can undergo angioplasty intra-operatively as well as postoperatively to enhance maturation (7). A skilled operator can use DUS intra-operatively to diagnose and direct treatment of such problems during construction of the access.

Any postoperative acquired lesions leading to impending fistula failure and non-maturation should be detected by a tight surveillance program and treated without delay. Physical examination by experienced staff can detect failure to mature, but complementary DUS can visualize stenoses while simultaneously providing flow and velocity measurements that help determine the physiological significance of the stenosis, and can be used as an interventional imaging tool for ultrasound-guided balloon angioplasty (8).

After the first stage of maturation, cannulations initiate the crucial second stage of maturation that may take several months until fibrotic tissue develops between the skin and the vein accompanied by dilatation of the puncture site. In some of the patients this process may lead to stenosis and maturation failure.

Our comprehensive access center incorporates DUS in every step of fistula maturation including preoperative mapping, intraoperative assessment with DUS-guided intraoperative angioplasty when necessary and postoperative maintenance, in order to reduce and detect impending early failure and increase maturation rates. Based on this algorithm we carried out a retrospective review of all fistulas constructed in the first half of 2010.

Methods: All patients had pre-operative DUS planning and entered our strict surveillance program based on DUS 10 days postoperatively at suture removal, and 1 and 3 months postoperatively. Angioplasty was performed for significant stenosis threatening fistula patency or impairing dialysis efficiency.

Results: 220 (90.1%) fistulas out of 244 new vascular accesses were created in 218 patients. Early failure rate was 2.3%. Primary patency at 12 months was 54%. Secondary patency at 1 and 2 years was 92% and 88% respectively. 182 (83%) fistulas were usable for dialysis at 1 month. Thirteen patients had DUS guided intraoperative angioplasty with 100% secondary patency at 6 months. Twenty-eight fistulas had angioplasty before cannulation due to significant stenosis in the fistula. All 28 started using the fistula at 2±1.1 months postoperatively and the secondary patency at 3 and 6 months was 100% and 96%, respectively.

Conclusions: Meticulous preoperative planning, together with aggressive surveillance and maintenance postoperatively that enables early postoperative detection of impending access failure, result in high maturation rates and low early failure. A high rate of fistula construction necessarily entails use of compromised vessels dictating liberal use of angioplasty to enable rapid maturation and surgical success.

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Creating Functional Arteriovenous Fistulas in Obese Individuals Using Cephalic Vein Outflow. The Deep AV Fistula: Options and Outcomes of Treatment

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Obesity in the United States is a major healthcare challenge. Over 100 million adults in the United States have a body mass index >30 kg/m². At the current rate of increasing obesity, it is estimated that by the year 2048 all American adults will be overweight or obese. The vascular access surgeon is frequently confronted with patients in need of hemodialysis vascular access where the access outflow cannulation vein is far deeper than the 6 mm maximum recommended cannulation depth noted by the NKF-DOQI Guidelines and Fistula First (1, 2). An autogenous vascular access is widely recommended when feasible and although it is generally accepted that an arteriovenous fistula (AVF) may be safely constructed in over-weight individuals, obesity makes vascular access procedures more challenging, with fewer AV fistulas created, more complex operations required, and access dysfunction more likely with shorter access survival (1, 2).

This abstract focuses on AVFs with cephalic vein outflow that are simply too deep for reliable cannulation. Our most common operations for these patients are lipectomy or elevation procedures (3, 4). Transposition procedures are used for basilic or brachial vein AVFs and are reviewed elsewhere. In our practice lipectomy or elevation procedures are completed in two stages, approximately 4-6 weeks following primary AVF construction. Lipectomy is preferred for those individuals where the cephalic vein is mature and a relatively straight conduit. Elevation (superficialization) of the outflow vein in these patients is not desirable due to vessel length limitations. Both upper arm and forearm lipectomy procedures have been reported with functional patencies exceeding 90% at two year follow-up.

For patients where the outflow vein has not only increased in diameter but has also elongated and become tortuous, elevation is our preferred option. As the vein is mobilized, this additional length is utilized to allow the AVF outflow conduit to reach the superficial position necessary for reliable cannulation, in addition the additional length is required for the vein to regain its native position, deep in the proximal arm. An additional important benefit is that the superficialized vein segment is then much straighter, allowing more reliable cannulation. Ultrasound examination plays a key role in selecting the most appropriate procedure and is most effectively done by the operating surgeon.

Few reports have been published regarding liposuction to establish a cannulatable AVF. The need for repeated passages of the liposuction cannula in proximity to a mature vascular access likely dampens enthusiasm for the procedure (5). A new investigational cannulation device (Venous Window Guide© Vital Access, Inc., Salt Lake City, UT, USA) is still in trial but early data suggest it may offer yet another option for reliable autogenous access in obese patients.

Creation of a functional autogenous access in obese individuals using a lipectomy or vein elevation procedure may be expected to result in a safe and reliable AVF. Staged operations are recommended for both techniques,

performed 4-6 weeks after the primary AVF creation. The selection of a lipectomy versus an elevation technique depends on individual patient anatomy including outflow vein length and the presence or absence of tortuosity. Ultrasound is an important tool in selecting the appropriate procedure for each patient.

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Accessory Veins: The Crisis Upon Us

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“The nail that sticks up gets hammered down” – Japanese proverb

For reasons which are not entirely clear, there continues to be controversy regarding the treatment of accessory veins to enhance maturation of immature fistulae. The evidence against this practice having any other than economic benefit for the practitioner is overwhelming, and has been detailed in several prior communications at this meeting (1, 2).

Because not even Level 2 evidence, let alone Level 1 evidence, has emerged to support this practice, there is little reason to replicate the argument here. The reader is directed to the references and the primary literature cited in those to draw his or her own conclusion. Rather, it may be useful to review the consequences of this practice in light of recent developments at the American Medical Association’s Relative Value System Update Committee (RUC), as relate to the soon-to-be obsolete embolization code 37204.

In reviewing and reevaluating this code, the CPT Panel chose to create four separate new embolization codes, one of which applies to the practice of accessory vein treatment by embolization. When reviewing use of existing codes for embolization, in spite of the fact that they are generally considered principally used in the treatment of malignancy, gastrointestinal bleeding, trauma and vascular malformations (over 95% of our practices use of these codes), it turned out that nephrologists accounted for roughly 25% of their use!

There is little doubt that interventional radiologists and surgeons also used this code excessively for “competing vessels”. The reason to consider the nephrologist association is that, unlike IRs and surgeons, there is little reason for this specialty to use this code other than in side branch embolization. Thus, this association essentially reflects only the practice of embolizing accessory vessels in hemodialysis access, because patients with ESRD generally do not get other embolization procedures except the occasional treatment of gastrointestinal bleeding.

Given the obvious overuse, it should not be surprising that when the new codes were assigned value by the RUC, the code for venous embolization was valued lowest, approximately half of the prior value of 37204.

When evaluating this development, one is struck by the juxtaposition of this obviously dramatic overuse of expensive technology and the abject lack of evidence supporting any benefit provided by treatment of side vessels in all but a tiny percentage of patients with immature fistulae. One can only conclude that the dramatic overuse of embolotherapy in the ESRD population was occurring for the financial benefit of the practitioner, and as history repeatedly teaches us according to the Japanese proverb above, the results were predictable.

Whether declining reimbursement will reduce the overuse of side branch embolization will remain to be seen. Not only is this practice unsupported by evidence, it carries risk of non-target embolization as well as coil erosion through the skin. Even with this dramatic reduction in reimbursement, it may continue to contribute significantly to the cost of health care if not reined in. It is highly likely however that regulators will now be far

more in-tune to the association of this code with the ESRD population and that scrutiny will only increase. One can surmise that with the new push toward quality based medicine, regulators will look at the two populations of patients, one in which embolization is performed routinely, and another in which embolization is performed extremely sparingly, and which will have exactly the same outcome (this is the same affairs in the literature), which will create further downward pressure on this inappropriate use of technology.

Is there any role for treatment of side branches in immature fistulae? The answer is unequivocally yes, but rarely. If angioplasty of visible stenoses has been performed, a period of maturation allowed to occur and followup examination shows no stenosis but persistent side branch(es), or if the fistulogram shows no stenosis and only side branch(es) suspected of competing, we have tools available to us to determine objectively whether these are truly competing vessels or not, in either situation. Whether by flow (ideal) or by physical examination (acceptable but less objective), temporarily occluding the suspect vessel can determine whether flow is indeed increased in the access. If all of these criteria are met, then typically treatment of a side branch will result in improvement of flow which is immediate and sustained.

In our practice, this is a tiny percentage of immature fistulae, approximately 1-2%, and thus an even tinier percentage of overall interventions. Further, there are less expensive, less risky alternatives to embolization, such as placing a surgical ligature around the side branch, which can readily be performed in the interventional suite. In summary, there is likely good reason that in spite of repeated suggestions to do so (1, 2), no prospective randomized trial of treatment of so-called competing vessels has been carried out. Whether the above-described reimbursement changes will result in a call for such a study is not clear, however as we delve further into the era of evidence- and quality-based medicine, those who wish to continue to get reimbursed for this treatment are likely going to need to prove it works. Don't say you were not warned.

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Etiology of Cephalic Arch Stenosis: Does Arch Anatomy and Physiology Contribute?

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The cephalic arch (CA) is clinical terminology coined to describe the portion of the cephalic vein (CV) from the deltopectoral groove to its termination in axillary or subclavian vein (1). In the upper limb, CV is used for fistula creation and to provide the needle access conduit in 95 % of AV. Approximately 30-40% of the CV based AVF are constructed in the upper arm and rest are in the forearm. The major cause of complications and failure of upper arm AVF is cephalic arch stenosis (CAS), reported in up to 40% of patients (2-4).

Though the exact reason for high prevalence of CAS in upper arm CV outflow fistulae is uncertain, the frequency of its occurrence clearly invokes the effect of the physiologic changes resulting from AVF creation on the anatomical peculiarities of this region. This article reviews some of the anatomic and physiologic factors that may play a role in development of stenosis in the cephalic arch with creation of an upper arm AV access.

Cephalic vein is a superficial vein in the upper limb, running in a subcutaneous plane, on the lateral aspect of the forearm and the upper arm above the deep fascia that drains into the axillary-subclavian junction of the deep venous system. The arch portion of this vein beyond the deltopectoral groove curves down in the subclavicular region, passes through a defect in the clavipectoral fascia and joins the deep vein at a variable angle. In this region it is crossed by the branches of thoracoacromial artery and pectoral nerves (1). Occasionally the vein develops around these structures there by giving it a duplicated appearance during radiologic imaging. It is also joined by several unnamed tributaries and hence possesses several intra luminal flow modulating valves (5).

With the creation of AVF the flow in the ipsilateral extremity increases 5-10 folds. Nearly 100% of this increased flow travels through the outflow vein of the AVF. In the case of an upper arm AVF this flow has to drain through

the CA. Ultra sound evaluation and computational fluid dynamic (CFD) evaluations have shown an alteration of spiral laminar flow to a turbulent flow in areas of change in direction such as swing points and juxta anastomotic areas. Though not universal, there is a higher propensity for vein wall pathology to develop in these areas. Thus the anatomy in the cephalic arch region with curving of the vein, crossing by vessels and nerves, passing through a fascial defect, tethering by the tributaries and presence of valves within make this region susceptible for the development of stenosis secondary to the changes in hemodynamic stressors caused by AVF creation.

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CAS: Surgery is the Best First Step

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A reported incidence of cephalic arch stenosis (CAS) between 39 -77% makes this a major morbidity in brachiocephalic arteriovenous fistula (AVF) (1, 2). Most stenotic complications in the vascular access outflow veins are managed with angioplasty, direct surgical intervention, or stent graft placement (1, 3, 4). While all three modalities help prolong access patency, none are curative. Re-stenosis following angioplasty or direct surgical repair can be managed with repeat angioplasty or intravascular stents. However, use of intravascular stents excludes the option of direct surgical repair. The goal for management of stenotic complications in AVF should be to provide well-functioning access with least number of interventions for the longest period of time. Hence we prefer direct surgical repair of CAS prior to placement of a stent graft.

Methods: We reviewed our prospectively maintained database and found 47 patients who underwent cephalic arch interventions between Jan 1st 2000 and Dec 31st 2010 who followed our protocol (Fig. 1) to obtain optimal fistula outcome.

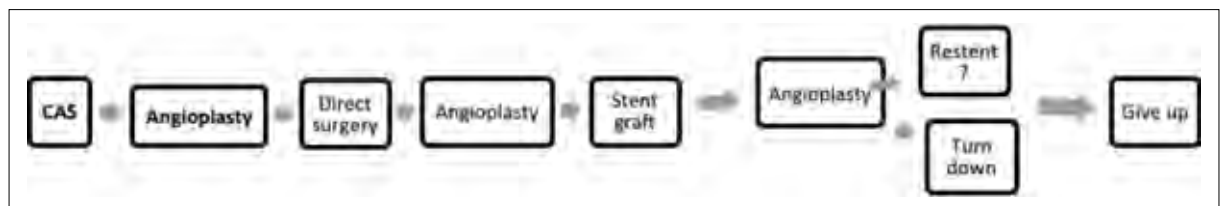


Fig. 1

Results: Thirteen of 47 patients who followed our protocol needed a direct surgical repair of the arch for failed angioplasty (failed attempt or requiring on an average >3 venoplasty per year). Procedural success was 100%. Majority 10 (77%) were female (5 Caucasian, 5 AA). Primary renal disease was diabetes in 5 (38.5%), Hypertension in 5 (38.5%) and miscellaneous in the remaining 3 (23%). Mean patient age was 57 years (+/- 17.1 years) and BMI was 32.8 (+/- 8.0) Kg/m². Nine (69.2%) patients had history of multiple access surgeries in the past. 1 patient had a single graft in the past and 3 had one catheter. Primary and cumulative patency for the access was 20.6 months (+/- 15.3 mo) and 67.9 months (+/- 42 mo). Interval from the first venoplasty until the surgery (on cephalic arch) varied widely. Mean interval was 12.6 mo (+/- 12 mo, range 3.1 - 43.8 mo). 3 patients died with functioning access and one received a transplant. 2 received stents after surgery (one stent – protocol violation). Only 3 fistulae failed at 44 (after stent – no compliance), 73 (after stent out of protocol - infection) and

73 (no stent - infection) months from creation. The primary and cumulative patency following surgery was 22.1 (+/- 34.1, range 1.1-124) and 39.2 (+/- 38.7, range 3.8-124) months. Prolonged primary patency (longest 124 months) following surgery was noticed in patients (n=3) who received arch surgical repair early after CAS (one or failed first angioplasty).

Summary: Direct arch repair is an underutilized surgical procedure that plays a major role in preserving and prolonging the access life in patients with CAS. There is a need to further evaluate this procedure as the first line treatment in management of CAS.

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VIABAHN® Stent-Graft for the Primary Treatment of Cephalic Arch Stenosis in Brachio-Cephalic Autogenous Hemodialysis Accesses

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Purpose: To demonstrate superior patency of VIABAHN® stent-graft in treating Cephalic Arch Stenosis.

Background: The cephalic arch is a unique anatomic structure in hemodialysis accesses due to the vascular architecture and propensity to intravascular scar formation leading to early access failure. While the technical success of endovascular balloon angioplasty treatments is generally satisfying, the outcome is wholly inadequate as the six month primary patency for angioplasty alone ranges from 8-43% (1,2). Angioplasty fails in the majority of cases due to initial rupture, or rapid re-stenosis. For either indication, these complications have been treated with placement of bare nitinol stents, none of which have an FDA indication for venous hemodialysis applications. In most instances these stents are only used as a last resort as their primary patency at six months is poor and are anecdotally known to complicate creation of future accesses. Shemesh et al demonstrated superior primary patency of Fluency® stent-grafts and noted the most aggressive stenosis occurred at the uncovered edges (3). Viabahn stent-grafts are fully covered by ePTFE and are notably flexible which is advantageous given the architecture of the cephalic arch.

Methods: A retrospective evaluation was performed. All patients presented with access dysfunction or thromboses and had an isolated cephalic arch stenosis with no other central or peripheral access stenoses. Consecutive patients from three treatment groups were selected: (1) angioplasty-treated only, (2) angioplasty treated with an uncovered Nitinol stent, and (3) angioplasty treated with a covered VIABAHN® stent. Primary patency rates from each of the three patient groups were accounted at 3, 6, and 12 months of initial treatment. Additional parameters included the number of interventions per clinical year, and development of Juxtaposed Subclavian-Axillary vein Stenosis (JSS) following the intervention at 12 months.

Follow Up and Reintervention: Following the initial intervention, patients were evaluated either by a referral for access dysfunction from the hemodialysis unit, or scheduled for a 3 month follow-up evaluation. At each visit a physical exam was performed and patients exhibiting excessive access pressure with complaints of prolonged access bleeding, rapid aneurysm growth, or high venous pressure were studied with angiography. Lumen restenosis greater than 50% was considered significant. Patients without symptoms on physical examination were not studied and were scheduled for another clinical examination in 3 months.

Results: This report contains data on 150 patients (50/group) collected over a three-year period. Kaplan-Meier analysis was performed. Patients treated only with angioplasty had primary patency rates of 63%, 22%, and 15%

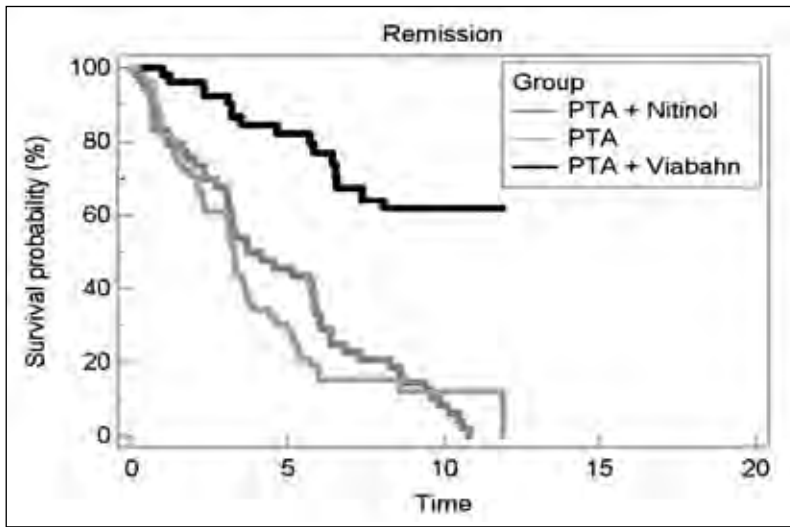


Fig. 1 - Primary Patency of Cephalic Arch lesions following treatment with Angioplasty alone, Angioplasty plus bare Nitinol stent, Angioplasty plus Viabahn Stent-graft.

at 3, 6, and 12-months, respectively, averaged 2.73 access interventions per clinical year, and 8% exhibited JSS. Patients additionally treated with an uncovered stent had primary patency rates of 72%, 43%, and 13% at 3, 6, and 12-months, respectively, averaged 2.43 access interventions per clinical year and 36% exhibited JSS. VIABAHN®-treated patients had primary patency rates of 91%, 75%, and 59% at 3, 6, and 12-months, respectively, averaged 1.33 access interventions per clinical year, and 6% exhibited JSS (Fig. 1).

Conclusions: The use of VIABAHN® to treat cephalic arch stenosis significantly improves the primary patency, dramatically reduces the number of interventions per access year, and does not contribute to JSS formation as compared to traditional angioplasty. While bare nitinol stents occasionally have a role in treating dysfunctional accesses, they should be used with caution as they do not improve outcomes when treating the cephalic arch and may induce JSS further complicating future access options.

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Stealing and Bleeding: Two Things You Get Sued For. Now What?

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The two most common sources of a lawsuit against a physician are a patient (thus the bleeding) and a business partner (thus the stealing). Well before any lawsuit is on the horizon, a physician with foresight needs to develop a plan to protect assets before they are at risk of loss. An asset protection plan begins with building a strong legal model for a physician's practice and private life through limited liability entities that minimize the exposure of both professional and personal property. Once the plan is implemented, it is imperative that each entity remain separate and independent from each other, for instance by having their own set of books, records, and bank accounts. Adequate insurance needs to be considered as well, including an umbrella policy, employment related coverage, regulatory coverage, and directors and officers coverage. A proper plan must also anticipate the future developments, for example how the entities will acquire assets or how personal or professional changes will be addressed. Last, but not least, the plan must account for the payment of taxes for all entities and individuals because no plan is immune from tax liability.

In addition to planning to protect assets if sued, a physician can also take action to avoid being sued. Litigation risks can be mitigated with processes and procedures that screen potential business partners and patients before a formal relationship is established. After a relationship is formed, doing good work and communicating thoroughly are obvious ways to avoid lawsuits, but are nonetheless worth mentioning due to their importance. Many studies have found that the number one cause of malpractice claims is the failure to communicate, which is likewise commonly the root of disputes with business partners or employees. Additionally, maintaining documentation goes a long way to staying out of the courtroom by preventing 'he said / she said' disputes, either with patients, business partners, or employees. Lastly, the most common-sense way to stay out of the courtroom is to not be the party that starts a legal fight. If a lawsuit is brewing, an attorney can help defuse the dispute with counseling on pre-suit options for a cooperative resolution. If a lawsuit is filed, the first thing to do is call your attorney immediately. There are many strategic decisions that need to be addressed at the front end of a lawsuit, including determining whether insurance coverage is available or whether certain rights must be exercised under a partnership or company agreement. Third party communications must be guarded; in short, before sending an email or talking to others, picture that communication as Exhibit A in front of the Judge and Jury in the trial against you. On the other hand, physicians must be completely open and honest with their own attorneys. Like most things, knowledge is power in litigation and if a physician's attorney does not have full knowledge of the facts, good or bad, the physician's case will be severely compromised. Complete disclosure of the facts will ensure that the attorney can counsel the physician on the risks the case presents, from the very best outcome to the absolute worst, and can develop a litigation strategy with the physician to avoid reactive and inefficient case management.

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The Future of Arteriovenous Grafts (AVGs)

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Historically, arteriovenous grafts (AVGs) have either been manufactured from synthetic materials or extracted and chemically tanned from non-human (xenogenic) sources. While these vascular tubes have provided life-sustaining function for thousands of patients in need of renal replacement therapy, they suffer from numerous modes of clinical failure including thrombosis, neointimal hyperplasia, infection, graft ultrafiltration (weeping), steal syndrome, and traumatic degeneration of graft material (1). Understanding each one of these distinct modes of failure poses unique opportunities to both biologically and structurally re-engineering the next generation of vascular access grafts. Critical issues to resolve for future AVG's will be improvements in the blood-contacting surface with the ultimate goal of forming a normal, non-activated, endothelial cell surface on the lining layer of the implanted conduit. It is also imperative to understand the physical and biologic factors that produce the proliferative vascular response most commonly seen in the outflow venous segment of the graft characterized as venous neointimal hyperplasia. Current attempts to alter and reduce this vascular response include changing the hemodynamic characteristics of the graft by modifying flow patterns, delivering anti-proliferative agents and/or applying biologic therapies to the outflow vein segment. Modest work has been done in an attempt to reduce graft infection through the use of antimicrobial (silver) coatings and limited information exists about improving host tissue incorporation into the matrix of the graft material to limit forging body reactions. Some PTFE grafts have been re-engineered and laminated to reduce weeping and/or improve early cannulation with limited long-term follow-up. Recently, the possibility of formally creating a tissue engineered vascular graft to meet many of the requirements outlined above has come to the forefront. Mature prototypes of at least two of these tissue engineered vascular grafts have undergone formal pre-clinical evaluation and are now entering early clinical trials. As science and technology continue to advance, the future of AVG's is to ultimately engineer an ideal vascular access vessel that is impermeable, nonthrombogenic, compliant, biocompatible, nonimmunogenic, durable, easy to handle, aseptic, resistant to infection, readily available, and cost effective (2).

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Heparin-Bonded Graft (Propaten) Versus Standard Graft in Prosthetic Arteriovenous Access

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Purpose: Natural vascular walls have bioactive characteristics which prevent clotting in blood vessels. Heparin biocompatible surface technologies provide thromboresistance that simulates critical properties of the vascular endothelium when blood is in contact with the surface (1). A stable covalent bonding of heparin to the surface ensures long-term bioactivity and sustains antithrombotic bioactivity for long periods. The coating functions continually to prevent thrombus formation, is not consumed and is non-leaching so it does not result in any significant systemic heparinization. Propaten (WL Gore & Associates, Flagstaff, AZ), an expanded polytetrafluoroethylene (ePTFE) graft with long-term bonding of heparin accomplished by covalent linkage of the anticoagulant, was introduced for use as a hemodialysis access conduit in 2006. The same heparin bonded ePTFE technology has been applied to vascular grafts implanted for below knee bypass surgery in non-randomized and retrospective clinical studies indicating graft patency rates similar to that achieved with native veins (2-4). A non-randomized trial in dialysis access patients demonstrated a 20% improvement in clot free graft patency for heparin bonded grafts at one year (5). Propaten has been used as a conduit for proximalization of the arterial inflow for dialysis access steal syndrome, also showing improved patency at 6 and 12 months compared with standard grafts (6). Heparin bonded grafts may carry the risk of heparin induced thrombocytopenia (HIT) and should not be used in patients with HIT (7). We carried out a prospective randomized trial to assess the performance of Propaten versus standard ePTFE grafts in resisting thrombosis, decreasing early failure and prolonging patency.

Methods: Patients scheduled for new prosthetic access construction were prospectively randomized to have standard ePTFE or Propaten grafts. Patients who were minors (under 18 years of age), those who required the signature of a legal guardian, patients with known hypercoagulability syndromes, patients on warfarin therapy for anticoagulation and those having lower limb access were not eligible for the study. The sample was calculated to 160 patients in order to demonstrate a 20% improvement in patency at a confidence level of 95%. One hundred sixty patients were enrolled from June 2007 until November 2011 and were followed up until July 2013 when the study concluded. All patients entered our routine surveillance program with Doppler ultrasound performed at one month and every three months thereafter for patency and development of stenosis. Angioplasty was performed as necessary according to Doppler ultrasound and clinical findings (8). Primary patency was defined as time from access construction to time of first intervention, clot free patency was defined as time to first thrombosis and secondary patency was time until the access was abandoned. The study was approved by the Ethics Committee of the Shaare Zedek Medical Center (NCT00737620).

Results: Eighty standard ePTFE and 80 Propaten grafts were constructed for hemodialysis access. Primary patency at 6 and 12 months was 29% and 14% for standard ePTFE, and 37% and 12% for Propaten ($p=0.48$). Clot free proportions at 6 and 12 months were 54% and 41% for standard PTFE and for Propaten they were 66% and 54% ($p=0.12$). Secondary patency at 12, 24 and 36 months were 83%, 83% and 81% for Propaten, and 81%, 73% and 68% for standard ePTFE respectively ($p=0.33$). The mean time to first thrombosis was 7.8 ± 10.6 months in the standart ePTFE group and 9.7 ± 10 ($p=0.17$) in the Propaten group. Sixteen standard ePTFE accesses (20%) thrombosed in the first month compared with 6 Propaten (8%) ($p=0.037$). There was no difference between the groups in anastomotic bleeding during surgery, time from surgery to initiation of dialysis or puncture site bleeding. No patients were excluded from the study after enrolment, and none were lost to follow up.

Conclusions: Propaten grafts had a tendency to improved patency compared with standard tapered ePTFE grafts, but the difference did not reach statistical significance. However the rate of early failure was significantly lower in the Propaten group. This prospective randomized study did not confirm the findings in previous non-randomized studies, that heparin bonded grafts perform significantly better than standard grafts. The risk of bleeding complications either at surgery or in puncture sites is not increased.

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When Hemodialysis Access Fails, Why Not PD?

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Rationale: The creation of a well-functioning permanent vascular access remains one of the most vexing problems in modern hemodialysis care. The cohort of patients reaching end stage renal disease (ESRD) is getting older, and the majority of patients have diabetes or diffuse vascular disease. These comorbidities make creation of a fistula, or even a graft, challenging (1).

Many nephrologists put themselves and their patients with poor vascular access into a declining cycle of repeated attempts at grafts or fistulas. The heartbreaking pattern usually proceeds through distal to proximal arm, then distally to proximally on the next arm. The patient or nephrologist may then settle for a tunneled internal jugular catheter or proceed to consider access in the thigh. I have seen these patients come into hospital for these "last ditch" accesses (lumbar vein, anyone?). When I suggest breaking out of this cycle with peritoneal dialysis, I am inevitably greeted with silence, followed by "he/she wouldn't do PD". It is obvious to me by the silence that the possibility of a modality switch to PD hadn't even been considered, much less broached to the patient.

Benefits: The obvious benefit of a switch to PD is that there is no need for vascular access. Even in patients who have had previous abdominal surgery, an experienced surgeon can usually successfully place a PD catheter, especially using advanced laparoscopy, where incidental adhesions can be lysed, and a redundant omentum can be tacked to the upper abdomen.

The patients with diffuse vascular disease, in whom vascular access is more likely to fail, may better tolerate the gentle daily dialysis and ultrafiltration intrinsic to the PD procedure. These patients are also likely to experience "myocardial stunning" during hemodialysis, wherein there are episodes of asymptomatic coronary ischemia and regional wall motion abnormalities that, over time, are associated with increased cardiovascular events and mortality. On the other hand, myocardial stunning is essentially nonexistent on PD (2).

Drawbacks: Residual kidney function (RKF) has been shown to be an important predictor of nutrition and survival in PD patients (3). RKF is better preserved in PD compared with all forms of HD. This is likely the result of the gentler dialysis with PD, so that the blood pressure and blood volume don't decrease dramatically as it sometimes does with HD, compromising renal blood flow. Furthermore, the flow of blood through the extracorporeal circuit in HD allows for the generation of a host of inflammatory cytokines, and these cytokines may hasten the decline of RKF. In many studies there is an early survival benefit to PD, and one explanation is the better preservation of the RKF.

By the time a HD patient has been deemed an access failure, they have likely been on the therapy for some time, and undergone numerous interventional procedures to attempt access creation. To add insult to injury, there is also usually repeated exposure to nephrotoxic radiocontrast dye. While there is no proof of this, it is likely that this cohort of patients with failed vascular access has little or no RKF. This is in contrast to the patient who has attended predialysis education and electively started on PD. Therefore the particular advantage of PD,

preservation of RKF, will not apply to these patients. However, there are now many studies of anuric patients on PD showing good outcomes, as long as careful attention is paid to maintenance of normal volume status (4).

PD is essentially a home-based procedure. The failed access patient usually comes from an in-center hemodialysis unit. While home-based dialysis has been repeatedly shown to be associated with a better quality of life (especially in the elderly!) (5) the switch to PD means that the patient now has to take some responsibility and ownership for their dialysis treatment. This may be a difficult transition for the in-center patient, especially if they have become socialized in the hemodialysis unit. Countries such as Canada and France have a visiting nurse program to set up the PDycler in the patient's home every day, and this can ease the transition back to the home.

Conclusion: Einstein said that the definition of insanity is doing the same thing over and over and expecting different results. Many nephrologists and patients get in the cycle of repeatedly attempting vascular access (an uncomfortable if not downright painful procedure) without stepping back and thinking about whether there might be a better way. It is important to consider getting "outside the box" and switching to PD.

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What's new with peritoneal dialysis?

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Peritoneal dialysis is a well-established treatment modality for end stage renal disease. It is considered particularly good in patients who are new to renal replacement therapy, with residual urine output and less comorbidity (1). However, it is also a good technique for the elderly with cardiac comorbidities who are likely being symptomatic during hemodialysis or having a better quality of life on home dialysis treatment. An interesting new indication, peritoneal ultrafiltration for patients with severe heart failure, has also been proposed.

A recent review (2) focused on three themes, debated by the PD community:

- The effects of more biocompatible PD solutions
- Encapsulating peritoneal sclerosis (EPS)
- Comparisons of survival between PD and conventional hemodialysis

Conventional PD dialysis fluid are hyperosmolar (high glucose concentration for ultrafiltration); contain lactate, which does not induce precipitation of calcium and is converted to bicarbonate in the liver after crossing the peritoneum; have a markedly low pH, approximately 5.2; and contain clinically relevant concentrations of glucose degradation products (GDPs), which may damage the peritoneal membrane. The new more "biocompatible" dialysis solutions could reduce complications of PD treatment, although their potential advantages are still to be clearly proven by randomized controlled trials (RCT) (2).

EPS is a rare but serious complication of long-term PD that is associated with a high morbidity and mortality, up to 50% of cases. It is characterized by diffuse thickening and sclerosis (which can develop into calcification) of the peritoneal membrane resulting in a decrease in ultrafiltration, ascites and ultimately partial or complete small bowel obstruction. Remarkably, its onset can occur after switching to hemodialysis or after kidney transplantation, contributing to mortality in this patient population (3). The incidence of PS increases with time on therapy. A recent Australian study reported, after 3, 5, and 8 years of PD, an incidence of 0.3%, 0.8%, and 3.9%, respectively (4). Thus, long term PD treatment, especially over 5 years, increases the risk of developing

this complication, although the majority of long-term PD patients are not affected. Early diagnosis is considered important for blocking progression of the disease. Diagnosis of EPS is based on the presence of clinical symptoms of obstructive ileus, with or without various degrees of systemic inflammatory reaction, together with the presence of peritoneal thickening and encapsulation, peritoneal calcification, bowel wall thickening, tethered bowel loops (cocoon) and loculated fluid collections (5). The International Society of Peritoneal Dialysis (ISPD) developed a consensus, stating that there is no evidence to withhold PD as a treatment option because of fear of development of EPS (5). Treatment with tamoxifen, a modulator of the estrogen receptor which also has antifibrotic properties, has been reported as effective, although mortality remains high (2). Nutritional support with total parenteral nutrition can be required.

Comparisons of survival between PD and hemodialysis is based on observational data, as it is very difficult to approach the problem with a RCT. The only available RCT (6) demonstrated, in a relatively small number of patients, that survival was better in the PD cohort. Interestingly, dialysis access may be the most relevant factor determining changes in survival rates between the two dialysis methods. In a large observational study conducted in Canada (7), during the first year of Dialysis there was no difference in survival between the PD patients and those on hemodialysis with an AV fistula or graft, while those with a CVC had an 80% higher risk of death. This highlights the concept that predialysis planning and elective start with a permanent access is the gold standard of care in both dialysis modalities (2).

Peritoneal ultrafiltration has been described as a very effective method for controlling fluid overload in patients with severe heart failure, even if renal impairment is not severe (8). Promising observational data should be confirmed by a RCT, but the rationale behind this novel treatment approach is strong. This concept is supported by a recent review (9) outlining the importance of crosstalk between the abdomen, heart, and kidneys in congestive heart failure.

Following the successful experience of the Dialysis Outcomes and Practice Patterns Study (DOPPS), which provided extremely useful information in many areas of hemodialysis, care, including vascular access, a Peritoneal Dialysis Outcomes and Practice Patterns Study (PDOPPS) has been launched (10). The PDOPPS, developed in collaboration with the ISPD, has the aim of improving the understanding of optimal practices for PD patients worldwide and to reduce barriers to PD use. An overview of this international program can be found in the ISPD web site (11). In this document, PDOPPS is described as a prospective cohort study and it will represent a highly visible resource to the PD community, providing a much-needed infrastructure and forum to promote effective international collaborative clinical research. PDOPPS has the objective of generating a valuable source of PD practice and outcomes data in participating countries. The PDOPPS Steering Committee has established six research workgroups, one of them is dedicated to PD catheter access and function.

Regarding PD catheter placement, a review of surgical techniques will be published soon in the *Journal of Vascular Access* (12). Advantages and disadvantages of open vs. laparoscopic techniques are discussed, suggesting that laparoscopic placement may be useful in selected patients, especially when rescuing malfunctioning catheters, and may increase the PD patient population in patients with previous abdominal surgeries. Another recent interesting article on the PD catheter addressed the issue of patient education (13) and investigating the application of ISPD practice guidelines for PD catheter placement and follow up care in a U.S.A. based practice. Numerous deviations from the ISPD guidelines were reported, patient satisfaction with education was suboptimal, and complications were frequent, indicating the need for improved patient education and care coordination for PD catheter placement.

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Hemodialysis Catheters: New Observations about Design and Performance Reversed Blood Lines Causes Problems

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Purpose: Few studies have assessed the blood flow patterns surrounding the tip of chronic (tunneled) hemodialysis catheters (1-3). The hemodynamic effects of different catheter tip designs, such as step tip vs. split tip, have not been well described.

We conducted a study to characterize the fluid flow patterns around the distal tips of nine different tunneled hemodialysis catheters. We used a bench top mechanical model that simulates conditions found during routine hemodialysis treatment. The bench-top model provided direct observation of fluid flow patterns around the catheter tip and allowed visual comparison of the hemodynamic effects of different catheter tip designs. We used an optical density method to measure catheter recirculation rates with the blood lines in standard and reversed configurations.

Methods: A bench top fluid flow model simulated the anatomic dimensions and physiologic conditions of the superior vena cava. In our 3-circuit fluid flow model we used a fluid viscosity that replicated the viscosity of whole blood with a hematocrit of 40%.

Three step tip catheters, three split tip catheters, one modified split tip and two symmetric tip catheters were evaluated. Seven of the nine catheters had side holes in the distal tip. Four catheters had arterial side holes, four catheters had venous side holes, and one catheter had both. The rate of fluid flow through the arterial and venous lumen of each catheter was 425ml/min for all testing procedures.

Results: Our study showed that all nine hemodialysis catheters worked well with minimal, if any, recirculation when used with the blood lines in standard configuration. Catheters with symmetrical tip designed showed stable flow patterns and the lowest recirculation rates in both standard and reversed configurations (4). Step tip catheters were more stable than split tip catheters. However, the presence of a flow divider increased the degree of turbulence around any catheter tip when the blood lines were in the reversed configuration. The Ash Split, the Hemosplit, and the Centros catheters all showed significant tip deflection and >20% recirculation when used in the reversed configuration. Such significant catheter tip movement may have implications for long-term development of central venous stenoses. Catheters with symmetrical tip designed showed stable flow patterns and the lowest recirculation rates in both standard and reversed configurations. Step tip catheters were more stable than split tip catheters. The presence of a flow divider increased the degree of turbulence around the catheter tip when the blood lines were connected in the reversed configuration.

Conclusion: In our test model all nine hemodialysis catheters performed well when the blood lines were connected in the standard configuration. When connect with blood lines reversed, the split tip catheters exhibited some undesirable behavior. The step tip catheters and symmetrical catheters worked well with standard and reversed blood lines.

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Routine Exchange of Tunneled Hemodialysis Catheters – What Are We Waiting For?

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When discussing preventative medicine, Benjamin Franklin's phrase "an ounce of prevention, is worth a pound of cure" is reiterated as though it were gospel. The medical mantra has shifted from treatment to prevention because of the overall improved outcomes and cost savings (1, 2). Preventative care is no longer relegated to primary care, but spans across the entire spectrum of medical, surgical and oncologic specialties. However, one arena where the motto of prevention has not been embraced is surprisingly in the setting of hemodialysis patients requiring tunneled dialysis catheters (TDC's). These catheter dependent patients are arguably the sickest and most desperate patients, without an option for a fistula or graft.

Tunneled dialysis catheters often serve as the only bridge to life saving hemodialysis and are utilized as an initial conduit to hemodialysis by up to eighty percent of hemodialysis patients (3, 4). Unfortunately, TDC's are plagued by various complications such as thrombus and fibrin sheath formations, infections and even vascular damage. Current practices dictate that patients must wait until one of these complications is present before any interventions, medical or otherwise ensue. This practice is akin to letting components on an airplane fail before any parts are fixed which would obviously lead to unacceptable outcomes. Why then do we wait until catheters fail to replace them?

Multiple studies have shown that exchange of TDC's over guidewire increases patency of the catheter after thrombus and fibrin sheath formation and significantly decreases recurrent infection in the setting of parenteral antibiotics (5, 6). In fact several studies have demonstrated high cure rate and prevention of devastating metastatic infections such as discitis/osteomyelitis in catheter associated bacteremia via systemic antibiotic therapy and catheter replacement over guidewire (7). Moreover, the Kidney Disease Outcomes Quality Initiative (KDOQI) by the National Kidney Foundation has endorsed hemodialysis catheter exchange over guidewire in the setting of sepsis, a society which is staunchly critical of TDC's (8). It therefore stands to reason that prophylactic catheter exchange would obviate the need to irrationally subject dialysis patients to unneeded hospitalizations and procedures. Routine exchange at regular intervals or at the first (or second?) onset of catheter complications such as fibrin sheath formation or vascular thrombosis, would likely obviate the ensuing feared complication of catheter associated bacteremia and sepsis.

Decreasing hospitalization due to bacteremia and sepsis would drastically reduce the overall costs of TDC's. One of the criticisms associated with TDC's is their immense overall costs relative to arteriovenous fistulas, largely due to frequent hospitalization secondary to catheter associated sepsis (9, 10). Ramanathan et al demonstrated that the average cost for a single catheter associated sepsis admission was \$23,451, of which only 21 percent was attributed to procedural component (catheter exchange or intervention) of the admission. Numerous medical device companies have spent millions of dollars in research trying to find a 'magic bullet' to combat biofilms and catheter associated infections via altering catheter materials, coating, impregnating medications, etc. The actual solution to catheter associated sepsis and infections may be much more simple and cheap. Routine exchange of catheters either in set intervals or the sign of complications could alleviate all the aforementioned complications and their deleterious effects on both patients and their associated financial burden.

Tunneled hemodialysis catheters have proven that they are not infallible devices with infinite lifespans, but rather essential components to the survival of millions of patients. Since it has been demonstrated that catheter exchange is able to cure infection and prolong vascular patency, it is absurd to think that we are waiting for these catheters to fail before their exchange. Given the extraordinary mortality rate and costs associated with catheter complications it might be time for TDC exchanges to become routine. Prospective randomized clinical studies to prove this point are needed. The question should therefore not be, 'routine exchange of dialysis catheters, yes or no' but rather 'how often and after what signs should we replace TDC's'.

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Simulation of Dialysis Access (SoDA) - *Hands-On Dialysis Access Simulation*

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The use of simulators for surgical training is rapidly gaining popularity. Simulation allows educators to control the training environment, giving physicians a chance to practice new techniques without the stress related to treating a real patient. Training and learning in the field of access for dialysis, including peritoneal dialysis and hemodialysis is well suited for the use of simulators, simulated case learning, and team training. Simulators range over a wide spectrum from simple suture learning devices, inexpensive systems for venous puncture simulation, with a pressurized tunneled rubber or graft conduit, to sophisticated computer designed simulators to teach interventional procedures such as vascular access angiogram, balloon angioplasty and placing of stents. Team training capitalizes on the principles used in aviation known as Human Factor (HF). The objectives of team training are to improve communication and leadership skills, and the use of checklists to prevent errors. In this context HF aims to promote a change in the attitudes towards vascular access from learning through mistakes in a non-punitive environment, to impact positively the employee performance and to increase staff retention by making the workplace safer, more efficient and user friendly. Simulation of Dialysis Access (SoDA) will introduce physicians to new techniques in dialysis access through a variety of hands-on experiences. Experts at each station will provide training that utilizes simulation technology, models and techniques geared to surgeons, interventional radiologists and allied health professionals. SoDA delivers examples of how simulation training can advance the field of dialysis access management. There are eight stations planned:

Station 1: Neck/Large Vein Ultra-Sound Anatomy – Placement of IJ Dialysis Catheters

Participants will practice hands-on needle cannulation of the internal jugular vein using ultrasound guidance on a realistic neck simulator.

Station 2: Vascular Mapping for Hemodialysis Access

At Station 2, participants will practice vascular mapping on live subjects. The faculty will educate using two ultrasound machines, and attendees will have the opportunity to hold a probe to examine arteries and veins, and suggest the best access points.

Station 3: Dialysis Access Cannulation

Using an ultrasound machine, participants will practice placing a dialysis needle into a dialysis access conduit that is under pressure and filled with red colored fluid to show proper placement.

Station 4: The Peritoneal Cockpit

Aviation safety teaching principles will be used to demonstrate the important tools and instruments needed for a peritoneal dialysis procedure, and why basic fact knowledge and the proper use of checklists can improve the quality of care for your patients.

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.

Station 6: Vascular Anastomoses Suture Lab

Participants will get a chance to suture a vein to artery anastomosis, with various suturing techniques discussed and demonstrated by experts.

Station 7: Tools in Access Surgery: Why Would You Use That?

Participants will be able to discuss the pro's and con's of various tools used in vascular access procedures from the top experts in the field.

Station 8: Communication Skills

SoDA participants will have the opportunity to work on their communication skills through moderated, pre-recorded simulation cases. By working on team communication skills, the team creates better processes, listening skills and patient treatment adherence, thereby improving the quality of patient care.

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